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Fluzone Quadrivalent Vaccine

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

Stand up to influenza with a **4-strain defense** that helps protect patients 6 months of age and older¹

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

Reserve your doses now for the 2014-2015 influenza season

CPT®a codes: 90685, 90686, 90688

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 types 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 full Prescribing Information.

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) **Suspension for Intramuscular Injection** 2013-2014 Formula

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	-

al or 2 doses depends on vaccination history as per Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines

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), $0.25~\mathrm{mL}$, 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.

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 incondusive; 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%)³ or tenderness (54%)², 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 myalqia (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%).

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 multicenter 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%), $20.2\% \ Black \ (Fluzone \ Quadrivalent, 20.5\%; TN-1, 19.9\%; TN-2, 19.1\%), 14.1\% \ Hispanic \ (Fluzone \ Quadrivalent, 14.3\%; TN-1, 13.2\%; TN-2, 14.7\%), and 7.3\% \ were of other racial/ethnic groups \ (Fluzone \ Quadrivalent, 6.8\%; TN-1, 13.2\%; TN-2, 14.7\%), and 7.3\% \ Were of other racial/ethnic groups \ (Fluzone \ Quadrivalent, 6.8\%; TN-2, 14.7\%), and 7.3\% \ Were of other racial/ethnic groups \ (Fluzone \ Quadrivalent, 6.8\%; TN-2, 14.7\%), and 7.3\% \ Were of other racial/ethnic groups \ (Fluzone \ Quadrivalent, 6.8\%; TN-1, 13.2\%; TN-2, 14.7\%), and 7.3\% \ Were of other racial/ethnic groups \ (Fluzone \ Quadrivalent, 6.8\%; TN-1, 13.2\%; TN-2, 14.7\%), and 7.3\% \ Were of other racial/ethnic groups \ (Fluzone \ Quadrivalent, 6.8\%; TN-1, 13.2\%; TN-1, 13$ 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°: 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)

	Fluzone Quadrivalent (N°=1223)			TIV-1° (B Victoria) (N°=310)		TIV-2 ^d (B Yamagata) (N°=308)			
	Any (%)	Grade 2 ^t (%)	Grade 39 (%)	Any (%)	Grade 2 ^t (%)	Grade 39 (%)	Any (%)	Grade 2 ^f (%)	Grade 3 (%)
Injection-site ad	verse rea	ctions							
- Painh	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	8.0	0.2	19.7	1.0	0.0	17.3	0.0	0.0
Systemic advers	se reactio	ns							
- Fever (≥100.4° F) ^j	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
- Myalgiah	26.7	6.6	1.9	26.6	9.4	1.6	25.0	6.8	2.7
- Headacheh	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	32.3	9.1	1.8	33.3	5.7	1.9	25.0	8.3	0.7
- Vomiting	14.8	6.2	1.0	11.3	4.4	0.6	13.9	6.3	0.0

^bThe safety analysis set includes all persons who received at least one dose of study vaccine

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

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

N is the number of participants in the safety analysis set '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

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: $>103.1^{\circ}F$ (6 months through 23 months); $\geq 102.1^{\circ}F$ (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

Assessed in children 24 months through 35 months of age

Assessed in children 6 months through 23 months of age

Fever measured by any route

Table 3: Study 1a: 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)

	Fluzone Quadrivalent (N°=1669)		TIV-1° (B Victoria) (N°=424)			TIV-2 ^d (B Yamagata) (N°=413)			
	Any (%)	Grade 2 ^f (%)	Grade 39 (%)	Any (%)	Grade 2 ^f (%)	Grade 39 (%)	Any (%)	Grade 2 ^f (%)	Grade 39 (%)
Injection-site ad	verse rea	ctions							
- 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 advers	e reactio	ns							
- 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

aNCT01240746

^bThe safety analysis set includes all persons who received at least one dose of study vaccine

º2010-2011 Fluzone TIV containing A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), and B/Brisbane/ 60/2008 (Victoria lineage), licensed

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

N is the number of participants in the safety analysis set

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

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

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).

[&]quot;-" Indicates information is not applicable

^aAssessed in children 24 months through 35 months of age

^bAssessed in children 6 months through 23 months of age

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, 69.3%), 10.2%; TIV-2, 65.3%, 10.2%; TIV-2, 69.3%; TIV 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°: 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

	0	Fluzone Juadrivalei (N°=190)			TIV-1° (B Victoria (N°=190)		(E	TIV-2 ^d 3 Yamagat (N°=190)	
	Any (%)	Grade 2 ^f (%)	Grade 39 (%)	Any (%)	Grade 2 ^f (%)	Grade 39 (%)	Any (%)	Grade 21 (%)	Grade 39 (%)
Injection-site ad			(/0)	(/9)	(/9)	(,,,	(/9)	(/9)	(/9)
- 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 advers	se reactio	ns							
- 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

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.

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°: 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)

	Fluzone Quadrivalent (N°=225)		TIV-1° (B Victoria) (N°=225)			TIV-2 ⁴ (B Yamagata) (N°=225)			
	Any (%)	Grade 2 ^f (%)	Grade 3 ⁹ (%)	Any (%)	Grade 2 ^f (%)	Grade 39 (%)	Any (%)	Grade 2 ^f (%)	Grade 3 ⁹ (%)
Injection-site ad	verse rea	ctions							
- 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 advers	e reactio	ns							
- 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

aNCT01218646

¹Grade 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

Grade 3 - Ínjection-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 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.

