CONTEMPORARY PEDIATRICS MARCH 2014 VOL. 31 NO. 3

Contemporary PEDIATRICS®

MARCH 2014
VOL. 31 | NO. 3

Expert Clinical Advice for Today's Pediatrician

ContemporaryPediatrics.com

PRACTICAL PEDIATRICS

Hometown USA's secret

Children's Claritin® Allergy Products

Claritin® Offers a Full Range of Non-Drowsy Allergy Relief for Kids

The Claritin® family of products delivers benefits for all of your patients with allergies:

- The great grape taste of Children's Claritin® Chewables and Children's Claritin® Syrup – both providing 24-hour relief
- The flexability and convenience of Claritin® RediTabs® that dissolve without water – for on-the-go relief in 12-hour and 24-hour formulations

	 Children's Claritin® Chewables	 Children's Claritin® Syrup	 Claritin® 12-Hour RediTabs® Tablets	 Claritin® 24-Hour RediTabs® Tablets
AGES	**Kids** 2 years and older	**Kids** 2 years and older	**Kids** 6 years and older	**Kids** 6 years and older
DOSAGE FORM	**Tablets** (Once daily)	**Syrup** (Once daily)	**Orally Disintegrating Tablets** (Twice daily)	**Orally Disintegrating Tablets** (Once daily)

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Expert Clinical Advice for Today's Pediatrician

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PRACTICAL PEDIATRICS

Hometown USA's secret
The Sex-trafficked child

PEER-REVIEWED

SELF-INJURY
Why teens do it, how to help

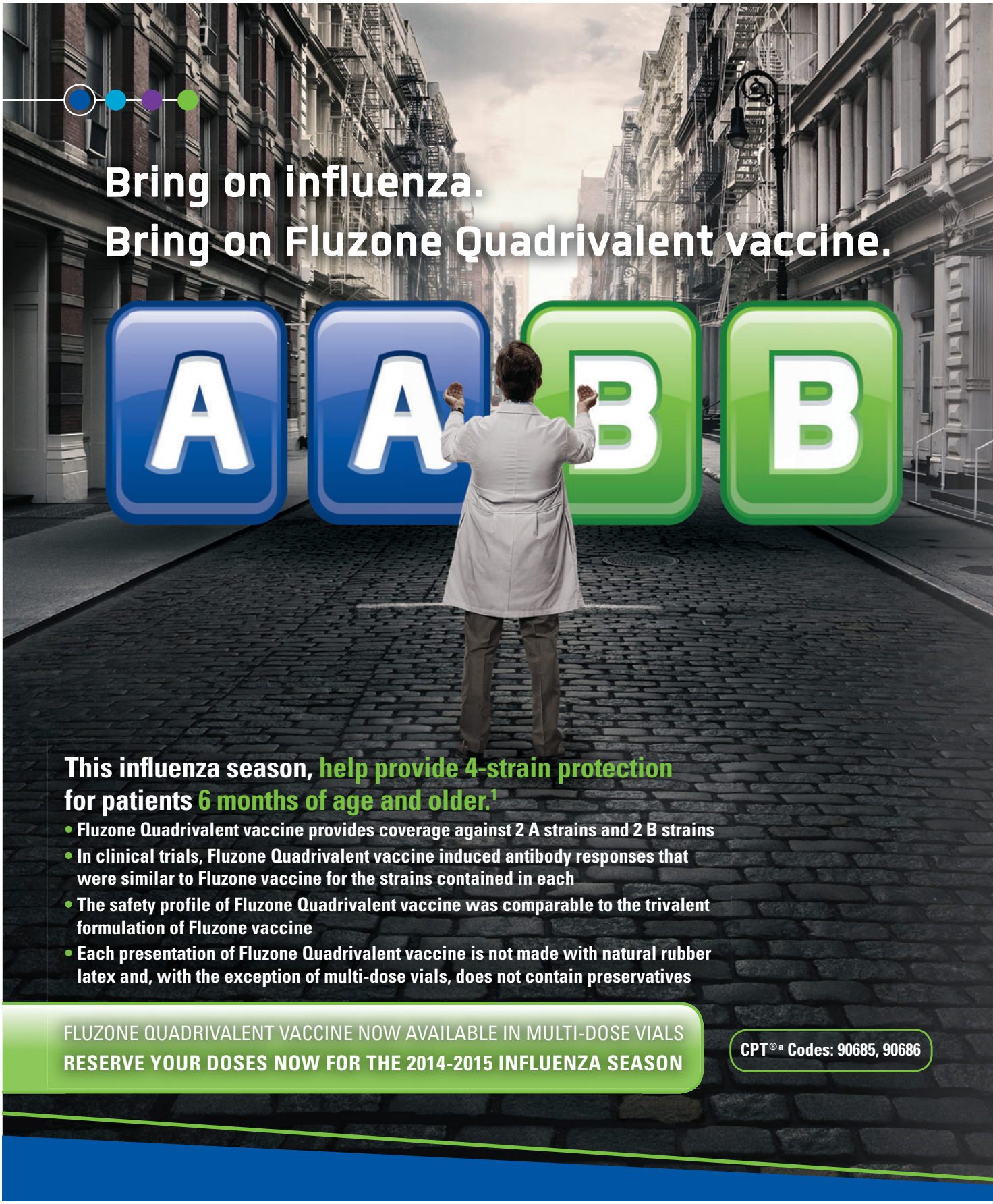
PUZZLER

Infant's seizures

SPECIAL REPORT

MARKETPLACE OR MEDICAID?
What to do with kids

ADVANSTAR MEDICAL COMMUNICATIONS GROUP



This influenza season, help provide 4-strain protection for patients 6 months of age and older.[1]

- Fluzone Quadrivalent vaccine provides coverage against 2 A strains and 2 B strains
- In clinical trials, Fluzone Quadrivalent vaccine induced antibody responses that were similar to Fluzone vaccine for the strains contained in each
- The safety profile of Fluzone Quadrivalent vaccine was comparable to the trivalent formulation of Fluzone vaccine
- Each presentation of Fluzone Quadrivalent vaccine is not made with natural rubber latex and, with the exception of multi-dose vials, does not contain preservatives

FLUZONE QUADRIVALENT VACCINE NOW AVAILABLE IN MULTI-DOSE VIALS

RESERVE YOUR DOSES NOW FOR THE 2014-2015 INFLUENZA SEASON

CPT®[a] Codes: 90685, 90686

SANOFI PASTEUR. Discovery Drive. Swiftwater, Pennsylvania 18370. www.sanofipasteur.us

IMPORTANT SAFETY INFORMATION

INDICATION

Fluzone Quadrivalent vaccine is an inactivated quadrivalent influenza virus vaccine indicated for the prevention of influenza disease caused by influenza subtype A and type B viruses contained in the vaccine. Fluzone Quadrivalent vaccine is approved for use in persons 6 months of age and older.

SAFETY INFORMATION

The most common local and systemic adverse reactions to Fluzone Quadrivalent vaccine include pain (tenderness in young children), erythema, and swelling at the injection site; myalgia, malaise, headache, and fever (irritability, abnormal crying, drowsiness, appetite loss, and vomiting in young children). Other adverse reactions may occur. Fluzone Quadrivalent vaccine should not be administered to anyone with a severe allergic reaction (eg, anaphylaxis) to any vaccine component, including egg protein, or thimerosal (the multi-dose vial is the only presentation containing thimerosal) or to a previous dose of any influenza vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks of receipt of previous influenza vaccination, the decision to give Fluzone Quadrivalent vaccine should be based on careful consideration of the potential benefits and risks. Vaccination with Fluzone Quadrivalent vaccine may not protect all individuals.

Before administering Fluzone Quadrivalent vaccine, please see accompanying brief summary of full Prescribing Information on next page.

To order Fluzone Quadrivalent vaccine for the 2014-2015 influenza season or learn about the Fluzone Partners Program, log onto **VaccineShoppe.com**® or call **1-800-VACCINE** (1-800-822-2463).

[a] CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association.
Fluzone and Fluzone Quadrivalent vaccines are manufactured and distributed by Sanofi Pasteur Inc.

Reference: 1. Fluzone Quadrivalent vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.; 2013.

Fluzone® Quadrivalent
INFLUENZA VIRUS VACCINE

SANOFI PASTEUR

Fluzone® Quadrivalent (Influenza Virus Vaccine) Suspension for Intramuscular Injection

2013-2014 Formula

℞ only

BRIEF SUMMARY: Please consult package insert for full prescribing information.

INDICATIONS AND USAGE

Fluzone® Quadrivalent is an inactivated quadrivalent influenza virus vaccine indicated for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Fluzone Quadrivalent is approved for use in persons 6 months of age and older.

DOSAGE AND ADMINISTRATION

• For intramuscular use only

Dose and Schedule

The dose and schedule for Fluzone Quadrivalent are presented in Table 1.

Table 1: Dose and Schedule for Fluzone Quadrivalent

Age	Dose	Schedule
6 months through 35 months	One or two doses[a] , 0.25 mL each	If 2 doses, administer at least 4 weeks apart
36 months through 8 years	One or two doses[a] , 0.5 mL each	If 2 doses, administer at least 4 weeks apart
9 years and older	One dose, 0.5 mL	-

[a]1 or 2 doses depends on vaccination history as per Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines
"-" Indicates information is not applicable

Administration

Inspect Fluzone Quadrivalent visually for particulate matter and/or discoloration prior to administration. If any of these defects or conditions exist, the vaccine should not be administered. Before administering a dose of vaccine, shake the prefilled syringe or single-dose vial. Withdraw the vaccine using a sterile needle and syringe. The preferred sites for intramuscular injection are the anterolateral aspect of the thigh in infants 6 months through 11 months of age, the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in persons 12 months through 35 months of age, or the deltoid muscle in persons ≥36 months of age. The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk. Do not administer this product intravenously, intradermally, or subcutaneously. Fluzone Quadrivalent vaccine should not be combined through reconstitution or mixed with any other vaccine.

DOSAGE FORMS AND STRENGTHS

Fluzone Quadrivalent is a suspension for injection. Fluzone Quadrivalent is supplied in 3 presentations: 1) Prefilled single-dose syringe (yellow syringe plunger rod), 0.25 mL, for persons 6 months through 35 months of age. 2) Prefilled single-dose syringe (purple syringe plunger rod), 0.5 mL, for persons 36 months of age and older. 3) Single-dose vial, 0.5 mL, for persons 36 months of age and older.

CONTRAINDICATIONS

Do not administer Fluzone Quadrivalent to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous dose of any influenza vaccine.

WARNINGS AND PRECAUTIONS

Guillain-Barré Syndrome

The 1976 swine influenza vaccine was associated with an elevated risk of Guillain-Barré syndrome (GBS). Evidence for a causal relation of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated.† If GBS has occurred within 6 weeks of previous influenza vaccination, the decision to give Fluzone Quadrivalent should be based on careful consideration of the potential benefits and risks.

Preventing and Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of Fluzone Quadrivalent.

Altered Immunocompetence

If Fluzone Quadrivalent is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.

Limitations of Vaccine Effectiveness

Vaccination with Fluzone Quadrivalent may not protect all recipients.

ADVERSE REACTIONS

In children 6 months through 35 months of age, the most common (≥10%) injection-site reactions were pain (57%)[a] or tenderness (54%)[b], erythema (37%), and swelling (22%); the most common solicited systemic adverse reactions were irritability (54%)[b], abnormal crying (41%)[b], malaise (38%)[a], drowsiness (38%)[b], appetite loss (32%)[b], myalgia (27%)[a], vomiting (15%)[b], and fever (14%). In children 3 years through 8 years of age, the most common (≥10%) injection-site reactions were pain (67%), erythema (34%), and swelling (25%); the most common solicited systemic adverse reactions were myalgia (39%), malaise (32%), and headache (23%). In adults 18 years and older, the most common (≥10%) injection-site reaction was pain (47%); the most common solicited systemic adverse reactions were myalgia (24%), headache (16%), and malaise (11%). In adults 65 years of age and older, the most common (≥10%) injection-site reaction was pain (33%); the most common solicited systemic adverse reactions were myalgia (18%), headache (13%), and malaise (11%).

[a]Assessed in children 24 months through 35 months of age
[b]Assessed in children 6 months through 23 months of age

Clinical Trials Experience

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

Children 6 Months Through 8 Years of Age

Study 1 (NCT01240746, see http://clinicaltrials.gov) was a single-blind, randomized, active-controlled multi-center safety and immunogenicity study conducted in the US. In this study, children 6 months through 35 months of age received one or two 0.25 mL doses of either Fluzone Quadrivalent or one of two formulations of a comparator trivalent influenza vaccine (TIV-1 or TIV-2), and children 3 years through 8 years of age received one or two 0.5 mL doses of either Fluzone Quadrivalent, TIV-1, or TIV-2. Each of the trivalent formulations contained an influenza type B virus that corresponded to one of the two type B viruses in Fluzone Quadrivalent (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage). For participants who received two doses, the doses were administered approximately 4 weeks apart. The safety analysis set included 1841 children 6 months through 35 months of age and 2506 children 3 years through 8 years of age. Among participants 6 months through 8 years of age in the three vaccine groups combined, 49.3% were female (Fluzone Quadrivalent, 49.2%; TIV-1, 49.8%; TIV-2, 49.4%), 58.4% Caucasian (Fluzone Quadrivalent, 58.4%; TIV-1, 58.9%; TIV-2, 57.8%), 20.2% Black (Fluzone Quadrivalent, 20.5%; TIV-1, 19.9%; TIV-2, 19.1%), 14.1% Hispanic (Fluzone Quadrivalent, 14.3%; TIV-1, 13.2%; TIV-2, 14.7%), and 7.3% were of other racial/ethnic groups (Fluzone Quadrivalent, 6.8%; TIV-1, 8.0%; TIV-2, 8.5%). Table 2 and Table 3 summarize solicited injection-site and systemic adverse reactions reported within 7 days post-vaccination via diary cards. Participants were monitored for unsolicited adverse events for 28 days after each dose and serious adverse events (SAEs) during the 6 months following the last dose.

Table 2: Study 1[a]: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Children 6 Months Through 35 Months of Age (Safety Analysis Set)[b]

	Fluzone Quadrivalent (N°=1223)			TIV-1[c] (B Victoria) (N°=310)			TIV-2[d] (B Yamagata) (N°=308)		
	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)
Injection-site adverse reactions									
- Pain[h]	57.0	10.2	1.0	52.3	11.5	0.8	50.3	5.4	2.7
- Tenderness[i]	54.1	11.3	1.9	48.4	8.2	1.9	49.7	10.3	0.0
- Erythema	37.3	1.5	0.2	32.9	1.0	0.0	33.3	1.0	0.0
- Swelling	21.6	0.8	0.2	19.7	1.0	0.0	17.3	0.0	0.0
Systemic adverse reactions									
- Fever (≥100.4° F)[i]	14.3	5.5	2.1	16.0	6.6	1.7	13.0	4.1	2.0
- Malaise[h]	38.1	14.5	4.6	35.2	14.8	4.7	32.4	12.8	6.8
- Myalgia[h]	26.7	6.6	1.9	26.6	9.4	1.6	25.0	6.8	2.7
- Headache[h]	8.9	2.5	0.6	9.4	3.9	0.0	12.2	4.7	0.0
- Irritability[i]	54.0	26.4	3.2	52.8	20.1	3.1	53.5	22.9	2.8
- Crying-abnormal[i]	41.2	12.3	3.3	36.5	8.2	1.9	29.9	10.4	2.1
-Drowsiness[i]	37.7	8.4	1.3	32.1	3.8	0.6	31.9	5.6	0.7
- Appetite loss[i]	32.3	9.1	1.8	33.3	5.7	1.9	25.0	8.3	0.7
- Vomiting[i]	14.8	6.2	1.0	11.3	4.4	0.6	13.9	6.3	0.0

[a]NCT01240746
[b]The safety analysis set includes all persons who received at least one dose of study vaccine
[c]2010-2011 Fluzone TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), licensed
[d]Investigational TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Florida/04/2006 (Yamagata lineage), non-licensed
[e]N is the number of participants in the safety analysis set
[f]Grade 2 - Injection-site pain: sufficiently discomforting to interfere with normal behavior or activities; Injection-site tenderness: cries and protests when injection-site is touched; Injection-site erythema, Injection-site swelling: ≥2.5 cm to <5 cm; Fever: >101.3°F to ≤103.1°F (6 months through 23 months); ≥101.2°F to ≤102.0° F (24 months through 35 months); Malaise, Myalgia, and Headache: some interference with activity; Irritability: requiring increased attention; Crying abnormal: 1 to 3 hours; Drowsiness: not interested in surroundings or did not wake up for a feed/meal; Appetite lost: missed 1 or 2 feeds/meals completely; Vomiting: 2 to 5 episodes per 24 hours
[g]Grade 3 - Injection-site pain: incapacitating, unable to perform usual activities; Injection-site tenderness: cries when injected limb is moved, or the movement of the injected limb is reduced; Injection-site erythema, Injection-site swelling: ≥5 cm; Fever: >103.1°F (6 months through 23 months); ≥102.1°F (24 months through 35 months); Malaise, Myalgia, and Headache: Significant; prevents daily activity; Irritability: inconsolable; Crying abnormal: >3 hours; Drowsiness: sleeping most of the time or difficult to wake up; Appetite lost: refuses ≥3 feeds/meals or refuses most feeds/meals; Vomiting: ≥6 episodes per 24 hours or requiring parenteral hydration
[h]Assessed in children 24 months through 35 months of age
[i]Assessed in children 6 months through 23 months of age
[j]Fever measured by any route