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

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.

1. Lasky T, Terracciano GJ, Magder L, et al. The Guillain-Barre' syndrome and the 1992-1993 and 1993-1994 influenza vaccines. N Engl J Med 1998;339:1797-802.

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)

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- · Annual influenza vaccination is recommended.
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bThe safety analysis set includes all persons who received study vaccine

^{60/2008 (}Victoria lineage), licensed

²2008-2009 Fluzone TIV containing A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2), and B/Florida/

^{04/2006 (}Yamagata lineage), licensed

N is the number of participants in the safety analysis set

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; Myalqia, Headache, Malaise, and Shivering; some interference with activity

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

Fever measured by any route

The safety analysis set includes all persons who received study vaccine

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CONTENT

TERESA MCNULTY Content Channel Director 440.891.2728 / tmcnulty@advanstar.com

CATHERINE M RADWAN Content Managing Editor 440.891.2636 / cradwan@advanstar.com

MIRANDA HESTER **Content Specialist**

KATHRYN FOXHALL MARIAN FREEDMAN

Contributing Editors ROBERT MCGARR

Group Art Director NICOLE DAVIS-SLOCUM Art Director

KAREN LENZEN Senior Production Manager

PUBLISHING & SALES

GEORGIANN DECENZO Executive Vice President 440.891.2778 / gdecenzo@advanstar.com

KEN SYLVIA Vice President, Group Publisher 732.346.3017 / ksylvia@advanstar.com

SAMANTHA ARMSTRONG Publisher

Office: 732.346.3083 / Mobile: 914.450.0609 sarmstrong@advanstar.com

DIANE CARPENTERI National Account Manager 732.346.3092 / dcarpenteri@advanstar.com

DREW DESARLE

Vice President Healthcare Technology Sales 440.826.2848 / ddesarle@advanstar.com

JOAN MALEY

Account Manager, Classified/Display Advertising

440.891.2722/jmaley@advanstar.com

JOANNA SHIPPOLI

Account Manager, Recruitment Advertising 440.891.2615/jshippoli@advanstar.com

DON BERMAN

Business Director, eMedia 212.951.6745 / dberman@advanstar.com

GAIL KAYE Director, Sales Data 732.346.3042/gkaye@advanstar.com

HANNAH CURIS Sales Support 732.346.3055 / hcuris@advanstar.com

RENEE SCHUSTER List Account Executive 440.891.2613 / rschuster@advanstar.com

MAUREEN CANNON Permissions

440.891.2742 / mcannon@advanstar.com

AUDIENCE DEVELOPMENT

JOY PUZZO Corporate Director

440.319.9570/jpuzzo@advanstar.com CHRISTINE SHAPPELL

Director 201.391.2359 / cshappell@advanstar.com

WENDY BONG

Manager 218.740.7244/wbong@advanstar.com

877-652-5295 ext. 121 / bkolb@wrightsmedia.com Outside US, UK, direct dial: 281-419-5725. Ext. 121

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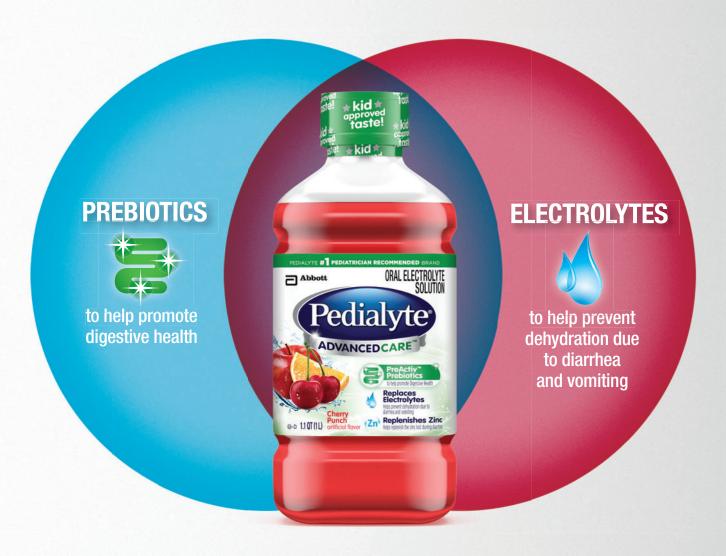
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JANUARY 2014

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Expert Clinical Advice for Today's Pediatrician

PEER-REVIEWED ARTICLE

Probing for scars: How to 16 ask the essential questions

The adolescent's physical exam should include his or her psychosocial history, which can identify stressors to overall health and well-being that can arise during this time of growth and change. The HEEADSSS interview is a practical, time-tested strategy that pediatricians can use to evaluate how teenaged patients are coping with the pressures of daily living, especially now in the context of electronic and social media. David A Klein, MD, MPH John M Goldenring, MD, MPH, JD William P Adelman, MD

PU77LFR

Dysuria in a young man 14

Shweta Saini, MD Elizabeth Secord, MD

DERMATOLOGY

Infant with a persistent 32 nodular rash

Samrat U Das, MD Pisespong Patamasucon, MD

PEDIATRICS V2.0

Improve your practice: 36 Keep it simple!

The KISS philosophy is a surefire way to optimize any pediatric practice. Andrew J Schuman, MD

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CP INTER@CTIVE

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9 **EDITORIAL** 30 years of *Contemporary Pediatrics* Jane A Oski, MD, MPH; Catherine M Radwan



YOUR VOICE Dispel the myth, save the child 12 Leonard Smith, DDS, MSC, FRCD(C), FAAPD, FICD

30 JOURNAL CLUB Narrow-spectrum and broad-spectrum antibiotics effective for inpatient pneumonia Marian Freedman; Commentary by Michael Burke, MD

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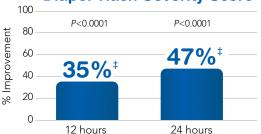


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References: 1. Data on file. **2.** Brown WM, Berg JE, Li Q, Kohut BE. A clinical study to evaluate the efficacy of two marketed zinc oxide-based diaper rash ointments in children with diaper dermatitis. Poster presented at: Clinical Dermatology Conference;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

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#1 with Pediatricians and Moms.



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TRENDING



LOTS OF ATTITUDE

ContemporaryPediatrics.com/2013survey

Valid findings? Anecdotal drivel? It's not as bad as all that? A lot worse than we can even begin to imagine? Just as we asked your opinions in our 1st Annual Issues & Attitudes **Survey**, we're getting lots of feedback on the feedback:

Anonymous: Uh, you neglected to say how many people actually responded to this survey. If there were only 10--these numbers don't mean a thing. It's been my experience that this is how low numbers get reported in surveys in order to hide the fact that no one bothered to respond. Unless you put in actual numbers, this article is useless.

Hello, Anonymous: Thank you for taking the time to comment on our article. Actually, we received over 400 responses to the survey, and while this may not merit a response rate with a corresponding P value, we did not approach this as a scientific survey. It was our intent to represent a wide cross-section of opinion on what our readers believed were the pressing concerns facing pediatricians, and we hoped that our readers might find the voices of their peers to be of interest. Sorry if you were disappointed.

We'll serve up more of your thoughts in the days to come, so hit the comment link and share your impressions. >> Gallogin or register to post comments



As part of this issue's critical update to HEEADSSS, the psychosocial assessment exam for adolescents, and the dedicated online Resource Center Contemporary Pediatrics



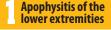
has created for it, we sat down with one of the article's authors, David A. Klein, MD, MPH, to find out why this tool on how to ask teens the essential questions matters more today than ever in reaching them in the isolation engendered, in part, by the very social media they love.

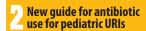
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Narrow-spectrum antibiotics for kids hospitalized w/communityacquired pneumonia associated w/ shorter hospital stay bit.ly/1bSi1Cp



Ginny Angert @GinPNP

Use the right tool for the job ---> Narrow versus broad antibiotics for pneumonia shar.es/Owg8z



J.J.AlbaCapitaine

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@ContemPeds American Academy of Pediatrics: no longer necessary to have sterilized baby bottles #pediatrics // better you can breastfeed



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CONTEMPORARY PEDIATRICS AT 30



Founding Editor-in-Chief Frank Oski's vision lives on.

eptember 2014 will mark 30 years since the first edition of *Contemporary Pediatrics* appeared in the mailboxes of pediatricians, pediatric nurse practitioners, and pediatric residents. In the inaugural issue, founding Editor-in-Chief Frank A. Oski, MD, pledged, "This new journal will emphasize the recent and the practical—the kind of information you can use with your patients immediately."

In order to remain true to his promise of relevance and utility, Frank assembled some of the most provocative, creative, and wise pediatricians he could imagine to serve as members of the Editorial Board. The Editorial Board reflected Frank's connection to his mentors; his colleagues in academic pediatrics; and his former students, residents, and fellows who had become trusted colleagues. The journal reflected his 3 passions in pediatrics: Education, Evidence/Research, and Advocacy.

The Editorial Board was made up of a cadre of the best and the brightest minds in general and subspecialty pediatrics. Frank Oski chose the initial and subsequent members of the board because their commitment to education and research was equal to his own. Their goal was to make the latest data and clinical innovations accessible to community-based pediatricians in a meaningful and immediate way. Bench to bedside was the mantra.

What was only murmured was the necessity of questioning scientific and medical dogma. Frank's students, residents, and fellows were familiar with his occasional contempt for "authority" because authority could be an opiate that stifled investigation. His hope was that *Contemporary Pediatrics* would be a journal that would break down barriers between academia



DR OSKI
is staff pediatrician,
Department of
Pediatrics, Tuba City
Regional Health Care
Corporation, Arizona.
She is also a member
of Contemporary
Pediatrics' Editorial
Advisory Board.

and community pediatrics and provide all practitioners with new evidence to support their daily practice. In that regard, *Contemporary Pediatrics* has succeeded under the editorial direction of both Frank Oski and his successor, Julia McMillan, MD. Practitioners, attending physicians, and residents refer to published algorithms and articles to inform patient care 30 years after this "throwaway" first emerged.