Table 3: Study 1[a]: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Children 3 Years Through 8 Years of Age (Safety Analysis Set)[b]

	Fluzone Quadrivalent (N°=1669)			TIV-1[c] (B Victoria) (N°=424)			TIV-2[d] (B Yamagata) (N°=413)		
	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)
Injection-site adverse reactions									
- Pain	66.6	15.8	2.1	64.6	9.5	2.0	63.8	11.6	2.8
- Erythema	34.1	2.9	1.8	36.8	3.4	1.2	35.2	2.5	1.8
- Swelling	24.8	2.8	1.4	25.4	1.5	1.2	25.9	2.5	1.8
Systemic adverse reactions									
- Fever (≥100.4° F)[h]	7.0	2.1	2.1	7.1	2.2	1.2	7.6	2.8	0.8
- Headache	23.1	6.8	2.2	21.2	5.1	2.7	24.4	7.5	2.0
- Malaise	31.9	11.2	5.5	32.8	11.4	5.6	33.4	10.8	5.0
- Myalgia	38.6	12.2	3.3	34.1	9.0	2.7	38.4	11.1	2.8

[a]NCT01240746
[b]The safety analysis set includes all persons who received at least one dose of study vaccine
[c]2010-2011 Fluzone TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), licensed
[d]Investigational TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Florida/04/2006 (Yamagata lineage), non-licensed
[e]N is the number of participants in the safety analysis set
[f]Grade 2 - Injection-site pain: sufficiently discomforting to interfere with normal behavior or activities; Injection-site erythema, Injection-site swelling: ≥2.5 cm to <5 cm; Fever: ≥101.2°F to ≤102.0°F; Headache, Malaise, and Myalgia: some interference with activity
[g]Grade 3 - Injection-site pain: incapacitating, unable to perform usual activities; Injection-site erythema, Injection-site swelling: ≥5 cm; Fever: ≥102.1°F; Headache, Malaise, and Myalgia: Significant; prevents daily activity
[h]Fever measured by any route

Among children 6 months through 8 years of age, unsolicited non-serious adverse events were reported in 1360 (47.0%) recipients in the Fluzone Quadrivalent group, 352 (48.0%) recipients in the TIV-1 group, and 346 (48.0%) recipients in the TIV-2 group. The most commonly reported unsolicited non-serious adverse events were cough, vomiting, and pyrexia. During the 28 days following vaccination, a total of 16 (0.6%) recipients in the Fluzone Quadrivalent group, 4 (0.5%) recipients in the TIV-1 group, and 4 (0.6%) recipients in the TIV-2 group, experienced at least one SAE; no deaths occurred. Throughout the study period, a total of 41 (1.4%) recipients in the Fluzone Quadrivalent group, 7 (1.0%) recipients in the TIV-1 group, and 14 (1.9%) recipients in the TIV-2 group, experienced at least one SAE. Three SAEs were considered to be possibly related to vaccination: croup in a Fluzone Quadrivalent recipient and 2 episodes of febrile seizure, 1 each in a TIV-1 recipient and a TIV-2 recipient. One death occurred in the TIV-1 group (a drowning 43 days post-vaccination).

Adults

In study 2 (NCT00988143, see http://clinicaltrials.gov), a multi-centered randomized, open-label trial conducted in the US, adults 18 years of age and older received one dose of either Fluzone Quadrivalent or one of two formulations of comparator trivalent influenza vaccine (TIV-1 or TIV-2). Each of the trivalent formulations contained an influenza type B virus that corresponded to one of the two type B viruses in Fluzone Quadrivalent (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage). The safety analysis set included 570 recipients, half aged 18-60 years and half aged 61 years or older. Among participants in the three vaccine groups combined, 67.2% were female (Fluzone Quadrivalent, 68.4%; TIV-1, 67.9%; TIV-2, 65.3%), 88.4% Caucasian (Fluzone Quadrivalent, 91.1%; TIV-1, 86.8%; TIV-2, 87.4%), 9.6% Black (Fluzone Quadrivalent, 6.8%; TIV-1, 12.1%; TIV-2, 10.0%), 0.4% Hispanic (Fluzone Quadrivalent, 0.0%; TIV-1, 0.5%; TIV-2, 0.5%), and 1.7% were of other racial/ethnic groups (Fluzone Quadrivalent, 2.1%; TIV-1, 0.5%; TIV-2, 2.2%). Table 4 summarizes solicited injection-site and systemic adverse reactions reported within 3 days post-vaccination via diary cards. Participants were monitored for unsolicited adverse events and SAEs during the 21 days following vaccination.

Table 4: Study 2[a]: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 3 Days After Vaccination in Adults 18 Years of Age and Older (Safety Analysis Set)[b]

	Fluzone Quadrivalent (N°=190)			TIV-1[c] (B Victoria) (N°=190)			TIV-2[d] (B Yamagata) (N°=190)		
	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)
Injection-site adverse reactions									
- Pain	47.4	6.8	0.5	52.1	7.9	0.5	43.2	6.3	0.0
- Erythema	1.1	0.0	0.0	1.6	0.5	0.0	1.6	0.5	0.0
- Swelling	0.5	0.0	0.0	3.2	0.5	0.0	1.1	0.0	0.0
- Induration	0.5	0.0	0.0	1.6	0.5	0.0	0.5	0.0	0.0
- Ecchymosis	0.5	0.0	0.0	0.5	0.0	0.0	0.5	0.0	0.0
Systemic adverse reactions									
- Myalgia	23.7	5.8	0.0	25.3	5.8	0.0	16.8	5.8	0.0
- Headache	15.8	3.2	0.5	18.4	6.3	0.5	18.0	4.2	0.0
- Malaise	10.5	1.6	1.1	14.7	3.2	1.1	12.1	4.7	0.5
- Shivering	2.6	0.5	0.0	5.3	1.1	0.0	3.2	0.5	0.0
- Fever (≥100.4° F)[h]	0.0	0.0	0.0	0.5	0.5	0.0	0.5	0.5	0.0

[a] NCT00988143

[b] The safety analysis set includes all persons who received study vaccine

[c] 2009-2010 Fluzone TIV containing A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), licensed

[d] 2008-2009 Fluzone TIV containing A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2), and B/Florida/04/2006 (Yamagata lineage), licensed

[e] N is the number of participants in the safety analysis set

[f] Grade 2 - Injection-site pain: Some interference with activity; Injection-site erythema, Injection-site swelling, Injection-site induration, and Injection-site ecchymosis: ≥5.1 to ≤10 cm; Fever: ≥101.2°F to ≤102.0°F; Myalgia, Headache, Malaise, and Shivering: some interference with activity

[g] Grade 3 - Injection-site pain: Significant; prevents daily activity; Injection-site erythema, Injection-site swelling, Injection-site induration, and Injection-site ecchymosis: >10 cm; Fever: ≥102.1°F; Myalgia, Headache, Malaise, and Shivering: Significant; prevents daily activity

[h] Fever measured by any route

Unsolicited non-serious adverse events were reported in 33 (17.4%) recipients in the Fluzone Quadrivalent group, 45 (23.7%) recipients in the TIV-1 group, and 45 (23.7%) recipients in the TIV-2 group. The most commonly reported unsolicited non-serious adverse events were headache, cough, and oropharyngeal pain. In the follow-up period, there were two SAEs, 1 (0.5%) in the Fluzone Quadrivalent group and 1 (0.5%) in the TIV-2 group. No deaths were reported during the trial period.

Geriatric Adults

In Study 3 (NCT01218646, see http://clinicaltrials.gov), a multi-center, randomized, double-blind trial conducted in the US, adults 65 years of age and older received one dose of either Fluzone Quadrivalent, or one of two formulations of comparator trivalent influenza vaccine (TIV-1 or TIV-2). Each of the trivalent formulations contained an influenza type B virus that corresponded to one of the two type B viruses in Fluzone Quadrivalent (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage). The safety analysis set included 675 recipients. Among participants in the three vaccine groups combined, 55.7% were female (Fluzone Quadrivalent, 57.3%; TIV-1, 56.0%; TIV-2, 53.8%), 89.5% Caucasian (Fluzone Quadrivalent, 87.6%; TIV-1, 89.8%; TIV-2, 91.1%), 2.2% Black (Fluzone Quadrivalent, 4.0%; TIV-1, 1.8%; TIV-2, 0.9%), 7.4% Hispanic (Fluzone Quadrivalent, 8.4%; TIV-1, 7.6%; TIV-2, 6.2%) and 0.9% were of other racial/ethnic groups (Fluzone Quadrivalent, 0.0%; TIV-1, 0.9%; TIV-2, 1.8%). Table 5 summarizes solicited injection-site and systemic adverse reactions reported within 7 days post-vaccination via diary cards. Participants were monitored for unsolicited adverse events and SAEs during the 21 days following vaccination.

Table 5: Study 3[a]: Percentage of Solicited Injection-site and Systemic Adverse Reactions Within 7 Days After Vaccination in Adults 65 Years of Age and Older (Safety Analysis Set)[b]

	Fluzone Quadrivalent (N°=225)			TIV-1[c] (B Victoria) (N°=225)			TIV-2[d] (B Yamagata) (N°=225)		
	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)	Any (%)	Grade 2[f] (%)	Grade 3[g] (%)
Injection-site adverse reactions									
- Pain	32.6	1.3	0.9	28.6	2.7	0.0	23.1	0.9	0.0
- Erythema	2.7	0.9	0.0	1.3	0.0	0.0	1.3	0.4	0.0
- Swelling	1.8	0.4	0.0	1.3	0.0	0.0	0.0	0.0	0.0
Systemic adverse reactions									
- Myalgia	18.3	4.0	0.4	18.3	4.0	0.0	14.2	2.7	0.4
- Headache	13.4	1.3	0.4	11.6	1.3	0.0	11.6	1.8	0.4
- Malaise	10.7	4.5	0.4	6.3	0.4	0.0	11.6	2.7	0.9
- Fever (≥100.4° F)[h]	1.3	0.0	0.4	0.0	0.0	0.0	0.9	0.4	0.4

[a] NCT01218646

[b] The safety analysis set includes all persons who received study vaccine

[c] 2010-2011 Fluzone TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/60/2008 (Victoria lineage), licensed

[d] Investigational TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Florida/04/2006 (Yamagata lineage), non-licensed

[e] N is the number of participants in the safety analysis set

[f] Grade 2 - Injection-site pain: some interference with activity; Injection-site erythema and Injection-site swelling: ≥5.1 to ≤10 cm; Fever: ≥101.2°F to ≤102.0°F; Myalgia, Headache, and Malaise: some interference with activity

[g] Grade 3 - Injection-site pain: Significant; prevents daily activity ; Injection-site erythema and Injection-site swelling: >10 cm; Fever: ≥102.1°F; Myalgia, Headache, and Malaise: Significant; prevents daily activity

[h] Fever measured by any route

Unsolicited non-serious adverse events were reported in 28 (12.4%) recipients in the Fluzone Quadrivalent group, 22 (9.8%) recipients in the TIV-1 group, and 22 (9.8%) recipients in the TIV-2 group. The most commonly reported adverse events were oropharyngeal pain, rhinorrhea, injection-site induration, and headache. Three SAEs were reported during the follow-up period, 2 (0.9%) in the TIV-1 group and 1 (0.4%) in the TIV-2 group. No deaths were reported during the trial period.

Post-Marketing Experience

Currently, there are no post-marketing data available for Fluzone Quadrivalent vaccine.

The following events have been spontaneously reported during the post-approval use of the trivalent formulation of Fluzone. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Fluzone.

- *Blood and Lymphatic System Disorders:* Thrombocytopenia, lymphadenopathy
- *Immune System Disorders:* Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- *Eye disorders:* Ocular hyperemia
- *Nervous System Disorders:* Guillain-Barré syndrome (GBS), convulsions, febrile convulsions, myelitis (including encephalomyelitis and transverse myelitis), facial palsy (Bell's palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination), dizziness, paresthesia
- *Vascular Disorders:* Vasculitis, vasodilatation/flushing
- *Respiratory, Thoracic and Mediastinal Disorders:* Dyspnea, pharyngitis, rhinitis, cough, wheezing, throat tightness
- *Skin and Subcutaneous Tissue Disorders:* Stevens-Johnson syndrome
- *General Disorders and Administration Site Conditions:* Pruritus, asthenia/fatigue, pain in extremities, chest pain
- *Gastrointestinal Disorders:* Vomiting

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with Fluzone Quadrivalent. It is also not known whether Fluzone Quadrivalent can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Fluzone Quadrivalent should be given to a pregnant woman only if clearly needed.

Sanofi Pasteur Inc. is conducting a prospective pregnancy exposure registry to collect data on pregnancy outcomes and newborn health status following vaccination with Fluzone Quadrivalent during pregnancy. Healthcare providers are encouraged to enroll women who receive Fluzone Quadrivalent during pregnancy in Sanofi Pasteur Inc.'s vaccination pregnancy registry by calling 1-800-822-2463.

Nursing Mothers

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

Pediatric Use

Safety and effectiveness of Fluzone Quadrivalent in children below the age of 6 months have not been established. Safety and immunogenicity of Fluzone Quadrivalent was evaluated in children 6 months through 8 years of age.

Geriatric Use

Safety and immunogenicity of Fluzone Quadrivalent was evaluated in adults 65 years of age and older. Antibody responses to Fluzone Quadrivalent are lower in persons ≥65 years of age than in younger adults.

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HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Single-dose, prefilled syringe (yellow plunger rod), without needle, 0.25 mL (NDC 49281-513-00) (not made with natural rubber latex). Supplied as package of 10 (NDC 49281-513-25).

Single-dose, prefilled syringe (purple plunger rod), without needle, 0.5 mL (NDC 49281-413-88) (not made with natural rubber latex). Supplied as package of 10 (NDC 49281-413-50).

Single-dose vial, 0.5 mL (NDC 49281-413-58) (not made with natural rubber latex). Supplied as package of 10 (NDC 49281-413-10).

Storage and Handling

Store all Fluzone Quadrivalent presentations refrigerated at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Discard if vaccine has been frozen.

Do not use after the expiration date shown on the label.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information). Inform the vaccine recipient or guardian:

- Fluzone Quadrivalent contains killed viruses and cannot cause influenza.
- Fluzone Quadrivalent stimulates the immune system to protect against influenza, but does not prevent other respiratory infections.
- Annual influenza vaccination is recommended.
- Report adverse reactions to their healthcare provider and/or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967.
- Sanofi Pasteur Inc. is conducting a prospective pregnancy exposure registry to collect data on pregnancy outcomes and newborn health status following vaccination with Fluzone Quadrivalent during pregnancy. Women who receive Fluzone Quadrivalent during pregnancy are encouraged to contact Sanofi Pasteur Inc. directly or have their healthcare provider contact Sanofi Pasteur Inc. at 1-800-822-2463.

Vaccine Information Statements must be provided to vaccine recipients or their guardians, as required by the National Childhood Vaccine Injury Act of 1986 prior to immunization. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Product information as of June 2013.

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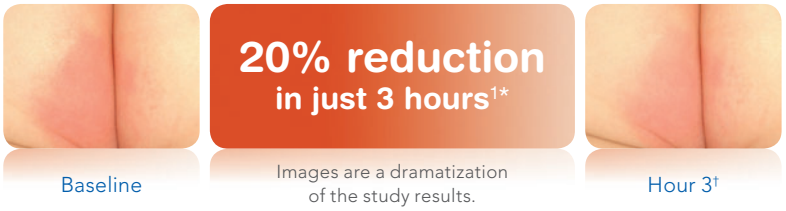

*Trial assessing the efficacy of DESITIN® Maximum Strength Original Paste for 3±1 hours in children (N=31) 3-36 months of age, with mild to moderate diaper rash, wearing diapers for 24 hours a day.[1]

†*P*=0.0001

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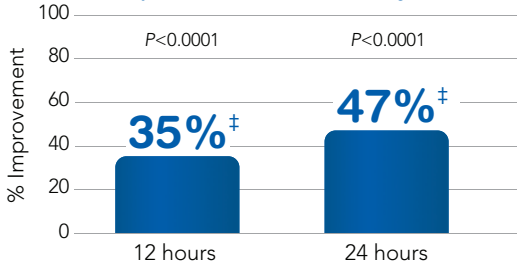
- Evaluation of erythema, papules, and dryness/scaling
- An average improvement score of **35% at 12 hours** (*P*<0.0001) and **47% at 24 hours** (*P*<0.0001)[2‡]



‡Efficacy and safety assessments were performed by a trained evaluator at baseline, and at 12 and 24 hours post-baseline (N=57). Subjects (2-36 months of age) must have received an "Overall Severity Score" of >1.5 as determined by evaluator at enrollment. Diaper rash severity was assessed using a 0- to 3-point scale (0=none; 3.0=severe).