The new journal and its Editorial Board were an extension of Frank Oski's lifelong commitment to teaching, but it was also a platform for reminding pediatricians of our collective responsibility for advocating on behalf of children. In a 2004 tribute to

3 Contemporary Pediatrics colleagues who had died too soon, former senior editor Judith Asch-Goodkin described Frank as having a "grand capacity for outrage" at a society that allowed too many children to live in poverty and suffer the poorer health outcomes associated with unequal access to care.

I knew that outrage intimately and learned from it on a daily basis because Frank Oski was my father.

The editorial page of *Contemporary Pediatrics* became my father's bully pulpit. It was a place for introducing not only the causes and consequences of very real threats to child health, but also a vision of a future where those threats could be conquered. Whether the issue was his tireless advocacy of breastfeeding (and against the marketing of formula to the public) or the perpetual funding of the defense industry that drew dollars away from evidence-based social programs that supported a better future for children, my father offered alternatives: incentives from private insurers; Medicaid and WIC for exclusive and/ or extended breastfeeding; and Children's Bonds rather



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than War or Defense Bonds to support social programs with a track record of success, such as universal access to prenatal care and Head Start. His success at

provoking a response was evidenced by the small but significant numbers of angry "Letters to the Editor." There were always supporters, but it was the letters from those who disagreed with him that he loved to share. These letters were proof that his ideas had been digested and that he had challenged readers.

Not all my father's provocations were introduced in an effort to spur action. After Education, Evidence, and Advocacy came Irreverence. His jokes were often just plain outrageous or awful, but they grabbed your attention. He inserted his jokes as frequently into his monthly editorials as into his public presentations, and they had the desired effect. He was the inveterate class

clown, but for the 64 too-short years in which he lived, he helped move the dialogue forward on so many issues that remain vital and central to children's health.

If he were alive today, I shudder to imagine his tirade for allowing the safety net to develop more gaping holes, for not staying far ahead of the antivaccine movement, and for not doing more as a professional community to ensure universal access to care for all. He would undoubtedly be full of praise for many of the accomplishments of pediatrics, but his bottom line might still be to "question authority."

Thirty years after the first issue of *Contemporary* Pediatrics and 17 years after his death, my father's vision lives on. He ended his first editorial by saying, "We'll try to keep you moving in the right direction." I know that he would be proud of what this journal has achieved.

IN MY DAY . . .

CATHERINE M RADWAN

As a child, I grew up with measles, mumps, rubella, chickenpox, and whooping cough, and I vividly remember being sick. I watched my youngest sister almost suffocate during an asthma attack when she couldn't breathe. I saw red "QUARANTINED" signs posted on houses in our neighborhood during an epidemic of scarlet fever. I heard the whispers about iron lungs, paralysis, and death as I stood in line to get polio shots from the school 3-year-old boy. nurse. Years later, I stood in line again with families of all ages to get sugar cubes dressed with a "miracle" polio vaccine that was going to eradicate this horrendous disease from the face of the earth.

My parents wanted to be modern parents, so they chose a pediatrician specifically trained in the care of babies and children. I realize now how fortunate I was.

When my own children were born, I chose a pediatric practice for its association with our local teaching hospital/medical school. Through my pediatricians, I experienced firsthand the wonders of modern medicine: the DPT, MMR, Hib, and oral polio vaccines; bubblegum-flavored amoxicillin; and smiley faces drawn around tuberculin skin tests. I followed their advice about



MS RADWAN is content managing editor for Contemporary Pediatrics. She is the mother of 4 and grandmother to 3 lovely girls, ages 13 and 5 years, and 10 months, and a bouncing

putting my babies to sleep on their stomachs or propped on their sides to prevent SIDS. My kids loved going to the office because the waiting room had such cool toys and they could pick out a sticker after the visit was finished. They still suffered the indignities of chicken pox—varicella vaccine was introduced later—but they didn't miss weeks of school being sick as I had.

Today, my newborn grandbabies experience kangaroo care in the delivery room and ride home from the hospital in safety-engineered infant seats. They sleep on their backs in empty cribs. They get life-saving vaccines including for seasonal influenza. Their growth is charted, and their parents are counseled 24/7. They

also meet their pediatric dentist before they can walk. Neither my grandkids nor their parents will ever know what misery had been wrought on families in the not-so-distant past, when infectious and contagious childhood diseases invaded our homes and ravaged our communities unchecked, when children died.

With the help of my incredible pediatric group of physicians, my children grew up to be healthy young adults who are now raising their own healthy kids, guided by "contemporary" pediatricians whose universal concern has been and always will be the health and well-being of children.

Thank you, and bless you all. In

IOM wants more research on sports concussions in kids

n Institute of Medicine (IOM) panel says that despite public concern about concussions in young people, we really know precious little about them, including how often they occur and their short- and long-term effects.

Among other things, it is unclear whether repetitive head impacts and multiple concussions can result in neurodegenerative diseases such as Alzheimer disease and the "emerging diagnostic entity" of chronic traumatic encephalopathy (CTE), says the 17-member panel of experts in neuroscience, head trauma in pediatric populations, sports medicine, and bioengineering.

The yearlong project included an extensive literature search and 2 public workshops.

There is a lack of data on concussion incidence across a variety of sports. However, 1 estimate of 1.6 million to 3.8 million annual US sports- and recreation-related traumatic brain injuries including concussions is probably conservative, as noted in the study itself, because many concussions go unreported. Yet the numbers indicate a significant public health problem, says the report.

There are also little data on concussions, as opposed to the more severe head injury of CTE, in children aged 5 to 12 years; there are few published studies on interventions including protective devices to lower concussion risk; and there are few data on "the psychometric properties of sideline screening tools."

The lack of evidence extends to the questions of treating concussions. The panel notes evidence that "the brain is more susceptible to injury while recovering," indicating it is best to lower the risk of repeat injury.

The committee provides some other hints on what should be done now, even with the limitations of knowledge. It warns that in the current culture there is a lack of appreciation of the risk of concussions, with young people being encouraged by coaches or their fellows to "play through it."

Use of properly fitting helmets should be promoted, say these experts, because there is evidence they reduce injuries including skull fractures, although there is limited science on whether they help prevent sports-related concussions. The same is true of mouthguards or facial protection, despite marketing statements that head or other gear reduce concussion risk.

Some studies on young people playing ice hockey and soccer show that rule enforcement and fair play policies can help reduce concussions, the report notes. Also, the concept of limiting the number of head contacts for any one player over a specific time is "fundamentally sound" but also without scientific evidence.

In its discussion of treatment and management of prolonged concussion symptoms and postconcussion syndrome, the report says there is limited research on interventions and when to begin them. Although there is some evidence that noncontact aerobic exercise may help with persistent symptoms, the research is limited on that tactic as well.

To remedy the dearth of evidence, the panel calls for numerous research activities by public agencies and private organizations. For example, it recommends that the Centers for Disease Control and Prevention establish a national surveillance system on the incidence of sports-related concussions, including those in children and young adults aged 5 to 21 years.

It also recommends that the National Institutes of Health and the Department of Defense undertake or fund various research projects, including "controlled, longitudinal, large-scale studies to assess short- and long-term cognitive, emotional, behavioral, neurobiological, and neuropathological consequences of concussions and repetitive head impacts over the life span."

The 286-page report, Sports-Related Concussions in Youth: Improving the Science, Changing the Culture, is available for free download at www.nap.edu. 🗬

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

DISPEL THE MYTH, SAVE THE CHILD

Baby teeth are vitally important. It's time we made their protection a North American public health priority.

LEONARD SMITH, DDS, MSC, FRCD(C), FAAPD, FICD

arly childhood caries (ECC) once was known Las baby bottle tooth decay. Among its causes were poor nutrition, a lack of basic dental care, and extended exposure of the teeth to sugars—often when babies were put to bed with bottles containing milk, formula, and fruit juice. Although known to be preventable, bottle decay was considered by many dental and medical professionals to be a normal part of childhood and a relatively harmless affliction to baby teeth—teeth that were going to fall out on their own once adult teeth emerged.

In truth, ECC is extraordinarily dangerous and destructive. It is the number one chronic, infectious disease in children aged 5 years and younger in North America. The condition is defined as the presence of decayed teeth or missing teeth due to decay; acute cases in children aged younger than 3 years are referred to as severe early childhood caries (S-ECC; Figure).²

The US National Center for Health Statistics reports

that ECC afflicts 28% of North American children aged between 2 and 5 years—about 5 million kids. Approximately 1.2 million (23%) of these children never receive treatment.^{3,4} The disease is epidemic among many minority, immigrant, rural, and remote populations.^{4,5} Some research estimates the incidence of ECC in Aboriginal children is greater than 70%. In 2001 alone, more than 6,000 Aboriginal children under age 5 in Canada had all their upper front teeth

> Advances in dental care and public awareness have failed to reduce the

incidence of ECC and S-ECC in North America. While dental associations in both Canada and the United States have recognized the seriousness of the problem, many dentists do not see the need to treat patients under the age of 3 years, even though current practice guidelines recommend that first dental visits should occur as early as 6 months of age and no later than 12 months.

The myth prevails

Today, the myth prevails among professionals and the public: Baby teeth are expendable; they'll be lost eventually, so why spend money on their protection?

The price of their loss makes for perhaps the most compelling reason. ECC-related dental surgery under general anesthesia is the single most common surgical procedure at most pediatric hospitals in Canada.^{7,8} According to the Canadian Institute for Health Information, "The roughly 19,000 day surgery operations for children younger than age 6 each year pose potential health risks to children and can be traumatic for both children and their families."8

Numerous studies point to the relationship between ECC or S-ECC and iron deficiency, iron deficiency

> anemia, 9,10 protein deficiencies (albumin), vitamin D deficiency,11-13 and increased salivary cortisol levels.14



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For more information on kids' oral health, check out this article from our October 2013 issue: ContemporaryPediatrics.com/oralhealth

DR SMITH is a pediatric dentist and diplomate of the American Board of Pediatric Dentistry; clinical assistant professor, Department of Pediatrics, University of Calgary Faculty of Medicine, Canada; and chairman and CEO of the Society for a Healthy Mouth, Healthy Child (Alberta) and the Foundation for a Healthy Mouth, Healthy Child (United States), nonprofit charitable organizations dedicated to eradicating early childhood caries.



removed due to dental disease.6



Severe early childhood caries (S-ECC). The patient was aged 2 years. This extreme decay is not uncommon. Any adult who has experienced the discomfort of a dental cavity can imagine the severe pain associated with this level of untreated decay.