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References: 1. Data on file. **2.** Brown WM, Berg JE, Li Q, Kohut BE. A clinical study to evaluate the efficacy of two marketed zinc oxide-based diaper rash ointments in children with diaper dermatitis. Poster presented at: Clinical Dermatology Conference; October 6-9, 2006; Las Vegas, NV. **3.** Product monograph. 68 FR 33377, June 4, 2003.

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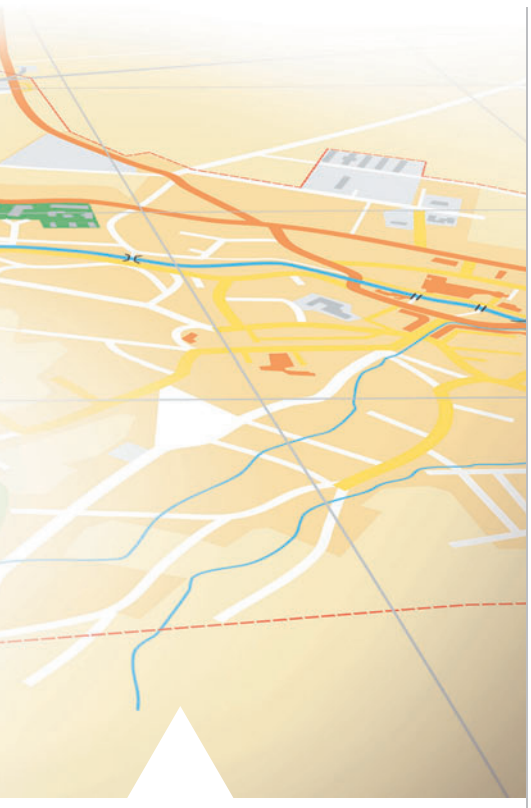

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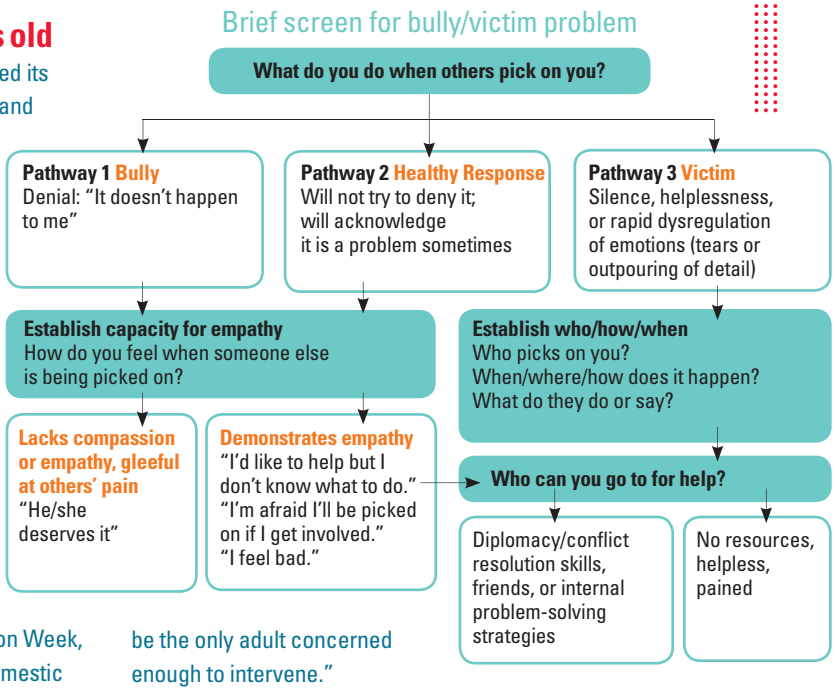
AGAINST A NEW DARKNESS

ContemporaryPediatrics.com/bullyingalgorithm

Mark Zuckerberg was 12 years old in 1996 when ***Contemporary Pediatrics*** devoted its cover story to the topic of childhood bullying and included this disconcertingly prescient screening algorithm.

Eight years after this article ran in our pages, Zuckerberg's brainchild, Facebook, was to become one of social media's most notorious digital schoolyards in which the bullying was virtual but the often-resulting child and teen suicides were all too real. Over the past 30 years, ***Contemporary Pediatrics*** has spotlighted many such cultural trends impacting the health of youngsters in its mission to better equip pediatricians for their effective care. In this issue, in service to the annual National Youth Violence Prevention Week, we report on teens who self-harm and the domestic epidemic of the sex-trafficking of children. As is so often the case, alert pediatricians may be literal lifelines to these young lives. As Dr. Kanani Titchen writes in her Guest Editorial, "their physician may be the only adult concerned enough to intervene."

30 YEARS Helping You Care for Kids



In the 3 intervening decades since our founding, the bully is no longer just on the playground, but while the risks may be darker, your vigilance can still become a beacon for the most vulnerable.

feedback

ACA: Our readers react

One pediatrician responds to the findings of our online poll "Has the ACA hit home yet?"(February 2014)

I just acquired a retiring pediatrician's practice in 2013, as she didn't want to deal with EMR, e-scripts, ACA, and all that. Since I have assumed her practice, I have seen a slow surge of patient census due to switching of Healthy Families to Medi-Cal (lost 180 patients). Now with Obamacare on my doorstep, I found out that even if I try to keep my existing patients by applying to their chosen insurance network, I couldn't get in as a provider because, according to them, provider enrollment is by invitation only and for some insurance I am not eligible because I have been practicing for less than 10 years. How true is this? I thought that the reason why we are switching to this kind of care is so that we can provide services to the increased surge of enrolled patients. Why are they limiting the network of providers?

This has been a grueling experience for me. What more [is it] for the new graduates who want to start their own practices? I find myself swimming against the incoming current. I am worried that I may be losing more of my existing patients if they sign [up] for this Obamacare. I bought a practice at the wrong time!

IVAN TANCHOCO, MD

How is the ACA affecting your practice? Sound off at **cradwan@advanstar.com**

Child sex trafficking in Hometown USA

Far from being a problem "somewhere else," child sexual exploitation is far more visible than you might think.

"Sam" sat before me, inappropriately dressed for the cold weather, dismissive, hurting, and guarded. At age 15, with divorced parents and shuffling back and forth between homes, Sam had been on her own, at least mentally, for a number of years already. She recently had run away from home but was found by her father and brought in for abdominal pain. I soon asked Sam's concerned father to leave the room, which he did, and after explaining the rules of confidentiality and mandated reporting, I dived into the "teenager questions," what I call questions about "sex, drugs, rock and roll"—reproductive health, illicit substance use, and abuse.

Because I knew the warning signs, and because Sam answered that she is sexually active "but only when drunk," I asked Sam a question I've never asked before: "Do you ever trade sex for money or shelter or *stuff*?" Her answer: "Yeah, sure, sometimes."

We continued our interview and I contacted our social worker, who continued the visit with Sam and her dad.

The commercial sexual exploitation of children is a domestic problem that affects 100,000 American children in the United States each year, according to the most reliable estimates.[1] In what has been termed "modern day slavery" by President Obama and "child sex trafficking" by others, children as young as 7 years old are being bought and sold for purposes of sexual exploitation, including prostitution and Internet pornography. Ten percent of US children living in shelters and 28% of US children living on the streets report exchanging sex for drugs or money.[2] Social workers, police officers, teachers, and physicians all may interact with these children regularly and unknowingly. Because the average age of a child entering "the life" is just 13 years old, pediatricians have a unique opportunity to help.[1]

However, pediatricians are not recognizing these children because we are under the mistaken notion that these children never make it to our care. A recent study found that 28% of European trafficking victims had seen a healthcare professional while still in captivity.[3] Even when health professionals acknowledged that trafficked victims appeared in their emergency departments, most healthcare providers lacked confidence that they would be able to identify these victims, and almost all had received no training in recognizing the signs of trafficked victims.[4] Preliminary survey data support this (Titchen, Chin, Sharif, unpublished data, 2013), showing that most medical students, residents, and physicians agree that it is important to know about human trafficking while a minority understand the scope of the problem and know what to do when they encounter a trafficked child.

Kanani Titchen, MD
is a pediatric resident at Thomas Jefferson University Hospital Philadelphia, Pennsylvania, and Alfred I. duPont Hospital for Children, Wilmington, Delaware.

Although trafficked children can be male or female, straight or gay, and of any race or ethnic background, they tend to have a few common characteristics. They may be from the foster care system, broken homes, or they may be runaways. Many are taught by their abusers to avoid eye contact, thus appearing "defiant" to healthcare practitioners. Many are dressed inappropriately for the weather or time of year. Some

will present with signs of physical abuse, particularly dental or head injuries, or repeated sexually transmitted diseases. Chronic abdominal pain is a common complaint of sexually violated girls. Some will be "branded" with a tattoo bearing their pimp's name. Occasionally, a controlling adult who speaks for the child or refuses to leave the exam room will accompany the child.[5-9]

In caring for these children, it is important to treat them as you would any other patient: Attend to physical needs; establish rapport and trust by inquiring about the child's immediate comfort and well-being; establish a private and confidential environment; and inquire sensitively yet directly about the patient's safety, nutrition, and autonomy, including the ability to come and go freely. Understand that you as the physician are one of many stepping-stones in this patient's journey back to health. Avoid the rescue fantasy, especially with older teens; one visit is unlikely to fix everything. Be up front about mandated reporting and confidentiality.[10]

Above all, give the patient a reason to return. Schedule a follow-up appointment for them; get them plugged into social work resources; and provide written instructions about their needed follow-up. This may be the patient's only legitimate excuse to ever meet with a healthcare practitioner again.[10] Do not give written information about abuse hotlines and other resources because these can endanger the patient. Do provide the easily memorized 888-3737-888 national human trafficking hotline phone number or the text address "BeFree" (233733) to patients verbally. If possible, provide your pager or work phone number to the patient for his or her cell phone.

I cannot say with certainty that Sam was trafficked, but she was certainly at risk. Sam was fortunate that she had at least one parent who was appropriately concerned and involved in her life. For many others, their physician may be the only adult concerned enough to intervene, but intervention hinges on the physician recognizing the warning signs. ■

"The commercial sexual exploitation of children is a domestic problem that affects 100,000 children in the United States each year."

US Department of Justice.[1]

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editor's note

Dr. Titchen and colleagues have founded a 501(c)(3) nonprofit organization through the sponsorship of the American Medical Women's Association (AMWA) to create an online resource to teach doctors the hidden signs of child sex trafficking and to provide the proper resources that can help these children to safety. For additional information about this initiative, visit

www.indiegogo.com/projects/stop-child-sex-trafficking--2

A call to care

There is a great need for global attention to pediatric burn injuries.

Katrina B Mitchell, MD
is a general surgery resident at New York-Presbyterian Hospital/Weill Cornell Medical Center, New York.

Have you been inspired to make a difference in the lives of children? Dispatches is written by frontline pediatricians exploring novel ways to advocate for children's health in their communities. If you have a special story to tell, tell us. Send your Dispatches to cradwan@advanstar.com

As a general surgery resident on my research sabbatical in East Africa, I observed the high burden of surgical disease children suffered there, particularly in trauma and burn injuries. Although international aid was being directed to infectious diseases, few governmental or nongovernmental funding agencies seemed to be addressing the issue of trauma and burn injuries in the pediatric population.

In my effort to understand this discrepancy, I came to realize that there was a lack of awareness in the medical and lay communities alike about pediatric trauma and burns. Hoping to change this, I began educating myself about the burden of pediatric burn injuries in the developing world, and then sharing what I had learned with my surgical, medical, and pediatric colleagues.

What I've learned

Trauma and burn injuries kill more children aged older than 5 years than HIV, malaria, and tuberculosis combined.[1] Overall, burn injuries are the third leading cause of pediatric death in the developing world, behind road traffic injuries and drowning.[2] Despite this, few international public health efforts historically have been directed at improving burn care from a systematic and institutional perspective. Furthermore, the United Nations Millennium Development Goal to reduce childhood mortality by two-thirds by 2020 cannot be achieved by tackling infectious diseases alone. The World Health Organization 2008 plan for the prevention of burn injuries clearly delineates the need for increased global attention to burns.[3]

Africa has one of the world's highest rates of burn injuries and deaths from burns, the largest at-risk pediatric population, and the fewest burn care facilities. Burn injuries in low- and middle-income countries is a leading cause of disability-adjusted life years.[4] Untreated childhood burns—even small ones—can result in severe deformity, loss of function, and social isolation.

Burn-injured children suffer social disability from disfiguring scars, and the trauma they experience is lifelong. Even with extensive plastic and reconstructive surgery, they never return to their preinjury appearance. Without proper treatment, even minor injuries can result in very poor functional and cosmetic outcomes. Worse, patients may develop invasive and aggressive cancers as a result of their burns. Preventing

burns and treating acute injury to avoid scars and lifelong disability is a major goal of burn surgeons working in the developing world.

How can we help?

Based on my experiences, I elected to take an extra year of research sabbatical to work with East African governmental and nongovernmental partners and my medical school/hospital affiliation in the United States to establish the first pediatric burn unit in northwestern Tanzania. We currently are in our 18-month pilot project phase that will enable local providers to improve existing infrastructure, establish burn care protocols, and lay the foundation for future development. Once providers have acquired additional education and training, they will be able to generate income from the burn unit project through patient care and fundraising. Overall, we hope to demonstrate improved outcomes for the unique needs of burn-injured patients and promote community education and outreach to improve burn injury prevention.

Given that our world is increasingly global, pediatricians can speak out on the issue of burn injuries affecting children not just within the United States, but throughout the world. Pediatricians can also offer guidance to surgeons caring for burn-injured children about pediatric nutrition, intravenous fluid resuscitation, and pain medication. Burn surgery equipment, wound care supplies, and rehabilitation equipment are inexpensive and can be sourced locally. Burn care treatment is simple and can be learned by medical and lay providers alike.

A mother cares for her small child who had an operation to close the scalp wound he sustained from a hut fire. See more of Dr. Mitchell's photos from her work in Tanzania at **ContemporaryPediatrics.com/Dispatches_Mitchell**

If you would like to become involved with the pediatric burn unit in Mwanza, Tanzania, please contact project director Jim Gallagher, MD, of the William Randolph Hearst Burn Center at New York-Presbyterian Hospital (burndrjim@gmail.com).

Pediatricians may also want to help orphanages in the northwestern Tanzania Lake Zone region, particularly the Forever Angels Baby Home (foreverangels.org). Founded by Amy and Ben Hathaway, this orphanage cares for children with medical needs such as nutritional supplementation, ostomies, and wounds.

Consider membership in the American Burn Association (ABA; ameriburn.org). The ABA provides a multitude of resources relevant to the pediatrician's role in burn care, including burn center referral criteria, basic wound care, and prevention initiatives.

Finally, MetroHealth Medical Center (www.metrohealth.org/traumaburnsandcriticalcare) is an ABA-certified burn center in Cleveland, Ohio, that may provide local resources for pediatricians interested in contributing to the care of burn-injured children.

I hope that through this Dispatches piece I will continue to spread awareness of pediatric burn injuries and what can be done to improve care in Africa and other parts of the developing world. ■

IMAGE CREDIT: DAVID CHALK

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Bullying behavior is the new public health concern

Twenty years of research makes it clear that between 5% and 20% of pupils in schools are bullied and between 2% and 20% of students are bullies, according to a new book from the American Public Health Association (APHA).

Even after more than 15 years of heightened awareness, most of the research on health problems related to bullying originates from outside the United States and most is based on self-reports by students, according to a chapter written by Diana Schroeder, MSN, RN, director of bullying prevention initiatives at Windber Research Institute, Pennsylvania. Most of the studies come from the psychological community and others from the medical community, she says.

Schroeder states the health outcomes most commonly associated with bullying are psychosomatic, and physical injuries are those least commonly associated.