Children with ECC and S-ECC experience debilitating pain that impedes sleep, good nutrition, and overall development—in some cases, for years. When treatment is delayed or denied, children with ECC endure toxic stress, which is the experience of powerful, frequent, or prolonged suffering. Toxic stress dramatically alters brain development in children. It's been linked to poor impulse control, mood control problems, learning disabilities, and impaired memory.¹⁵

This profound level of stress may be equivalent to recurrent abuse and chronic neglect.¹⁶ Indeed, research shows a correlation between child abuse and neglect and the incidence of ECC and S-ECC. 16-22 Abused and neglected children grow up to become adults who suffer significantly higher rates of obesity, type 2 diabetes, cardiovascular disease, hypertension, anxiety disorders, addictive behaviors, and suicide.²³ In many jurisdictions, the failure to report observed cases of neglect compels authorities to levy charges.

So what does this legal obligation mean for parents who put their babies to bed with bottles of sugar-filled liquids? What does it mean for a pediatrician who tells parents to see a dentist about their baby's dental issues? What does it mean for a dentist who refuses to see young patients simply because they are not yet 3 years old?

It means we all need to acknowledge ECC as a serious public health problem.

Western health care has evolved to assign the treatment of teeth to dentists and the treatment of

the rest of the body to physicians. ECC has thrived in this disciplinary divide and underscores the need to treat patients holistically. The mouth is a gateway to the body; the health of one is inextricably tied to the well-being of the other. As an infectious disease, ECC can spread throughout the body to affect other organs. For example, untreated, the disease has led to brain abscesses that require costly and complex surgical intervention and has sometimes proved fatal.²⁴⁻²⁶

Prevention is the best treatment

ECC prevention is simple and inexpensive. The solution is a coordinated campaign to boost awareness throughout North America. To succeed, the campaign must engage medical and dental associations and professionals, social workers, insurance bodies, health care organizations, and public health authorities at all levels. In the true spirit of collaboration, their goal should be to develop an ongoing, multiplatform, public education program that:

- acknowledges dental disease as a serious medical condition;
- > stresses the need for all children to have their first dental visit at 6 months of age but no later than 12
- promotes proper prenatal and perinatal nutrition;
- > teaches parents the simple procedures for cleaning the teeth of even the youngest children²⁷; and that
- familiarizes children with the ease of cleaning and the importance of healthy teeth.

Together, we must work to integrate infant medical and dental care to explore correlations between oral health and physiological development. To stem the spread of ECC and diminish its current impact, we must also seize opportunities to provide low-cost or free dental consultation services to low-income citizens and those who live in remote communities.

The benefits of this campaign are obvious. The sooner we all make ECC a priority, the sooner we will slash related health care costs, dramatically reduce the number of ECC cases, and eliminate the lasting effects of this debilitating and totally preventable disease.



For references, go to ContemporaryPediatrics.com/caries

Dysuria in a ing man

SHWETA SAINI, MD, AND ELIZABETH SECORD, MD

THE CASE

An 18-year-old, immune-deficient young man presents to his immunologist's office with a 1-day history of dysuria. He has common variable immunodeficiency disease (CVID) complicated by bronchiectasis and a number of autoimmune processes, including type 1 diabetes for which he is currently on an insulin pump; Evans syndrome for which he has had a splenectomy; autoimmune hepatitis; and lymphocytic colitis. He reveals that he recently had unprotected sexual intercourse with a new male partner while vacationing in Florida the week prior to this presentation. He also thinks he may have been dehydrated while on vacation.

CONTINUED ON PAGE 40

The young man denies hematuria, flank pain, groin pain, back pain, fever, skin rash, urethral discharge, or arthralgia. He reports a history of a urinary tract infection (UTI) in the past and his symptoms now seem the same to him. He was treated by his pediatrician for the previous episode more than 2 years ago.

On physical examination, the patient is noted to be afebrile and normotensive with heart rate and respiratory rate within normal limits. He is well nourished and is not in any acute distress. His examination is within normal limits with no costovertebral angle tenderness, no genital lesions, and no urethral discharge. There is no conjunctival injection, joint swelling, or erythema.

Differential diagnosis

Dysuria is the one of the most common presentations of UTIs.1 The patient has been diagnosed with a UTI in the past and the symptoms felt the same to him this time as well.

It is possible that the patient has a sexually transmitted infection (STI). This is a very likely possibility based on his history of unprotected intercourse, which can also present with urinary complaints. Because of concerns of STI, empiric treatment for gonorrhea and

DR SAINI is a pediatric resident at St John Providence Children's Hospital, Detroit, Michigan. DR SECORD is division chief, Allergy, Asthma, Immunology, and clinical associate professor, Pediatrics, at Children's Hospital of Michigan, Detroit. The authors have nothing to disclose in regard to affiliations with or financial interests in any organizations that may have a financial interest in any part of this article.



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PHUBING FOR SCARS HOW TO Ask the essential questions

DAVID A KLEIN, MD, MPH; JOHN M GOLDENRING, MD, MPH, JD; AND WILLIAM P ADELMAN, MD

The HEEADSSS psychosocial interview is a practical, time-tested strategy that pediatricians can use to evaluate how their teenaged patients are coping with the pressures of daily living, especially now in the context of electronic and social media.

or most teenagers, a psychosocial history is at least as important as the physical exam. This essential psychosocial history can be obtained using the HEEADSSS method of interviewing adolescents. The HEEADSSS interview focuses on assessment of the Home environment, Education and employment, Eating, peer-related Activities, Drugs, Sexuality, Suicide/depression, and Safety from injury and violence (Table 1).1,2

Because adolescence is a time of growth and development when threats to health can arise, these threats are often related to physical and social exploration. For example, sexual exploration may lead to sexually transmitted infections or unintended pregnancies. Experimentation with drugs or alcohol is another cause of morbidity and mortality that is

implicated in deadly motor vehicle crashes in the age group. In fact, unintentional injuries, homicide, and suicide are among the leading causes of adolescent deaths in the United States, and are the top 3 causes for those aged 15 years and older.3

Moreover, consequences of adolescents' stressors may include obesity, eating disorders, depression, or other mental health problems. These issues are not easily identified or addressed using a strictly physiologic orientation.

Without an adequate psychosocial history, one is unlikely to spot problems early enough to significantly reduce adolescent morbidity and mortality. The HEEADSSS interview is a practical, time-tested strategy that physicians can use to obtain a "psychosocial review of systems" for adolescent patients.

DR KLEIN is an adolescent medicine fellow, Department of Pediatrics, San Antonio Military Medical Center, Fort Sam Houston, Texas. DR GOLDENRING is an adolescent medicine specialist, medical director, and a medical-legal consultant, Oceanside, California. DR ADELMAN is an adolescent medicine specialist and associate professor, Department of Pediatrics, Uniformed Services University of the Health Sciences, Bethesda, Maryland. The opinions and assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the US Air Force, the US Army, or the US military at large. 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.

Since the second version of HEEADSSS was created in 2004, nearly all teenagers have obtained access to the Internet and three-quarters of them use cell phones and send text messages.4-7 This utilization of media profoundly affects the lives of adolescents; media may now contribute to 10% to 20% of any specific health problem.⁷ Thus, questions on new media use are critically important and are included in this HEEADSSS 3.0 update. In addition, this update emphasizes a strengths-based approach to the adolescent interview to foster patientphysician rapport and successful interventions.

How to use the psychosocial screen

You should begin spending time alone with your patients at whatever age they first exhibit the psychosocial changes associated with puberty. Generally, it is preferable to conduct the psychosocial interview when the adolescent is relatively well.8 Nonetheless, situations of crisis or illness may sometimes facilitate effective history taking because vulnerability may foster trusting relationships. At every visit, the adolescent should be assessed for new stressors and overall well-being.

Working with parents

If the parents are present, first introduce yourself to the adolescent to make clear that the teenager is the patient. Then try having the adolescent introduce the other people in the room. Parents, family members, or other involved adults should not be present during the HEEADSSS interview because a parent's presence is likely to limit how much sensitive information the patient will provide. Allowing a parent to sit in on the interview also makes it more difficult to exclude him or her at subsequent visits when the patient may have more private issues to discuss.

This does not mean that parents should be ignored. Before asking adults to leave the room, always ask whether they have any concerns and assure them of further interaction once the interview is over. Be certain to explain the purpose, such as: "We speak privately with our patients about stressors that may appear during adolescence so they can practice taking responsibility for their health care needs." With explanation, adults accept the need for confidential care.9

DISCUSSING CONFIDENTIALITY

You may say, for example: "During this visit, I'll ask you some very personal questions to best help you. I promise that whatever you say will be kept private between us, and not be passed along to your parents or anybody else outside this office, unless you give permission."

Clinicians may end the introduction with:

"The only exception would be in a circumstance in which a disclosure to someone is required by law." Some specify the circumstances (eg, the patient is planning to kill or seriously injure himself or someone else; or the patient is experiencing, or is planning to commit, physical or sexual abuse or neglect).

Other clinicians prefer a nonqualified ending:

"If you tell me something that is so bad for your health that I think it is best to get somebody else involved in your care, like a parent or another doctor, I will tell you that. If you disagree, then together we can discuss the way to proceed." This method reinforces the strength of the physician-patient relationship.

Each physician must determine what limits on confidentiality are prescribed by the laws of the particular state in which the physician practices.^a State-by-state confidentiality quidelines are available from the Guttmacher Institute (www.guttmacher. org) and from the National Center for Adolescent Health and Law (www.adolescenthealthlaw.org).

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^aGuttmacher Institute. State policies in brief. An overview of minors' consent law. http://www.guttmacher.org/statecenter/spibs/spib_ OMCL.pdf. Updated December 1, 2013. Accessed December 4, 2013.