Unfortunately, most evidence supporting association between being bullied and mental health problems is looking at the children within a short time of the events, writes Gianluca Gini, PhD, of the University of Padova, Italy, in another chapter. However, the few studies looking at long-term outcomes report that bullied children "show adjustment problems also in late adolescence and in adulthood." For example, 1 meta-analysis of 29 longitudinal studies found that bullying victims are twice as likely to report depression later in life than noninvolved students.

Gini points out that some research indicates early bullying behavior is linked to later criminal behavior and other antisocial behaviors, and increased attention is being given to a possible comorbidity of bullying and early substance use. Bullying might represent a warning sign for other problem behaviors, he says.

On the other hand, Gini notes, "According to the literature, among the many protective factors that can be identified, parental and school support play important protective roles in children and adolescent development and well-being."

Schroeder advises communities to create communication avenues for educating healthcare providers about schools' bullying policies and programs, and ways for providers to talk to the school if there is a concern about a child being bullied. She advises healthcare professionals to regularly ask children and families about a child's exposure to bullying and other aggressive behaviors at school.

Among the risk factors associated with bullying, Schroeder says, are mental health or behavioral issues; being gay or being perceived to be gay; and being emotionally abused or neglected at home.

Screening requires a plan for follow-up if there is an issue, Schroeder warns, and the professional may consider contacting the school nurse, counselor, or principal. The healthcare professional's expertise on the health consequences of bullying may increase awareness at the school, she says.

There are 4 school policies that some federal partners in bullying prevention advise schools against, says another chapter contributor Susan P. Limber, PhD, of Clemson University, South Carolina. They are zero-tolerance policies that include punishments such as suspension and expulsion for students who bully; conflict resolution and student mediation efforts because by definition there is a power imbalance between the bully and the victim; group treatment for bullies that may reinforce antisocial behavior; and most short, simple solutions.

The recommended policy is the comprehensive bullying prevention program developed by Dan Olweus, PhD, in Norway in the early 1980s. It includes showing warmth and interest in the students, establishing firm but reasonable rules for behavior, and having consistent but nonhostile consequences.

Some of the program's components include supervising students' activities; ensuring that all staff intervene immediately when they see bullying; meeting separately with students doing the bullying and those being bullied; meeting with the parents of students involved;

and developing individual interventions as needed.

Other chapters in the book focus on school climate reform; practical implications for the school administrator; and economic evaluation of bullying prevention programs.

A Public Health Approach to Bullying Prevention by Matthew G. Masiello, MD, MPH, and Diana Schroeder, MSN, RN, can be purchased in both book and e-book formats at the APHA's online bookstore.

The US Department of Health and Human Services website www.stopbullying.gov offers various federal and nonfederal toolkits, training materials, and a listing of state policies and laws in addition to other resources for bullying prevention. ■

Report card grades states on motor vehicle safety laws for children

The number of states with good booster seat laws has risen from 0 in 1989 to 31 plus the District of Columbia, according to Advocates for Highway and Auto Safety (AHAS). However, no state passed a new booster seat law in 2013.

The definition of a good booster seat law, according to AHAS, is that, at a minimum, children aged 4 to 7 years are placed in booster seats certified by the manufacturer to meet US Department of Transportation safety standards.

The organization follows the enactment of highway safety laws nationally and released its report card as many states began their 2014 legislative sessions.

Sixteen states (Alabama, Arkansas, Connecticut, Idaho, Iowa, Kentucky, Louisiana, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oklahoma, and South Carolina) have booster seat laws for part of the age group but not for all children aged to 7 years.

The report points to the estimate by the Partners for Child Passenger Safety that "using a booster seat with a seat belt instead of a seat belt alone reduces a child's risk of injury in a crash by 59%."

Three states (Florida, Ohio, and South Dakota) either have not adopted any booster seat law or have a law that permits only secondary enforcement, which means that law enforcement officers may enforce the booster seat law only if they stop a vehicle for another issue. They cannot stop a vehicle only for nonuse of the booster seat.

All states have child safety seat laws, most often for children aged younger than 4 to 6 years, according to the National Highway Traffic Safety Administration (NHTSA). In January, NHTSA proposed an upgrade to the standards for child safety seats that would include side impact tests. Under the rule, the car seats "must demonstrate they can safely restrain a child by preventing harmful head contact with an intruding vehicle door and reducing the crash forces transmitted to the child's head and chest."

In the area of adolescent driving laws, AHAS says that no state currently meets all 7 of its recommendations for graduated driver's license laws for teenagers, which are: minimum age for a learner's permit of 16 years; a 6-month period when a beginning adolescent driver must be supervised by an adult licensed driver; 30 to 50 hours of supervised driving with an adult; prohibiting unsupervised night driving during an intermediate stage; limits on the number of teenaged passengers who can ride with an adolescent driver without adult supervision; prohibition on all use of cellular devices for adolescent drivers; and requiring teenaged drivers to be aged 18 years for an unrestricted license.

Thirteen states meet at least 5 of these laws, 5 states meet fewer than 2. Most states have the 6-month period of required adult supervision, but only 8 have the minimum age of 16 years for the learner's permit. Only 15 states have the law for unrestricted driving only for those aged 18 years and older.

The number of people killed in motor vehicle crashes increased in 2012 by 3.3%—to 33,561. However, this was the first increase since 2005, which recorded 43,510 fatalities. Preliminary data from NHTSA show there was a decline in motor vehicle fatalities in the first half of 2013. ■

Marketplace or Medicaid?

What do to with kids

Pediatric providers should be able to direct families to the best coverage options.

MARI EDLIN

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To read an extended version of this article, go to ContemporaryPediatrics.com/MarketplaceorMedicaid

The number of medically uninsured children between 2008 and 2012 dropped to 5.3 million, and the coverage rate rose to 92.8%, according to the US Census Bureau American Community Survey.

That might be the good news, but currently 70% of uninsured children are eligible but not enrolled in Medicaid or the Children's Health Insurance Program (CHIP), says the Urban Institute.

The Institute's Health Insurance Policy Simulation Model indicates that under the Affordable Care Act (ACA), 75% of parents who are enrolled in a subsidized health insurance exchange plan will have a child eligible for Medicaid or CHIP.

There is progress to be made in curing the ills of the healthcare system. The process by which parents seek coverage in the new exchanges while their children qualify for Medicaid or CHIP is confusing for many families, along with enrolling and renewing eligible uninsured children and dealing with "churn," the annual shifting between Medicaid and marketplace policies.

As director of CHIP in New Hampshire for 15 years, Tricia Brooks, who now serves as research associate professor at the Georgetown University Center for Children and Families, Washington, DC, knows first hand about the potential problems associated with Medicaid, but she also recognizes the program's benefits.

Split coverage for families

Brooks is not convinced that split coverage within a family is such a major issue. She points to the robust benefits provided by Medicaid, including the Early and

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BEST CHILDREN'S HOSPITALS U.S.NEWS & WORLD REPORT RANKED IN 10 SPECIALTIES 2013-14

HOW TO HELP FAMILIES WITH KIDS SIGN UP FOR HEALTH COVERAGE

InsureKidsNow lists 10 actions that community health centers can take to help enroll eligible children into Medicaid and CHIP:

1. Train staff to alert patients about Medicaid and CHIP and how to apply.
2. Provide Medicaid and CHIP information, such as posters, flyers, brochures, and videos, in waiting areas.
3. Work with your state to comply with the Medicaid "outstation" requirement.
4. Train staff to help with applications and renewals.
5. Set up an online application station.
6. Integrate outreach activities with neighboring programs.
7. Partner with other community institutions serving children likely to qualify for Medicaid or CHIP.
8. Conduct outreach at special events.
9. Customize enrollment for special populations.
10. Provide application help to community health center employees.

Abbreviation: CHIP, Children's Health Insurance Program.

US Department of Health and Human Services. Connecting kids to coverage: 10 things community health centers can do. InsureKidsNow website. http://www.insurekidsnow.gov/professionals/outreach/strategies/chc/10_things_to_do.pdf. Accessed February 24, 2014.

Periodic Screening, Diagnostic, and Treatment benefit provided to children aged younger than 21 years, which the American Academy of Pediatrics (AAP) calls the "gold standard."

"Those benefits are more comprehensive than the exchange's essential health benefits or commercial insurance, " she says.

Brooks also praises Medicaid over private insurance for its more streamlined approach to management, presenting fewer barriers to accessing care, and limiting cost share to nominal charges.

By contrast, Margaret Murray, CEO of the Association of Community Affiliated Plans (ACAP), Washington, DC, is concerned that parents covered under the exchange while their children are in Medicaid or CHIP—she estimates 41%—may be confused in seeking healthcare. That would mean different providers and copayments and 2 points of contact, she says.

Handling split coverage in the provider setting

With a split in coverage, there definitely can be some confusion once parents, with children in hand, face the registration staff at their local pediatrician's office, says Kenneth Schellhase, MD, medical director for the Children's Community Health Plan in Wisconsin and a family practitioner.

Confusion reigns when parents no longer qualify for Medicaid—their incomes are above the federal poverty level for the state or they have neglected to renew their coverage—but their children remain eligible for Medicaid. "[Physicians'] staff members should be able to explain ACA regulations and direct parents to the best coverage options for both parents and children," Schellhase says, "preferably during a private conversation."

Schellhase notes 2 scenarios that could potentially lead to somewhat "delicate" issues—when parents are undocumented and their children are US citizens, and if parents' income has dropped, either scenario pushing them back into Medicaid coverage or shifting their children to the government program.

"It is difficult to answer questions such as 'why aren't you covered' when parents aren't citizens or face the stigma of enrolling in Medicaid," he says. "The pediatric staff must be able to broach these issues without betraying any sign of surprise and not send a message that something is wrong."

Brooks also offers some practical advice for provider offices. "Since the front office always confirms the source of coverage for the patient being seen, staff could simply ask if any member of the family is uninsured, and if the answer is 'yes,' have a supply of brochures or fact sheets to give to individuals," she says. "Or staff might hand out the brochure and make the statement that 'if any family member is uninsured, there are affordable coverage options.'"

"But it gets a little tricky in states that aren't expanding Medicaid because [then] there is the coverage gap," Brooks says. "Also, for those who qualify for marketplace coverage, there is a deadline looming and that has impact on how an office might want to do outreach." (Open enrollment for 2014 ends March 31.)

Brooks adds that because

pediatricians might not be aware of the insurance status of their patients until they are suggesting a test or treatment, and the parent expresses concern about costs, it is important for the staff to work with families to enroll them in coverage or meet other needs the family may have, such as services from a social worker.

Unfortunately, reimbursement for those services is not common and that inhibits the provider from becoming a robust 'health home' for kids, she says.

Reimbursement on the line

Although Medicaid pays a lower reimbursement rate, the ACA provided 100% federal funding for states to boost Medicaid reimbursement rates for primary care providers to Medicare levels. Schellhase says it is difficult to see how this might play out in each state, depending both on the number of new Medicaid beneficiaries in states with expansion and on the size of enrollment in the exchanges. Reimbursement depends on the issuer.

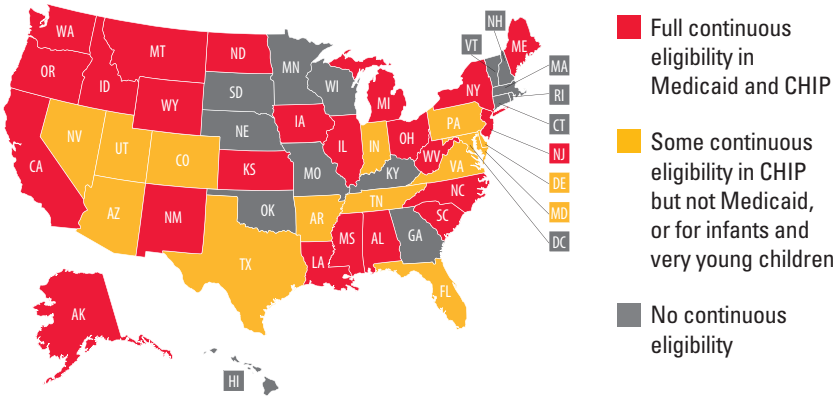
"However, the higher funding for Medicaid is running out at the end of 2014, so it will be important for stakeholders to advocate for their states to maintain the higher reimbursement," Brooks says. "I would think pediatricians would want to engage in that effort."

As the system churns

To address churn, 22 states have adopted 12-month continuous eligibility that allows children aged 0 to 18 years to maintain Medicaid or CHIP coverage for up to 1 year if family income changes (Figure)[1]: Alabama, California, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Michigan, Mississippi, Montana, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, South Carolina, Washington, West Virginia, and Wyoming.

FIGURE

STATES PROVIDING 12-MONTH CONTINUOUS MEDICAID/CHIP ELIGIBILITY FOR CHILDREN



Abbreviation: CHIP, Children's Health Insurance Plan. Data current as of January 2013.
Kortchmar S, et al.[1]

Brooks says this program is important for keeping children enrolled and putting states in a stronger position to measure the quality of care and health outcomes.

On February 3, 2014, US Senator Jay Rockefeller (D-WV) introduced to the Senate the *Medicaid and CHIP Continuous Quality Act of 2014* that would require every state to adopt the 12-month program. According to his office, the bill would also provide performance bonuses to states for meeting criteria for enrollment and retention in the Medicaid program and make accurate reports on the quality of care provided.

"Twelve-month continuous enrollment eases the administrative burden on healthcare providers and reduces the resources that health plans and state Medicaid programs must devote to processing new memberships or applications and verifying and reverifying eligibility," says Murray.

Improving coverage

Thomas Long, MD, chairman of the Committee on Child Care Finance, AAP, is concerned that too few dollars are going to Medicaid although children represent more than half the US population. "All kids should be covered or we won't have healthy adults," he says.

Funding for CHIP, however, will run out in fiscal year 2015. If funding ends, an AAP policy statement published in *Pediatrics* in January 2014 suggests that children meeting certain eligibility criteria would transition to the exchange with restricted access or lose insurance. ■

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BY MARIAN FREEDMAN | COMMENTARY BY MICHAEL G BURKE, MD | f CONTEMPORARYPEDIATRICS

Monovalent rotavirus vaccine elevates intussusception risk

A comparison of the risk of intussusception after receipt of monovalent versus pentavalent rotavirus vaccine or versus historical background rates of intussusception found that the monovalent vaccine significantly increases that risk.

Investigators analyzed data for almost 208,000 doses, both first and second, of monovalent rotavirus vaccine and almost 2 million doses of pentavalent rotavirus vaccine during a roughly 5-year period. Among infants aged 4 to 34 weeks who received monovalent vaccine, investigators identified 6 cases of intussusception within 7 days of administration of either the first or second dose, resulting in a significant relative risk of 8.4 compared with historical background rates.

For the pentavalent rotavirus vaccine, 8 intussusception cases were observed, a nonsignificant relative risk of 1.1. The relative risk of intussusception within 7 days after doses 1 and 2 of the monovalent rotavirus vaccination, compared with this risk after doses 1 and 2 of the 3-dose pentavalent rotavirus vaccination series, was 9.4. Investigators estimated that 5.3 per 100,000 infants vaccinated with 2 doses of monovalent rotavirus vaccine were at risk of intussusception (Weintraub ES, et al. *N Engl J Med*. 2014;370[6]:513-519).

commentary

This article was published simultaneously with a second, large postlicensure assessment of monovalent and pentavalent rotavirus vaccines in the United States. Together these articles suggest that not just the monovalent but the pentavalent rotavirus vaccine as well are linked to a slightly increased risk of intussusception (Yih WK, et al. *N Engl J Med*. 2014;370[6]:503-512). In an accompanying editorial, Glass and Parashar help to put this in perspective by reminding us what we get for that risk. They cite estimates that in an annual cohort of 4.5 million US infants, rotavirus vaccine might cause 45 to 213 cases of intussusception while preventing more than 50,000 hospitalizations and more than 150,000 emergency department visits (Glass RI, et al. *N Engl J Med*. 2014;370[6]:568-570). I suspect that any of us who remembers a deathly ill infant with rotavirus will be willing to take this risk. *—Michael Burke, MD*

Office-based parent training reduces disruptive toddler behavior

Participation in parent training groups can effectively improve parenting practices and behavior in young children with disruptive behaviors, a randomized trial conducted at 11 diverse pediatric practices around Boston demonstrated.

Included in the trial were 150 parents (mostly mothers) of 2- to 4-year-old children who scored at the 80th percentile or higher on the Infant-Toddler Social-Emotional Assessment scale, which predicts disruptive behavior disorders. Investigators assigned half the parents to a parent training group (6 to 12 parents in a group); the other half were assigned to a waiting list, which served as the control group. An additional 123 parents were assigned to receive the intervention without a randomly selected comparison group.

The parent training, which was based on the Incredible Years program, encouraged proactive, nurturing parenting while discouraging

harsh, punitive approaches. The groups, which met for 2 hours weekly for 10 weeks (usually in a pediatric office), relied on videotaped modeling, group discussion, role plays, and home practice tasks in 4 areas: play; praise and rewards; effective limit setting; and handling misbehavior. A clinical psychologist or social worker as well as a pediatric practice staff member led each group.

At the beginning and end of the trial, investigators used parental questionnaires, a parenting scale, childhood behavior inventory, and structured videotaped parent-child interactions to observe changes during the study period. Compared with baseline, both the randomized and nonrandomized intervention groups demonstrated or reported less negative parenting, fewer child disruptive behaviors, and fewer negative parent-child interactions both at the intervention's conclusion and at the 12-month follow-up, whereas the control group showed less improvement (Perrin EC, et al. *JAMA Pediatr*. 2014;168[1]:16-24).

commentary

This sounds great, especially if you have parents who will sign up and show up for a weekly 2-hour intervention. However, who will pay? Is the evidence strong enough that insurers, Medicaid, and other payers would pick up the tab to avoid costs associated with later poor school performance? Would school districts invest in the program to improve the school readiness of these high-risk children? *—Michael Burke, MD*

Procalcitonin predicts bacterial coinfection in acute bronchiolitis

An elevated level of serum procalcitonin (PCT) in an infant with acute bronchiolitis should raise a clinician's suspicions that the child may have a bacterial coinfection, a new study indicates.

Investigators analyzed the records of 40 infants admitted to the pediatric intensive care unit for acute bronchiolitis. Chest radiographs (CXRs), various cultures, and procalcitonin and white blood count (WBC) measurements were performed for all patients, aged 0 to 9 months. Bacterial coinfection was diagnosed in 15 (38%) of the 40 study patients based on positive CXR (6/15), urine culture (2/15), or tracheal aspirate culture (8/15).

A comparison of the mean values of PCT and WBC measurements for those with positive bacterial cultures and infants without evidence of bacterial coinfection showed that PCT is a far more reliable marker than WBC for bacterial coinfection because of its substantially higher sensitivity and specificity.

Whereas a cutoff value of 1.5 ng/mL of procalcitonin had a sensitivity of 0.80 and a specificity of 1.00 for bacterial coinfection, WBC's significance was minor, with a sensitivity of 0.33 and a specificity of 0.96 (Laham JL, et al. *Pediatr Emerg Care*. 2014;30[1]:11-15).

commentary

These patients may be quite different from the babies who are generally admitted with bronchiolitis to an inpatient pediatric unit near you. In this study, all the babies were admitted to an intensive care unit and their rate of secondary bacterial infections was higher than that of children with bronchiolitis in most previous reports. Even in less ill babies with bronchiolitis, however, testing for serious bacterial infection (SBI) is common. In a recent retrospective 2-center study, Librizzi and colleagues found that 46% of 1,233 children aged younger than 2 years admitted with bronchiolitis underwent some sort of testing for SBI. Young age and fever were associated with higher rates of testing. Testing was linked to increased likelihood of antibiotic therapy and longer length of stay—all this despite multiple studies showing bacterial illness to be uncommon in association with bronchiolitis (Librizzi J, et al. *Hosp Pediatr*. 2014;4[1]:33-38). If your hospital has available rapid testing for procalcitonin, it may help you avoid the temptation to test for bacterial disease in babies with bronchiolitis. *—Michael Burke, MD*

Year's 10 most helpful articles

Here is Dr. Michael Burke's choice of the 10 most helpful articles he reviewed for Journal Club in *Contemporary Pediatrics* during the past 12 months:

1 Is increased fructose consumption tied to obesity? Page KA, et al. *JAMA*. 2013;309(1):63-70 (March 2013)

2 Adolescent ADHD has major negative effect on adult functioning. Brook JS, et al. *Pediatrics*. 2013;131(1):5-13 (March 2013)

3 A new technique facilitates collection of infant urine samples. Herreros Fernández ML, et al. *Arch Dis Child*. 2013;98(1):27-29 (March 2013)

4 Exercise has positive effects on children with ADHD. Pontifex MB, et al. *J Pediatr*. 2013;162(3):543-551 (May 2013)

5 Almost half of teenaged drivers text when behind the wheel. O'Malley Olsen E, et al. *Pediatrics*. 2013;131(6):e1708-e1715 (August 2013)

6 Knowing limited English affects ED care. Gallagher RA, et al. *Pediatr Emerg Care*. 2013;29(5):579-583 (August 2013)

7 Pediatric practices can successfully deliver parental smoking interventions. Winickoff JP, et al. *Pediatrics*. 2013;132(1):109-117 (September 2013)

8 Parents want to know risks of head CT imaging. Boutis K, et al. *Pediatrics*. 2013;132(2):305-311 (October 2013)

9 Narrow-spectrum and broad-spectrum antibiotics effective for inpatient pneumonia. Williams DJ, et al. *Pediatrics*. 2013;132(5):e1141-e1148 (January 2014)

10 Insights into racial differences in vitamin D levels. Powe CE, et al. *N Engl J Med*. 2013;369(21):1991-2000 (February 2014)

also of note

Don't let mild early symptoms delay diagnosis of *Kingella kingae* osteoarticular infections. Early clinical features of these infections typically are mild and insidious, leading to delayed diagnosis. A retrospective review reports on a series of 10 unusually severe cases in which diagnosis was delayed an average of 13 days. After surgical treatment and antibiotic therapy, all patients had satisfactory outcomes (Mallet C, et al. *Pediatr Infect Dis J*. 2014;33[1]:1-4).

puzzler

Infant girl's seizures have family ties

ERICA LABAR, MD, FAAP,
AND RYAN SMITH, MD, FAAP

THE CASE

A 4-month-old, previously healthy infant girl presents to the local pediatric emergency department (ED) after an episode of generalized tonic-clonic seizure activity witnessed at home. Her past medical history is significant for 41 weeks' gestation and being born to a gravida 1 para 0 white female via cesarean delivery for breech presentation. According to the patient's mother, the infant's growth and development have been entirely within normal limits so far.

Review of systems is negative for recent sickness, fevers, rash, poor feeding, vomiting, diarrhea, or decreased urine output. There are no known ill contacts, and there have been no unusual exposures or recent travel.

She lives at home with her mother and maternal grandparents. There are no prescription medications kept in the home.

TURN TO PAGE 32 ▶

Self-injury: Why teens do it, how to help

CLAIRE M BRICKELL, MD, AND MICHAEL S JELLINEK, MD

Dr Brickell is a resident in child and adolescent psychiatry, Massachusetts General Hospital/ McLean Hospital, Boston.

Dr Jellinek is professor of psychiatry and pediatrics, Harvard Medical School, and chief clinical officer, Partners HealthCare System, Boston, Massachusetts. He is also an editorial advisory board member for *Contemporary Pediatrics*. The authors have nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.

Pediatricians are most likely the first clinicians to discover that a teenager is engaging in self-harming behavior, and it's their initial evaluation of the context and severity of the self-injury as well as their empathetic relationship with the patient that sets the stage for treatment.

Every year, pediatricians care for adolescents who hurt themselves deliberately, in ways that include cutting, burning, abrading, and hitting. Roughly 1 in 6 teenagers has tried self-harm at least once.[1] The majority of teenagers do so only mildly or occasionally, but approximately 5% hurt themselves in serious and persistent ways.[2,3] Collectively, these actions are referred to as self-injurious behavior (SIB), which is defined as the deliberate, direct destruction of body tissues. Notably, most teenagers who engage in SIB do so without the intent to kill themselves. Clinicians and researchers thus often speak of nonsuicidal self-injury (NSSI), the focus of this article.[4]

A pediatrician is likely the first clinician to discover that a teenager has been self-harming. Wounds or scars may be uncovered during a routine physical examination, or a panicked parent may call for an urgent evaluation of a son or daughter. The first clinical encounter can be difficult for everyone: Parents often experience guilt, betrayal, or outrage; the adolescent may feel exposed and ashamed; the pediatrician might respond with frustration or just incomprehension. The first clinical encounter is also critical for setting the stage for successful treatment. As a 15-year-old patient with a history of self-injury stated during a therapy session, "I hate it

when people freak out. It makes me feel disgusting, and then I don't want to talk."

The goal of this article is to introduce the phenomenon of NSSI, including information on who self-injures and why. In terms of treatment, a variety of effective and evidence-based interventions for self-injury are available, but most require specific training and are implemented over a lengthy period of time, usually by psychiatrists.[5] Therefore, this discussion focuses on the preliminary evaluation of NSSI, with an emphasis for primary care physicians on how to present a supportive and nonjudgmental stance that can facilitate further assessment.

Why self-injure?

It is intuitive to classify self-injury as a problem and to assume that once the behavior has stopped the patient will feel better. However, studies show that the most common function of self-injury is to manage a range of negative emotions or to create feeling where there is only numbness or emptiness.[6] In other words, the *problem* for the patient is feeling unbearably sad, anxious, ashamed, or lonely—or not feeling anything at all. Self-injury is a *solution* that, in the short term, can be incredibly effective at easing intolerable emotions.

In this type of situation, NSSI provides relief immediately and independently of any response from the outside world. Adolescents do not start self-injuring "just to get attention." In fact, many teenagers self-injure in secret for months or years before they are discovered, and rather than seeking attention will take active steps to hide their behavior. Once discovered, the behavior can take on a whole new dimension. Depending on the reaction they get from those around them, teenagers who have few emotional skills may quickly learn to use NSSI as a way to affect others.

For example, if a teenager starts cutting herself because she feels lonely and cannot bear it, and her family responds by rushing to express love and support, it is likely that she will start hurting herself every time she needs affection. Or, if a teenager is miserable at school and is allowed to stay home every time he starts hitting himself, he may continue hitting himself whenever things get particularly tense at school. Not surprisingly, then, adolescents in community samples report using NSSI as a means of influencing people and of communicating distress.[3]

As these examples suggest, NSSI can work to avoid something unpleasant or to provoke a reaction, even if it is a negative one. Therefore, many practitioners may dismiss adolescents who self-injure as manipulative. However, it is normal to want attention. Everyone tries to minimize suffering and to maximize pleasure. The problem is that the self-harming adolescent may not know how to ask for help in a direct or effective way. Self-injury is a temporary and blundering solution to a failure to communicate or to have critical needs met.

1 IN 6
TEENAGERS HAS TRIED SELF-HARM AT LEAST ONCE

Far from being the master manipulators that some may make them out to be, teenagers who cut or hit themselves are often trying to manage their emotions and their relationships without really knowing how. Simply put, in our experience, many adolescents who self-injure do so because they do not know what else to do. This is an important underpinning of many of the treatments for NSSI, which aim to teach alternative problem-solving methods.

Who self-injures

Based on the explanations we have offered, young people use NSSI to manage negative or empty feelings and to communicate suffering when they lack the ability to apply more effective solutions. Therefore, it makes sense that rates of self-injury are highest in those with troubling emotions, complex or stormy relationships, and poor coping skills.[5]

The *Diagnostic and Statistical Manual of Mental Disorders, DSM-IV-TR*, mentioned NSSI only as a symptom of borderline personality disorder (BPD), which in adults is defined as a pervasive pattern of unstable relationships, self-identity, and emotion, accompanied by impulsivity.[7] Thus, NSSI in adolescence was considered a marker of severe and potentially lifelong illness. However, research suggests that NSSI often occurs independently of BPD; for example, in patients with depression or substance abuse or even in those with no other diagnosable psychopathology.[5,8] Therefore, NSSI is now recognized as a distinct condition in the DSM-5.[4] Future research will likely define subtypes of NSSI, some of which are more likely to persist into

adulthood than others.

Estimates of the prevalence of self-injury vary according to assessment methodology and by whether or not nonfatal suicide attempts are included in the count. However, self-injury is accepted to be especially common in teenagers. Rates in community samples average around 18% as compared with 6% in the adult population.[1,9] Rates are comparable in North America, Europe, Australia, and Asia, indicating that NSSI is an international phenomenon.[1] Although NSSI has been traditionally associated with girls and women, more recently studies suggest there may not be a gender difference in prevalence.[10]

NSSI and suicide

By definition, NSSI is self-injury carried out without the wish to die. In the moment, people who engage in this type of self-injury are not exhibiting suicidal behavior. On the contrary, they often use NSSI as a way to make being alive more bearable. Nevertheless, NSSI is a risk factor for later suicide attempts.

As a recent review article highlights, individuals who engage in NSSI are more likely to think about suicide and to actually attempt killing themselves.[11] Nonsuicidal self-injury that occurs more frequently and in more severe forms is also a strong predictor of suicidal behavior. In a clinical sample of depressed teenagers, NSSI predicted future suicide attempts just as strongly as past suicide attempts.[12] This link between NSSI and suicide held up even when the reviewers controlled for demographic differences, psychosocial conditions, and comorbid psychopathologies.

It remains unclear whether NSSI leads directly to suicidal behavior or if unbearable feelings lead to both. Regardless, adolescents who engage in NSSI should be assessed for immediate suicide risk as part of their clinical evaluation, even if suicide is not necessarily the sole or central focus.

Clinical examples

Teenagers turn to self-injury as a solution to problems for various reasons, including genetics, temperament, or particular stressors. Thus, self-injury might be the sign of a relatively healthy teenager under extreme duress, or of a generally vulnerable teenager under more mild circumstances. For example:

CASE 1: *Consider a teenager whose boyfriend breaks up with her just 2 weeks after her best friend moves to another city. She has experienced some mild anxiety for years but is usually able to keep it in check. She does well in school and enjoys her guitar lessons. Today, however, she feels sad and alone, certain that she will never be happy again. With her boyfriend and her best friend gone, there is no one who will understand how she is feeling. She knows of a friend who cuts herself. While in the shower after school, she superficially cuts her wrist with the blade from her shaving razor. The pain helps her "snap out of it," and by the time her mother comes home from work she is able to tell her that she is feeling sad.*

CASE 2: *More concerning is the teenager who has been in treatment for attention deficit disorder since elementary school. He used to be able to keep up with his schoolwork, thanks to medication and help from teachers, but now that high school has started he is overwhelmed. He is afraid that his new friends will make fun of him if they find out that he has a learning disability, and he is ashamed to ask for more support. He stops turning in his homework on time and daydreams and doodles in class. He feels dumb, pathetic, and anxious about all the work that he has not done. He and his parents have started fighting about his slipping grades. He spends more and more time alone in his room playing video games. He is not sleeping well. He starts thinking that it would be better if he just did not wake up in the morning. While sitting in class, he rubs the skin of his forearm hard with an eraser until it blisters and bleeds. This calms him down enough so that he can get through the hour without running out of class or yelling at the teacher.*

CASE 3: *At the most severe end of the spectrum is the teenager who has been cutting and burning herself almost every day for months. It feels as if everyone in the world is against her. She used to have friends, but they are frustrated that she is not getting better. They are sick of her sending text messages in the middle of the night asking for help. She just cannot seem to get a handle on her mood, which swings from angry to sad and back again for reasons she cannot explain. Cutting herself is like hitting a "reset" button and helps her stay calm, but it only lasts until her next text message goes unanswered. Her parents are at their wits' end, and she is fairly sure that if they could get rid of her, they would. She feels terribly guilty about being such a mess and also furious when they will not let her go out with the new guy she met. The next time her mother takes away the car keys,*

she walks into the kitchen and puts her hand on the stove. The pain feels like appropriate punishment for being such a bad person, but her mother still does not seem to understand just how bad she makes her feel. Later that night she sneaks out of the house, calls her new "boyfriend," and has sex with him. She comes home before anyone is awake, thinks about killing herself, and looks for her razor.

As these vignettes illustrate, teenagers have different problems that they are trying to solve, and some are more or less well equipped to do so. It is the pediatrician's job to evaluate the context and severity of self-injury to set the stage for successful further treatment.

Evaluating NSSI

When evaluating a teenager who engages in NSSI, it is important to first establish a general relationship with the patient by asking about school, home life, friendships, and activities. Then, a pediatrician can ease into asking about NSSI (Table 1). A good first question is "What does your self-injury help you with?" This is the same as simply asking "Why do you self-injure?" but the former question is less likely to be perceived as accusatory. Phrased in this way, the question demonstrates an understanding of the use of NSSI as a solution or self-treatment. Thus, it can open the door to a more specific discussion of psychiatric symptoms (depression, anger, anxiety) and interpersonal stressors (strained relationships with parents, breakups, loss of friendships).

Another approach is to ask the patient to remember a specific instance of self-injury. Helpful questions can include: "Do you remember how you were feeling before you injured yourself? How did that change after you injured yourself? How do you feel about it now?" Try to create a place that is nonjudgmental and safe.

Next, a pediatrician should try to gain information on the patient's mood and the logistics of self-injury: "How do you do it? What instrument do you use? How often do you do it? What part of your body is involved?" The doctor should also provide factual medical information that can help minimize complications and additional injury. For example, physicians can counsel patients about the risks of blood-borne illnesses and ensure tetanus vaccinations are up to date.

Self-injury is a sign that a teenager is both experiencing uncomfortable feelings and is ill equipped to manage them. Therefore, the

TABLE 1 ASSESSING SELF-INJURY

WHAT TO ASSESS	SAMPLE QUESTIONS
The function of self-injury	○ What does your self-injury help you with? ○ Do you remember how you were feeling before you injured yourself? How did that change afterward?
The method of self-injury	○ How do you do it? ○ What instrument do you use? ○ How often do you do it? ○ What part of your body is involved?
The potential for medical complications	○ Have you required medical attention (eg, stitches)? ○ Do you use a clean blade or have you shared a blade with anyone? ○ When was your last tetanus shot?
Other dangerous behaviors	○ Do you do anything else to make yourself feel better that might be risky in the long run? ○ Have you used drugs or alcohol to make yourself feel better? ○ Do you find yourself restricting your food or purging after meals? ○ Are you sexually active? Do you feel comfortable with your level of sexual activity?
Abuse or bullying	○ Has anyone hurt you—physically or mentally—in a way that is still affecting you? ○ Do you feel safe at home? ○ Do you feel safe at school?
The risk of suicide	○ Have things ever gotten so bad that you thought you might be better off dead? Have you thought about killing yourself? ○ Are you thinking of killing yourself now? ○ Do you have a plan for how you might do it? What is the relationship between your self-injury and thoughts of suicide?
Areas of strength	○ What is going well in your life? ○ Who are the people you can count on? ○ Who or what do you turn to for comfort?

general practitioner should ask about other dangerous behaviors that, like self-injury, tend to be used to cope with stress. Disordered eating, substance abuse, and risky sexual activity all are associated with self-injury and can have independent medical consequences that warrant evaluation.[5] Normalizing the experience can help teenagers talk about behaviors that they believe might get them into trouble. Try asking "Do you do anything else to make yourself feel better that might be risky in the long run?" or "Has your stress gotten so bad that you have turned to drugs or alcohol to try to escape?"

Of note, although many practitioners used to take for granted that teenagers who engage in NSSI had experienced childhood abuse, recent research has indicated that the relationship is much more modest.[13] Many who have been abused do not go on to self-injure and many who self-injure have never been abused. Nevertheless, abuse does happen, both inside and outside the home, and the office of a trusted physician may be a good place to talk about it. A helpful first way to inquire is to ask "Has anyone hurt you—physically or mentally—in a way that is still affecting you?" In addition to screening for abuse by adults, the practitioner should specifically ask about bullying, which is often overlooked and can be severe.

Finally, although we have shown that NSSI should not be confounded with suicidal behavior, it is critical to evaluate for suicide risk. This is an area where it is helpful to be matter-of-fact, with progression from the general to the specific: "Have things ever gotten so bad that you thought you might be better off dead? Have you thought about killing yourself? Are you thinking of killing yourself now? Do you have a plan for how you might do it?" The word "kill," although jarring, is chosen to be distinct from the word "hurt."

For the sake of building an alliance, and of doing a complete evaluation, it is essential to also ask about what is going well for the patient. Is there a friend who is particularly supportive? Is there a class at which the patient excels? Does the patient have an artistic or musical talent? These relationships and skills are the basis for some level of self-esteem. They can be drawn on in therapy to help the teenager to get better and also to provide a picture of someone who is more than just a "self-injurer."

Confidentiality

Many teenagers will ask if what they reveal can be kept secret. Although conversations between physicians and their patients are generally confidential, when safety is at stake a patient's parents will need to be informed. In the case of NSSI, this means the answer to that question is often "no." It is important to explain to teenagers that their safety is your primary concern and that you will do what it takes to preserve it.

You can offer to help them tell their parents about the problem, and to mediate what is likely to be an emotionally charged conversation. You can also assure them that you will not talk to their parents without their knowledge. It is important that parents or legal guardians be informed so that they can support and participate in treatment. Most teenagers who are talking about NSSI for the first time are embarking on a lengthy road involving many encounters with healthcare professionals. It may be expedient in the short term, but it is most certainly damaging in the long term to promise confidentiality that you cannot or should not deliver.

Psychopharmacologic treatment

Currently, the US Food and Drug Administration has not approved any medication for the specific treatment of self-injury. Patients who additionally suffer from depression and/or anxiety may benefit from the pharmacologic treatments of those conditions. Researchers have also suggested that NSSI works to control negative emotions via the endogenous opioid system.[14] This raises the possibility that the opioid antagonist naltrexone (ReVia) might be effective in the treatment of NSSI, perhaps by blocking reward pathways and preventing positive reinforcement. Although helpful to treat associated disorders such as depression, medication is not a treatment for NSSI.

Psychotherapy

Different types of therapy for the treatment of NSSI have in common the necessity for consistent therapeutic contact for a relatively long time. Practically speaking, a teenager who self-injures warrants a referral to a mental health professional (Table 2). How and with what urgency the referral is made depends on the risk to the particular patient in question. Teenagers who are more fragile, more isolated, less successful, and who have families with fewer resources will require referral more urgently to a mental

TABLE 2 MANAGEMENT OF NONSUICIDAL SELF-INJURY

INTERVENTION	DETAILS
Create a safe, trusting environment to further ongoing communication	○ Assess for strengths as well as weaknesses ○ Look at self-injury from the patient's point of view
Perform a thorough evaluation	
Involve parents and other appropriate adults	○ Legal guardians need to know about dangerous activities
Make a referral to a mental health practitioner	○ Adolescents with high risk for suicide should receive emergent psychiatric care ○ There are specialized treatments for BPD but none yet for NSSI

Abbreviations: BPD, borderline personality disorder; NSSI, nonsuicidal self-injury.

health clinician than others who are not at such high risk.

Any patient who is at imminent risk for suicide should be evaluated immediately by a crisis team or in an emergency department. He or she may require inpatient hospitalization to ensure safety in the short term. The inpatient team should then assist the pediatrician and the family in establishing longer-term outpatient mental health care.

Thus far, treatment for self-injury has been considered only in the context of treatment for BPD. Perhaps with the development of the *DSM-5*'s new diagnosis, trials of treatments specifically designed for NSSI will come. The good news is that there are several empirically validated psychosocial treatments for BPD and its symptoms, including NSSI. These include transference-focused psychotherapy, mentalization-based psychotherapy, and dialectical behavior therapy, as well as manual-assisted cognitive-behavioral therapy.[5] These therapies differ in theoretical underpinnings, method of application, and emphasis of treatment, but all provide the patient with the opportunity to acquire new skills for the management of ways to solve the problems of emotional distress and interpersonal conflict.

Conclusion

The goal of the pediatrician's care is to establish a safe doctor-patient relationship, which will help the patient accept services and participate actively in treatment. Given the disturbing nature of self-injury and the frequent assumption that those who self-injure are "just manipulating" those around them, it can be difficult for the pediatrician to reach the respectful and nonjudgmental stance that is most effective in building a safe, trusting relationship. A better understanding of why teenagers self-injure and what can be done to help them get better is a first step in creating a comfortable, empathetic relationship. This work is difficult—but rewarding. ■

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The sex-trafficked child

Children can be victims of sex trafficking without ever leaving home, and it's almost certain that pediatricians are encountering trafficked victims every day without realizing it.

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Child sex trafficking is some dark, nefarious atrocity that occurs in other places, on the other side of the world. At least, that's what we'd like to believe. The sad truth is that human trafficking—specifically, child sex trafficking—is a thriving industry, one very thoroughly ensconced in the United States. Nearly 100,000 children are trafficked in the United States annually.[1]

The Victims of Trafficking and Violence Protection Act of 2000 (TVPA, PL 106-386) defines this activity as "'sex trafficking in which a commercial sex act is induced by force, fraud, or coercion, or in which the person induced to perform such act has not attained 18 years of age . . . .' Experts generally agree that the trafficking term applies to minors whether the child's actions were forced or appear to be voluntary."[2]

Jordan Greenbaum, MD, medical director, Stephanie Blank Center for Safe and Healthy Children, Children's Healthcare of Atlanta Child Protection Center, says, "Victims don't choose their lifestyle with any kind of 'informed consent.' They are manipulated, betrayed, and deluded by adults far more savvy than they. They truly are victims, rather than 'bad kids' who choose their life, and they are not 'offenders.'"

Aimee Grace, MD, MPH, works with the Stanford Advocacy Track Human Trafficking and Healthcare Project, Stanford University School of Medicine, California, and explains that awareness—or lack thereof—complicates the problem. "Community pediatricians should know that human trafficking is not just an international problem," Grace says. "It is very real in our American communities."

To read an extended version of this article with references and additional resources, go to **ContemporaryPediatrics.com/sex_trafficked_child**

Greenbaum believes that many pediatricians encounter trafficked children without realizing it. "This is not something that simply happens abroad, or only involves foreign victims," she says. "Most of the victims we see are US citizens."

Detra West, BS, MS, a sociologist, associate dean of students and director of diversity and inclusion at Hiram College, Hiram, Ohio, agrees. "There's a complete network of individuals from every walk of life who are involved in this," says West, who teaches courses in human trafficking at the college. "We're not just talking about the Big Bad Wolf. We're talking about people we work with, perhaps. People who are abolitionists, who claim to be against it, can be participating in it."

The trafficked child

Child trafficking victims are usually recruited and exploited in prostitution by family members, friends, and strangers, as well as by traffickers/pimps who pose as "boyfriends." Although many victims are young people in the child welfare system and/or runaways, some are recruited from middle-class families. These trafficked children may have a history of physical and sexual abuse in the home or be trafficked and sold for sex by a drug-addicted parent. A child can be a victim of sex trafficking without ever leaving his or her home.[3]

Runaways or children in foster care are also very vulnerable "because they are already in the system and can be used and abused this way, and no one questions it," West says. "Most kids in foster care are there for a reason, because they have been in situations already of neglect, abuse, physical abuse. If a child is exhibiting problems, maybe issues in school, people automatically dismiss it."

Greenbaum says pediatricians should be vigilant, and knowing some of the risk factors helps to determine when additional screening needs to occur. Risk factors can include:

- runaway/throwaway status;
- history of abuse/neglect;
- history of dysfunctional family;
- poverty;
- mental health problems; and
- drug-use problems.

However, physicians should avoid tunnel vision, because, "of course, not all kids have [discernible] risk factors," Greenbaum points out.

Statistics may underestimate the number of familial traffickers. Potentially, as many as 30% of domestically trafficked minors who receive services through WestCare Nevada, a Las Vegas-area shelter for at-risk youth, are exploited by family members. When Shared Hope International aligned with US Department of Justice-funded human trafficking task forces to assess domestic minor sex trafficking in 10 US locations, interviewees from all 10 locations recounted cases in which parents or guardians acted as traffickers.[3,4] Data collected by the National Center for Missing and Exploited Children (NCMEC) indicate that 69% of identified child pornography victims were abused and/or exploited by people familiar to the children, including parents, other relatives, neighbors, friends, babysitters, or guardians' partners.[1]

FAST FACT
75% of child victims engaged in prostitution are under the control of a pimp.[22]

Although many sources say most victims are first trafficked between the ages of 12 and 14 years,[1,5-7] West says victims often start much younger—from 3 to 8 years, an age cited by trafficking-awareness organizations such as Dosomething.org and traffickinghope.org.

Identifying the victims

Identifying and rescuing child victims are complicated by the complexity of sex trafficking networks, methods of control imposed by traffickers, and the challenges victims face in seeking assistance.

Aggravating the situation, Grace notes, is that community pediatricians are very likely seeing child trafficking victims "but may not be aware of it," she says, adding victims may face many atrocities, including labor and sexual trafficking. "Some people believe that if you don't see human trafficking, it's because you're not looking for it," Grace says.

Yet such victims are everywhere. They live at home with their parents or foster families, and it's almost certain that physicians and others within the healthcare industry are encountering them.[8] There are indicators, clinical and otherwise, that pediatricians and other healthcare providers may observe (Table).

Traffickers will often tattoo children,[9] typically on the neck or a little symbol on the shoulder. Because children aren't legally permitted to receive tattoos before the age of 18 years, any such mark should be an immediate red flag to healthcare providers. "That is

a clear indication that someone is trafficking this child," West says. "The trick for the physician is to talk directly to the child. Even if the parent wants to answer all the questions, the conversation needs to involve the child. Typically, the child will sound rehearsed. The eyes will dart to the parent to get approval. Some of that's normal."

Grace says there are things pediatricians should *avoid* doing so as not to further endanger a child. "A pediatrician should avoid terms such as 'human trafficking victim' as this will likely have no meaning for the child/adolescent," she says.

Greenbaum agrees, adding that the person accompanying the child may be the trafficker or tell the trafficker what the child says. "That can endanger the child and/or her family. The pediatrician should take steps to make sure the conversation is private, uninterrupted, and that the child feels safe," she says. Then asking specific questions—such as history of sexually transmitted infections, age of boyfriends, pregnancies, number of sex partners, history of abuse or drug use—can provide very revealing information.

"And in cases in which the pediatrician is suspicious," Greenbaum says, "the physician may want to ask direct questions, such as 'Has anyone ever asked you to have sex with someone else?' 'Have you ever had to exchange sex for something you needed or wanted?'"

Grace says physicians can learn to identify a trafficked patient, and she refers to the US Department of Health and Human Services Office of Refugee Resettlement as a good resource. The Rescue and Restore Victims of Human Trafficking Campaign Tool Kits provide a wealth of information, including tips for identifying and assisting victims, screening questions, the trafficking victims' mindset, communicating with human trafficking victims, health problems seen in traffic victims, and resources such as PowerPoint presentations, posters, and brochures for healthcare providers.[10]

A physical exam will often yield evidence of the victim being controlled.[11-13] He or she may exhibit bruises or other signs of battering and have fear or depression. Urinary tract or bladder infections in girls, especially recurring bladder infections, can be an indication of possible abuse, as are sexually transmitted diseases, HIV/AIDS, pelvic pain, and rectal trauma. Malnourishment, retarded growth, and poorly formed or rotted teeth are especially acute with pediatric trafficking victims. Bruises, scars and other signs of physical abuse may be apparent in areas that won't damage victims' outward appearance, such as the lower back.

Treatment and care paths often

TABLE SIGNS AND SYMPTOMS OF HEALTH PROBLEMS THAT MAY IDENTIFY A SEX-TRAFFICKED PATIENT

Physical trauma

- Cigarette burns
- Bruises
- Burns
- Injuries that do not correlate with history provided
- Tattoos
- Aggravated medical conditions that are never addressed
- Malnourishment and serious dental problems are especially acute with child trafficking victims who often suffer from retarded growth and poorly formed or rotted teeth.
- Bruises, scars, and other signs of physical abuse and torture may be apparent if one knows where to look. Sex-industry victims are often beaten in areas that won't damage their outward appearance, such as the lower back.[11,18]

Reproductive issues

- High risk of STI transmissions
- Pregnancy
- Abortion-related issues
- Sexually transmitted infections
- HIV
- Rectal trauma
- Genitourinary difficulties
- Unwanted pregnancy
- Infertility from chronic infections or unsafe abortions
- Infections from unsanitary medical procedures from unqualified persons[11,12]

H.E.A.R. your patient

- **H**uman trafficking and health professionals
- **E**xamine history, **e**xamine body, **e**xamine **e**motion
- **A**sk specific questions:
  - "Is anyone forcing you to do anything you do not want to do?"
  - "Can you leave your job or situation if you want?"
  - "Have you or your family been threatened if you try to leave?"
- **R**eview options, **r**efer, **r**eport[13]

Abbreviations: HIV, human immunodeficiency virus; STI, sexually transmitted infection. US Department of Health and Human Services[11]; Zimmerman C, et al[12]; Moore A[13]; Barrows J, et al.[18]

differ for a trafficked child compared with a victim of more typical domestic abuse. For the trafficked victim, the psychological ramifications of being owned, of being someone else's property, can create overwhelming psychosocial hurdles. From a physical standpoint, the victim has often received insufficient healthcare or medical attention.[11] West notes that when a trafficker seeks treatment for a child, he or she is seeking not so much *care* as *cure*. He or she wants the child *cured* so that child can return to making money. This cure versus care mentality may translate to lack of follow-up, failure to comply with treatment recommendations, and ultimately long-term physical and psychiatric complications for the child.[14]

Grace says pediatricians should know that there are many legal resources available to help victims of trafficking, based on the Victims of Trafficking and Violence Protection Act of 2000.[15] West adds that for situations in which a physician reports suspected abuse, the authorities bring in others to take over. So, the pressure isn't on the pediatrician to know *all* the symptoms with which a trafficked child may present.[16]

Reporting is imperative

Grace recommends, "Pediatricians should refer to Child Protective Services if the child is under 18; for those 18 and older, pediatricians must observe confidentiality, but can encourage the victim to report the crime."

Is it possible for a trafficked child to eventually grow up and have some semblance of a normal life?

"Surviving all that, coming through all that, and having some form of recovery, that's the best possible outcome," West says. "Can a person walk away from that kind of abuse and end up perfectly normal? I don't know. I think most psychologists would say they'll be [posttraumatic stress disorder] victims."

While trafficked children experience a different abuse model than "typically" abused children, without intervention and effective treatment (physical and psychological) both groups may evolve from abused children into adults who abuse.[7,17] Removing a child from a trafficking situation may save future generations by interrupting the cycle.

That's where community pediatricians can make a difference, Grace notes. "Let me add what pediatricians *should* do. Call a social worker, call the National Human Trafficking Hotline (888-373-7888), and call 911 if there is urgent danger. Pediatricians should also establish a relationship of trust, remind victims of their legal rights, and assure the victims that they are there to help."

Greenbaum concurs. "Exploited youth have immense needs and the pediatrician should reach out to other organizations for help," she says. "No one can do it alone." ■

TRAINING RESOURCES

Children's Healthcare of Atlanta, Georgia, offers streaming online CME seminars for pediatric clinicians:

Introduction to Child Sex Trafficking for Healthcare Professionals:
http://choa.peachnewmedia.com/store/seminar/seminar.php?seminar=16642

The Importance of the Medical Interview for the Sexually Trafficked Child:
http://choa.peachnewmedia.com/store/seminar/seminar.php?seminar=16665

What You Need to Know About Providing Medical Examinations for the Sexually Trafficked Child:
http://choa.peachnewmedia.com/store/seminar/seminar.php?seminar=16662

What Else Do We Need to Know?:
http://choa.peachnewmedia.com/store/seminar/seminar.php?seminar=16670

How to identify victims and what to do:

US Department of Health and Human Services Office of Refugee Resettlement:
http://www.acf.hhs.gov/programs/orr/resource/rescue-restore-campaign-tool-kits

To identify local, state, and federal resources, medical providers may request assistance from the **National Human Trafficking Resource Center Hotline 1-888-373-7888,** which offers information in 170 languages and operates 24/7.

Assistance for transnational victims may be obtained from **US Immigration and Customs Enforcement, Victim Notification Program at 1-866-872-4973.**

FAST FACT
28% of victims came into contact with the healthcare system while in captivity.[8]

INFANT GIRL'S SEIZURES HAVE FAMILY TIES

ED workup

Most of the evaluation including physical exam, computerized tomography of the head, complete blood count, and the majority of a complete metabolic panel is unremarkable. Serum glucose is resulted at 35 mg/dL. This increases to 59 mg/dL after intravenous (IV) administration of 10% dextrose in water (D10W) and a typical infant formula feeding. Despite additional interventions, including repeated feedings and boluses of D10W, the serum glucose continues to decrease to a trough of 33 mg/dL.

At this time, additional family members arrive and are able to provide a history of the patient's father having a similar seizure at the age of 3 months, which was also associated with a low blood sugar level. With the addition of D10W1/4NS (normal saline) maintenance IV fluids and continued oral feeding ad lib, our patient is stabilized to a serum glucose of 81 mg/dL. She is then admitted for additional management and consult with Pediatric Endocrinology.

TABLE 1
DIFFERENTIAL DIAGNOSIS OF HYPOGLYCEMIA IN INFANCY

- Prematurity
- Transient hyperinsulinemia in infants of diabetic mothers
- Sepsis
- Perinatal asphyxia
- Congenital heart disease
- Inborn errors of metabolism
- Hypothyroidism
- Adrenal insufficiency
- Congenital hyperinsulinism

From Najati N, et al.[3]

Hospital course

During the admission, our patient has an additional episode of hypoglycemia to 40 mg/dL. At that time, an insulin level was elevated at 26 µIU/mL, despite the low blood glucose, and serum ammonia was measured elevated at 235 µmol/L. After stabilization, a trial of diazoxide (Proglycem) is started at 3mg/kg/dose by mouth 3 times daily. This results in euglycemia and allows for the discontinuation of parenteral glucose administration. Additional evaluation, including imaging of the abdomen, fails to reveal a pancreatic adenoma or other abnormal focus within the pancreas to account for the hypoglycemia.

Epidemiology

Neonatal hypoglycemia, as defined by a plasma glucose level below 47 mg/dL,[1] is a relatively common abnormality seen in the newborn period. It is estimated that 10% of newborns are unable to maintain a blood glucose level greater than 30 mg/dL if feeding is delayed for 3 to 6 hours.[2] When early feeding is initiated, the overall prevalence of hypoglycemia in the first 24 hours of life is estimated to be 0.4%.[3] Several causes of hypoglycemia have been identified, including prematurity; transient hyperinsulinemia (in infants of diabetic mothers); sepsis; perinatal asphyxia; congenital heart disease; inborn errors of metabolism; hypothyroidism; adrenal insufficiency; and congenital hyperinsulinism (CHI; Table 1).

While several of these diagnoses are readily reversible, CHI causes persistent hypoglycemia necessitating long-term management. Classic CHI is caused by a genetic mutation that leads to an inappropriate secretion of insulin by the pancreatic beta cells.[4] This relatively rare disease has an estimated incidence of 1 in 50,000 live births[4] and accounts for 1.9% of cases of neonatal hypoglycemia.[5] Sixty percent of cases are diagnosed within the first 72 hours of life.[6] The majority of the remaining cases are diagnosed within the first year of life with a second peak of diagnoses occurring when infant feedings become less frequent, allowing for depletion of the infant's glucose stores. Only 15% of CHI cases are diagnosed after the first year. For patients with CHI, medical and/or surgical management is necessary to maintain normal blood glucose values and prevent long-term neurological sequelae.

Molecular pathogenesis

Congenital hyperinsulinism is most commonly caused by a genetic mutation resulting in deregulation of insulin secretion from the endocrine pancreas (Table 2).[4] The process of insulin release from the pancreatic beta cell has been well described. An increase in the adenosine triphosphate (ATP)/adenosine diphosphate (ADP) ratio activates the plasma membrane sulfonylurea receptor 1 (SUR1), leading to the closure of its potassium channel. This leads to the

opening of a voltage-dependent calcium channel. Intracellular calcium then increases, triggering the release of insulin from storage granules within the beta cell. Thus, the closure of the SUR1 potassium channel results in insulin release.

The *ABCC8* gene codes for the SUR1 receptor protein and the *KCNJ11* gene codes for the Kir6.2 (inward-rectifying) subunit of the potassium channel.[4] Mutations in either the *ABCC8* or *KCNJ11* genes result in permanent closure of the potassium channel and, therefore, increased insulin release. Six other genes have also been identified and mutations in these genes result in enzyme anomalies that lead to insulin oversecretion. Despite the current knowledge of these genetic mutations, no known cause is found in 45% to 55% of patients with CHI.

Diagnosis

Symptoms of hypoglycemia in the neonate can include tremors, hypotonia, cyanosis, hypothermia, and seizure.[7] Although many patients present in the neonatal period, others may present in infancy or early childhood (aged 1 to 20 months). Seizure is the presenting symptom in half of patients aged older than 1 month. Identification and rapid intervention is important to prevent or minimize the sequelae of untreated hypoglycemia.

Diagnostic criteria have been developed to identify those patients with CHI (Table 3).[7] These include: fasting and postprandial hypoglycemia with unsuppressed insulin secretion; a positive response to subcutaneous or intramuscular administration of glucagon; negative ketone bodies in urine; and prolonged dependence on treatment to prevent hypoglycemia throughout the first months/years of life.

TABLE 2
GENE MUTATIONS AND ENCODED PROTEIN/ENZYME ASSOCIATED WITH CONGENITAL HYPERLINSULINISM

ABCC8	SUR1 receptor protein
KCNJ11	Kir6.2 potassium channel subunit
GCK	Glucokinase
GLUD1	Glutamate dehydrogenase
HADH	L-3-hydroxyacyl-CoA dehydrogenase
SLC16A1	Monocarboxylate transporter
UCP2	UCP2 protein
HNF4A	Transcription factor

Abbreviations: CoA, coenzyme A; Kir, inward-rectifying potassium channel; SUR, sulfonylurea receptor; UCP, uncoupling protein.
From Arnoux JB, et al.[4]

Medical treatment

Medical management of CHI is aimed at obtaining and sustaining normal blood glucose levels. Initial therapy involves administration of glucose enterally or intravenously at a rate of 8 to 10 mg/kg/min for a neonate or young infant.[7] Continuous glucagon infusion is used in cases of severe CHI when glucose administration alone is inadequate to restore euglycemia. Glucagon is a polypeptide hormone that promotes glycogenolysis, effectively counteracting the excess insulin.[4]

Oral diazoxide at a dose of 5 to 15 mg/kg/day given orally divided 3 times per day is used as first-line maintenance pharmacologic therapy in these patients.[4,7] Diazoxide acts on the pancreatic beta cell and opens the ATP-sensitive potassium channel, thereby inhibiting insulin release.[4] The most common adverse

TABLE 3
DIAGNOSTIC CRITERIA FOR CONGENITAL HYPERINSULINISM

1. Fasting and postprandial hypoglycemia (<47mg/dL) with unsuppressed insulin secretion (>1mU/l)
2. Positive response to administration of 0.5 mg of glucagon (glucose increase by 36-54 mg/dL)
3. Negative ketone bodies in urine analysis
4. Prolonged dependence on treatment to prevent hypoglycemia in infancy/childhood

From Arnoux JB, et al.[7]

effect of this therapy is hypertrichosis, which is reversible upon discontinuation of the medication.[4,7] Potentially severe adverse effects include sodium and fluid retention and cardiovascular complications including pulmonary hypertension, most prominently in the neonate.

Patients who fail to respond to diazoxide may be treated with somatostatin analogues, such as octreotide (Sandostatin), which have inhibitory actions on the gastrointestinal and endocrine systems.[7] Octreotide can be given at a dose of 10 to 50 µg/kg/day via either a continuous infusion or every 6 to 8 hours subcutaneously.

A potential adverse effect of octreotide is necrotizing enterocolitis (NEC), which may be fatal in some neonates.[8] Octreotide reduces arterial blood flow of the celiac, superior mesenteric, and inferior mesenteric arteries, effectively reducing overall gastrointestinal tract perfusion, which may lead to the development of NEC in these patients. Those receiving this therapy should be monitored closely for signs/symptoms of NEC.

An emerging therapy is lanreotide acetate (Somatuline), a long-acting somatostatin analogue that has been shown to be effective with monthly dosing.[9,10] This alternative therapy may improve quality of life for these patients by reducing dosing interval or the need for pump infusion.

Surgical management

When medical therapy is ineffective, imaging should be considered to identify focal pancreatic abnormalities that may respond to surgical intervention. The ^{18}F-fluoro-L-dihydroxyphenylalanine positron emission tomography (PET)/CT-angiography scan is used to distinguish focal from diffuse forms of CHI.[11] Pancreatic islet cells have been shown to take up levodopa and convert it to dopamine via dopa decarboxylase.[6] The uptake of fluorodopa is therefore increased in overactive islet cells.[11] This scan may be used to differentiate patients with localized lesions from those with diffuse disease. The "pancreas percentage" technique (differentiating radiotracer uptake in the head, body, and tail) may also be used in conjunction with the PET scan interpretation to identify a focal lesion.

While PET/CT scan imaging has improved, focus localization techniques remain limited. Intraoperative high-resolution ultrasound allows real-time visualization of blood vessels and pancreatic and bile ducts that are undetectable by PET scan.[12] This procedure also can identify the "legs of focus" previously unidentifiable by histology.

Our patient

Genetic testing in our patient reveals a glutamate dehydrogenase 1 gene mutation. This mutation commonly presents with hyperinsulinemia and hyperammonemia in the newborn as a result of diffusely increased insulin secretion. She is doing well with diazoxide, 5 mg/kg by mouth 3 times daily, and to date remains euglycemic.

Prognosis for patients with CHI depends on timely intervention and long-term glucose control. Neurologic deficit is a common consequence of prolonged hypoglycemia. This can be severe in neonates, presenting as coma or status epilepticus. Glucose intolerance and diabetes are possible long-term complications for patients with hyperinsulinemia.[4] ■

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ANDREW J SCHUMAN, MD
SECTION EDITOR

Improve your practice: Get the most from your EHR

With a few tweaks and some patience, EHR technology won't remain burdensome.

There are many reasons why pediatricians are adopting electronic health record (EHR) systems. Pediatricians can become eligible for enhanced insurance payments by using their EHRs to gain patient-centered medical home (PCMH) status. Some pediatricians with more than 20% of Medicaid patients in their practice are receiving incentive dollars from the government for demonstrating meaningful use of an EHR. Other pediatricians have adopted their EHRs to become eligible to join Accountable Care Organizations (ACOs), which require EHR-generated data proving that the practice is achieving quality measures.

In my view, the best reason for adopting an EHR is that it enables practices to take better care of their patients. However, as evidenced in *Contemporary Pediatrics*' "First Issues and Attitudes Survey" published in December 2013 (*Contemp Pediatr.* 2013:30[12]:24-32), 43% of pediatricians using EHRs consider them an "ineffective and burdensome technology," and 21% of pediatricians are on their second EHR while 5% are on their third. This is very unfortunate because an EHR should improve, not hinder, your workflow and productivity.

With more than 750 EHRs to choose from, it is easy to implement the "wrong" EHR for your practice style and workflow. In this article, I'll detail how to effectively use your EHR. I'll also discuss which EHRs you should consider adopting if you are planning to switch EHRs.

Increasing EHR efficiency

The ergonomics of your exam rooms have an immense impact on how you use your EHR (Table 1). In my opinion, the most efficient setup of an EHR involves workstations in each exam room, positioned strategically so you can view parent and patient while inputting information into the EHR. Having a workstation with a computer stand, comfortable seat, large screen, mouse, and keyboard makes it easy to input information. Better yet, have a printer in each exam room, so that you or the nurse or medical assistant who rooms your patient can provide school notes, physical forms, and instructions without leaving the room to retrieve them from the printer down the hall.

Computers and printers are

TABLE 1 INEFFECTIVE AND EFFECTIVE WAYS TO USE YOUR EHR

FUNCTION	INEFFECTIVE/BURDENSOME	EFFECTIVE/EASILY ACCOMPLISHED
Corroboration of patient information–demographics, active problems, and medications	Verbally confirming data while rooming a patient	Using a "previsit" summary that a patient will review and annotate prior to office visit
Vital signs, screening tests, rapid diagnostic tests	Separate triage room for measurements, screening room for vision and hearing tests, labs performed in lab area of office	All measurements, screens, and lab diagnostics performed in the exam room
Computer equipment for data input	Notebooks carried by staff from room to room	All exam rooms equipped with computer workstations
Ordering of labs, immunizations	Provider must input orders prior to tests being done or vaccines drawn up for administration	Standing orders so that rooming personnel (medical assistant or nurse) can enter orders per protocol that will be later cosigned by provider
Data entry	Physician will enter chief complaint; review family history, medication lists and medical problem lists; and place orders	Rooming staff responsible for entering chief complaint, updating medication and problem lists, and reviewing family history
Patient forms, notes, and handouts	Printed on printer "down the hall" and must be retrieved and handed to parents.	All exam rooms equipped with printers. Commonly used forms available in every room. Forms sent to patient portal.
Provider EHR notes	Notes typed in all required fields	Providers expedite note entry via use of shortcuts, macros, dictation. Use of scribes.
Consequence of EHR use on staff, providers, and patients		

Abbreviation: EHR, electronic health record.

inexpensive nowadays so don't be foolhardy and skimp on this important expense. With a little effort and some Velcro, you can childproof your computer workstation. Obviously, you must learn good computer habits and lock the screen when leaving the room so children, even those with inattentive parents, won't be tempted to play with the computer. In many years of EHR use, I've never had any children damage computer workstations.

Good EHR habits

Documenting a patient visit in an EHR is a collaborative effort among receptionist, rooming nurse or medical assistant, and provider. The receptionist should print out a "previsit" summary for the patient that includes demographic information, problem list, current medications, and upcoming appointments. The parent can review this information while in the waiting room, and when the patient is roomed, any corrections or additions can be inputted into the system. You need to expedite the taking of vital signs and screening tests by having all equipment available in the room.

Workflow efficiencies have been discussed in 2 previous installments of Peds v2.0. (See "Thinking inside the box: Optimizing office workflow" [*Contemp Pediatr.* 2013;30(3):41-44]; and "Improve your practice: Keep it simple!" [*Contemp Pediatr.* 2014;31(1):36-39].) A trained and efficient rooming staff will measure patients, take vitals, perform age-appropriate screening tests, and preprint all necessary forms so that you can hand these to the patient at the conclusion of the visit. Additionally, nurses will perform urine dips and strep tests when appropriate. Lastly, they can put in chief complaint and input orders for immunizations to be given at the conclusion of the visit. It then becomes a simple matter for you to input the history of present illness; pertinent physical findings; assessment; plan; and generate prescriptions, labs, and orders

for diagnostic studies or referrals.

If you did your research prior to investing in your EHR, you can expedite entry with macros, utilize visit templates, and even dictate portions of your notes using a voice recognition program before leaving the exam room. Many programs support the use of check boxes for information entry. Find the most efficient way to document your portion of the medical chart using any means necessary. You should not be writing a tome, but a note that meets all required elements of either a level 3 or level 4 visit, so that you will pass insurance company audits. (See "Level 4 office-visit coding" [*Contemp Pediatr.* 2013;30(2):37-41].) Well visits can be documented most easily by maximizing templates that integrate check boxes into the chart note.

Is there a scribe in your future?

Let's face it—some pediatricians' computer skills are better than others. For some our EHRs have just too many buttons to click, and others find charting in an EHR "ineffective and burdensome." Technology-phobic pediatricians might consider hiring a medical office "scribe." Scribes are often paid as much as $20 per hour to shadow a physician throughout the day and generate all chart notes that the physician will review and sign.

There are national companies, such as ScribeAmerica (Aventura, Florida) and ScribeConnect (Carbondale, Illinois), that train and certify interested individuals to work in medical offices as scribes. Interested physicians can google "scribe medical services" and talk directly with these companies to learn the nuances of using scribes in their offices. Studies have shown that using scribes in a medical environment improves patient satisfaction because physicians can concentrate on communicating with patients rather than being distracted by the EHR. Scribes also improve productivity substantially. In most instances, the additional revenue will more than cover their addition to your staff.[1,2]

More shortcuts

Most of the better EHRs incorporate 1 or more mechanisms to facilitate the entry of information into the EHR by using shortcut tools. Typically, these include pick lists or dot phrase macros that prepopulate chosen fields. You need to practice and experiment with your EHR system so you can learn to navigate and enter data quickly.

It also may be worth your while to investigate the use of inexpensive

EHRS BY THE NUMBERS

A recent comprehensive survey of over 17,000 physicians (State of the Ambulatory EHR Replacement Market Place: 2013 Conditions and Top Performing Vendors; Black Book) indicates that 70% of office-based physicians are now using either a "basic" or a "fully functional" EHR system. A basic EHR system can document patient demographics, problem lists, medication lists, as well as clinical notes, and includes the ability to write and print prescriptions and view diagnostic reports.

In contrast, the survey indicates that 29% of office-based physicians have invested in a fully functional "comprehensive" EHR that includes the ability to order laboratory and radiology tests, electronically transmit prescriptions and orders, and view x-rays and other diagnostic studies. Fully functional EHRs also integrate clinical decision support tools that provide warnings of drug interactions, highlight out-of-range test levels, and provide reminders regarding guideline-based screening.

Family physicians have been early adopters of EHR technology in large measure because they will be subject to reduced Medicare payments if they don't adopt an EHR system by 2015. Of particular note is that the 2013 Black Box survey indicates that 80% of pediatricians have adopted an EHR (basic or fully functional), ranking only below radiologists (84%) and emergency department physicians (83%), and are now exceeding even family physicians (70%) in their adoption rates. I'd like to believe that these Pediatrics v2.0 articles have played perhaps a small role in this achievement by motivating pediatricians to embrace technologies that can improve our practices.

TABLE 2 MOST POPULAR EHR SYSTEMS

for practices with between 1 and 3 physicians, ranked by market share

- eClinicalWorks
- Allscripts
- Epic Systems
- Practice Fusion
- NextGen Healthcare
- McKesson Provider Technologies
- General Electric Healthcare IT
- Amazing Charts
- Cerner
- athenahealth

Abbreviation: EHR, electronic health record.
Source: Glenn B.[3]

programs such as PhraseExpress (Bartels Media GmbH; Wittlich, Germany) that can help expedite documentation by providing key combination shortcuts to insert sentences or paragraphs quickly. There are other programs, including Macro Express from Insight Software Solutions (Kaysville, Utah), that can be used to automate repetitive actions in your EHR such as assigning a diagnosis and procedure code as well as checkout instructions.

When you need to adopt a new EHR

If, after everything is said and done, you have made the decision to migrate to a new system, the most difficult decision is which EHR to select. Consider a pediatric-specific EHR such as Office Practicum (Connexin Software; New York, New York) or the Physician's Computer Company's EHR (Winooski, Vermont). Seek opinions from other pediatricians using EHRs by joining the American Academy of Pediatrics Section on Administration and Practice Management and enrolling in its listserv. You can also be guided by current surveys and ratings and choose an EHR that has been successful in the marketplace and well rated by physician users.

Medical Economics, the sister publication of *Contemporary Pediatrics*, recently dedicated an entire issue to the top 100 EHRs (October 2013) and is well worth your review. According to an article published July 8, 2013, on the *Medical Economics* website, just a handful of EHRs have proven to be the most popular among physicians in small practices.[3] These are listed in Table 2.

If you are thinking of changing EHRs, keep in mind that the EHR marketplace is currently somewhat in turmoil because many vendors won't have the resources to meet the stringent government requirements for meaningful use stages 2 and 3, coming in the years ahead. As a consequence, many companies will merge or leave the marketplace altogether.

Also, consider that beyond hardware costs, most EHRs are very expensive. I have watched Practice Fusion (San Francisco, California) become a popular EHR among primary care providers and would strongly consider adopting this "cloud-based" system if I were switching. Unique among its competitors, Practice Fusion is both free and "fully functional," and the online tutorials I've viewed are quite compelling. The software is supported by advertisements that do not hamper workflow. The program is currently certified for meaningful use stage 2 status; the company is well funded; and this system continually rates high in physician EHR satisfaction surveys. Furthermore, the program supports electronic prescribing and interfaces with many national lab services as well as billing services.

It's up to you . . .

By implementing the efficiencies discussed in this article, I am optimistic that many pediatricians will improve their workflow and perhaps even enjoy using an EHR. However, if it's time to make a switch, learn from your missteps. Do a good job of researching your options and choose wisely. ■

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CONTINUED FROM PAGE 40

dermcase } RED, ITCHY SKIN LESIONS

Background

Although relatively common in infants and young children, onset of mastocytosis in adolescents and adults is unusual, occurring in 1 of 1,000 to 8,000 new patients evaluated by a dermatologist.[1,2] The disorder has no predilection for a particular race or sex.[2] Because patients typically are healthy and asymptomatic, diagnosis is easily missed and often delayed for years after the onset of skin lesions. In 1 study, the average time from the onset of skin findings to diagnosis was 10 years.[3]

Cutaneous mastocytosis is the most common form, accounting for 90% of cases. Urticaria pigmentosa (UP) is the most common manifestation of the cutaneous form, characterized by round to oval, golden red-brown, slightly elevated papules and/or plaques.[4]

The cause of UP is unknown. However, it is characterized by an increased number of normal mast cells in the involved skin.[2] When activated by a stimulus, mast cells release chemical mediators such as prostaglandins and histamine that results in swelling, itching, and redness. Rubbing, scratching, and other forms of minor trauma and environmental stress such as extremes of temperature can cause the degranulation of mast cells, resulting in erythematous, indurated, and pruritic lesions occasionally progressing to blistering. The most common causes are physical irritation and heat.[5]

Discussion

Urticaria pigmentosa is clinically seen as an asymptomatic and minimally itchy, or rarely as an intensely pruritic, papule or plaque that can occur anywhere on the cutaneous surface, with a predilection for the arms and legs.[6] The color is described as golden brown in light-skinned individuals to dark brown in dark-pigmented patients.

Skin biopsy is usually unnecessary because the diagnosis can be confirmed by rubbing the skin, resulting in a wheal and flare reaction or Darier sign. Although most skin lesions are not symptomatic, patients occasionally complain of pruritus.[5] The differential diagnosis may include histiocytosis; pigmented purpura; sarcoidosis; and disorders associated with hyperpigmentation, such as pigmented nevi, café au lait macules, and postinflammatory hyperpigmentation.

When the diagnosis is unclear, a skin biopsy should be obtained to confirm the clinical suspicion. Routine histologic staining may not clearly show the increased number of mast cells, and therefore stains such as toluidine blue, Giemsa, or fluorescein isothiocynate-avidin are needed.[5,6] A count of more than 20 mast cells per high-power field is considered an increased number of mast cells.[4]

Although extracutaneous symptoms are rare, systemic manifestations most commonly involve the bone marrow, bowel, central nervous system, liver, and spleen. Clinical presentations include abdominal cramps, vomiting, headaches, mental confusion, anemia, and hypotensive episodes.[4] Common laboratory tests ordered include complete blood count (CBC) with differential, liver function tests, and serum tryptase.[7]

The clinical manifestations and prognosis of UP vary depending on the age of onset. In young children, UP usually presents as a cutaneous disorder with moderate-sized lesions, averaging 1 to 2 cm in size and varying from solitary to disseminated distribution.[8] It is a benign disease in young children, with an expectation that the cutaneous manifestations will completely resolve within the first 2 decades of life. The onset of UP in adults and adolescents is rare but often asymptomatic. Lesions tend to be small (usually 2 to 4 mm), red to bronze in color, more persistent, and more likely to be associated with systemic findings.

Although there is no cure for UP, it is important to educate patients about the general self-limited and innocent course. To prevent future exacerbations, patients are advised to avoid stimuli that may trigger symptoms.

Mr Vo is a third-year medical student at the University of Ottawa, Ontario, Canada. **Ms Gupta** is a third-year medical student, University of Ottawa, Ontario, Canada. **Dr Cohen**, the section editor for Dermcase, is professor of pediatrics and dermatology, Johns Hopkins University School of Medicine, Baltimore, Maryland. The authors and section editor have nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article. Vignettes are based on real cases that have been modified to allow the authors and editor to focus on key teaching points. Images also may be edited or substituted for teaching purposes.

For the continuation of Dermcase and the complete references, go to **ContemporaryPediatrics.com/dermcase0314**

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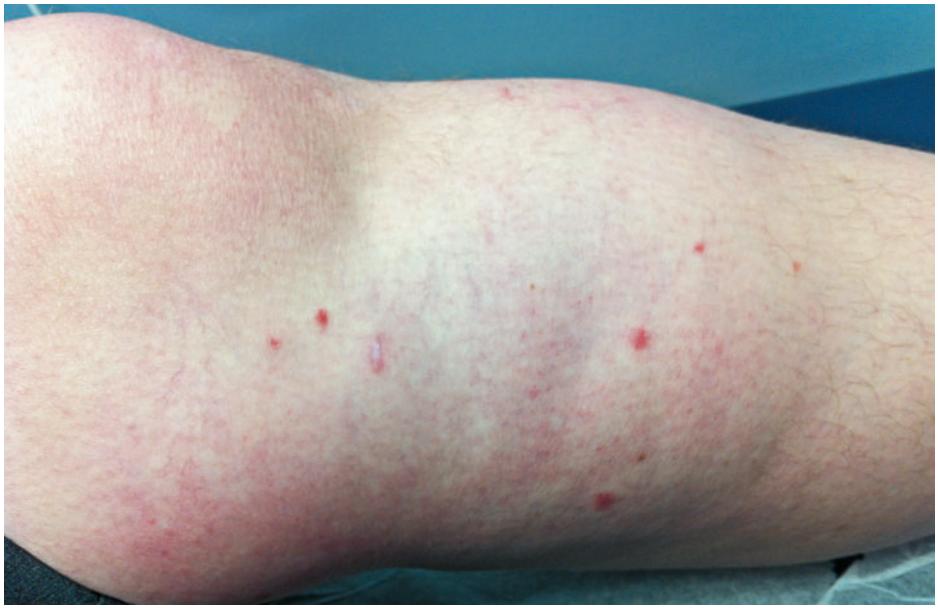

An 18-year-old girl presents with red macules and papules that appeared on her legs, trunk, and arms and that swelled if rubbed.

Red, itchy skin lesions triggered by pregnancy

ANTHONY VO, MS3, AND AMBIKA GUPTA, MS3

THE CASE

You are asked to evaluate a healthy 18-year-old girl with a history of "mosquito bites" on her arms and legs that appeared after her first pregnancy 2 years ago. Although not symptomatic, the lesions become redder and more swollen intermittently, particularly when accidentally scratched or rubbed. She states that these "bites" persisted after her first pregnancy and increased significantly with her second pregnancy this year. She does not recall these bites regressing since then. FOR MORE ON THIS CASE TURN TO PAGE 39. ▶

IMAGE CREDIT / AUTHOR SUPPLIED

DERMCASE *diagnosis* } URTICARIA PIGMENTOSA

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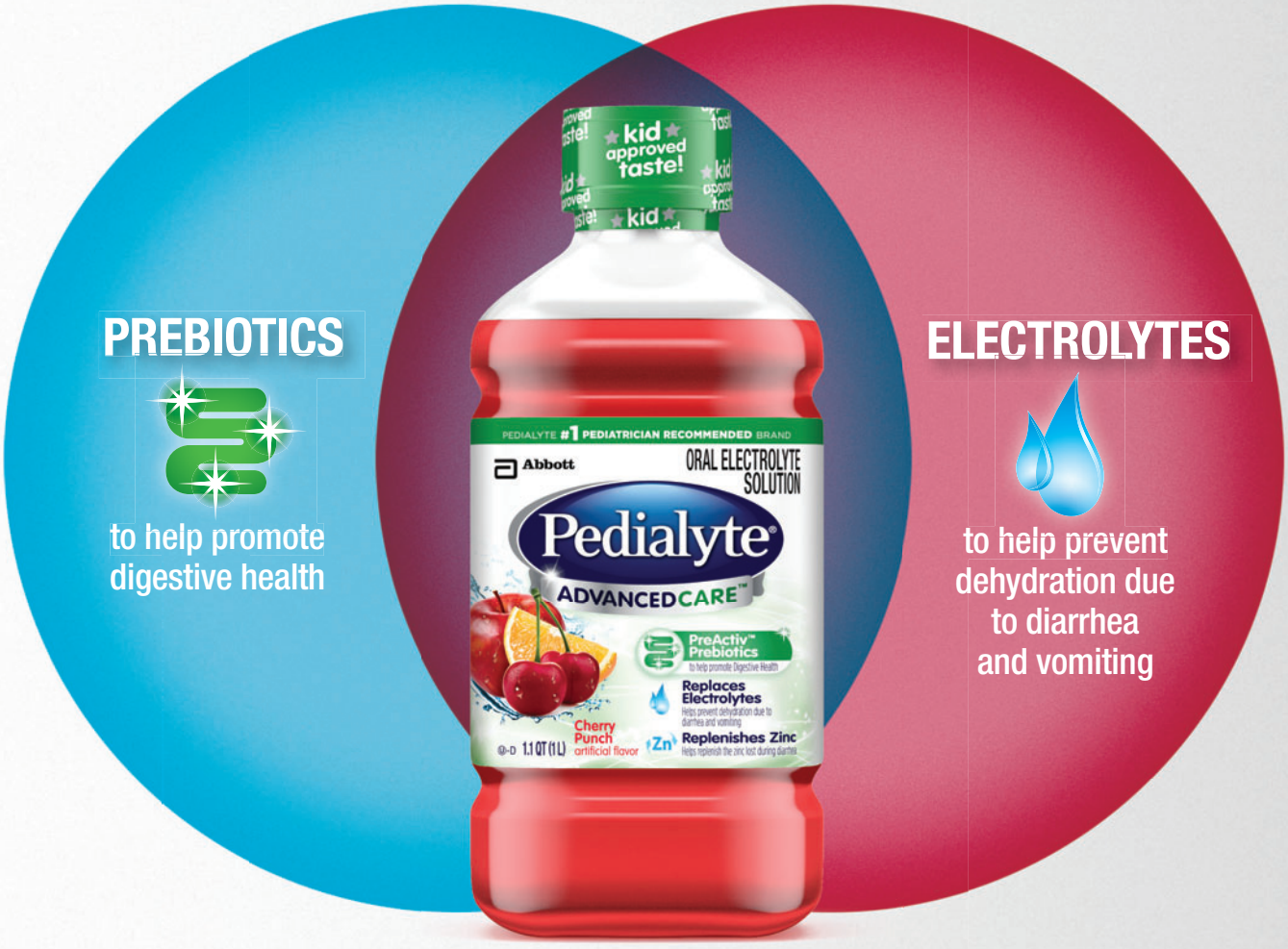

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