Making a good beginning

Starting the interview with nonthreatening conversation about the patient's hobbies or current events may help to ease anxiety, foster rapport and trust, and encourage disclosure. Then you might say: "I would like to take a few minutes to see how you are handling stress and whether your behaviors are safe."10,11 Once young people start talking, they are likely to keep talking. You will succeed better, however, if you explain the concept and limitations of confidentiality as part of this initial conversation.^{12,13} (See "Discussing confidentiality," above.)

The beauty of HEEADSSS is that by using the acronym, you can naturally proceed from very important but usually less threatening questions

TABLE 1 The HEEADSSS psychosocial interview for adolescents

Questions if time permits or **Potential first-line questions** if situation warrants exploration Who lives with you? Where do you live? Have you moved recently? Home What are relationships like at home? Have you ever had to live away from home? (Why?) Can you talk to anyone at home about stress? (Who?) Have you ever run away? (Why?) Is there anyone new at home? Has someone left recently? Is there any physical violence at home? Do you have a smart phone or computer at home? In your room? What do you use it for? (May ask this in the activities section.) Tell me about school. How many days have you missed from school this month/ Education quarter/semester? Is your school a safe place? (Why?) Have you been and bullied at school? Have you changed schools in the past few years? employment Do you feel connected to your school? Do you feel as if Tell me about your friends at school. you belong? Have you ever had to repeat a class/grade? Are there adults at school you feel you could talk to Have you ever been suspended? Expelled? Have you ever about something important? (Who?) considered dropping out? Do you have any failing grades? Any recent changes? How well do you get along with the people at school? Work? What are your future education/employment plans/ Have your responsibilities at work increased? What are your favorite subjects at school? Your least favorite Are you working? Where? How much? subjects? Does your weight or body shape cause you any stress? If What do you like and not like about your body? **Eating** so, tell me about it. Have you done anything else to try to manage your Have there been any recent changes in your weight? weight? Have you dieted in the last year? How? How often? Tell me about your exercise routine. What do you think would be a healthy diet? How does that compare to your current eating patterns? What would it be like if you gained (lost) 10 lb? Does it ever seem as though your eating is out of control? Have you ever taken diet pills? **Activities** What do you do for fun? How do you spend time with Do you participate in any sports? friends? Family? (With whom, where, when?) Do you regularly attend religious or spiritual activities? Some teenagers tell me that they spend much of their Have you messaged photos or texts that you have later free time online. What types of things do you use the regretted? Can you think of a friend who was harmed by spending time How many hours do you spend on any given day in online? front of a screen, such as a computer, TV, or phone? Do How often do you view pornography (or nude images or you wish you spent less time on these things? videos) online? What types of books do you read for fun? How do you feel after playing video games? What music do you like to listen to? Do any of your friends or family members use Is there any history of alcohol or drug problems in your **Drugs** tobacco? Alcohol? Other drugs? Do you use tobacco or electronic cigarettes? Does anyone at home use tobacco? Alcohol? Other drugs, energy drinks, steroids, or Do you ever drink or use drugs when you're alone? medications not prescribed to you? (Assess frequency, intensity, patterns of use or abuse, and how patient obtains or pays for drugs, alcohol, or tobacco.)

(Ask the CRAFFT questions in Table 5, page 25.)

Potential first-line questions

Sexuality

Have you ever been in a romantic relationship? Tell me about the people that you've dated.

Have any of your relationships ever been sexual relationships (such as involving kissing or touching)?

Are you attracted to anyone now? OR: Tell me about your sexual life.

Are you interested in boys? Girls? Both? Not yet

Questions if time permits or if situation warrants exploration

Are your sexual activities enjoyable?

Have any of your relationships been violent?

What does the term "safer sex" mean to you?

Have you ever sent unclothed pictures of yourself on e-mail or the Internet?

Have you ever been forced or pressured into doing something sexual that you didn't want to do?

Have you ever been touched sexually in a way that you didn't want?

Have you ever been raped, on a date or any other time? How many sexual partners have you had altogether? (Girls) Have you ever been pregnant or worried that you may be pregnant?

(Boys) Have you ever gotten someone pregnant or worried that might have happened?

What are you using for birth control? Are you satisfied with your method?

Do you use condoms every time you have intercourse? What gets in the way?

Have you ever had a sexually transmitted infection or worried that you had an infection?

Suicide/ depression

Do you feel "stressed" or anxious more than usual (or more than you prefer to feel)?

Do you feel sad or down more than usual?

Are you "bored" much of the time?

Are you having trouble getting to sleep?

Have you thought a lot about hurting yourself or

Tell me about a time when someone picked on you or made you feel uncomfortable online.

(Consider the PHQ-2 screening tool [Table 6, page 26] to supplement.)

Safety

Have you ever been seriously injured? (How?) How about anyone else you know?

Do you always wear a seatbelt in the car? Have you ever met in person (or plan to meet) with

anyone whom you first encountered online?

When was the last time you sent a text message while driving?

Tell me about a time when you have ridden with a driver who was drunk or high. When? How often? Is there a lot of violence at your home or school? In your neighborhood? Among your friends?

Tell me about a time when you felt sad while using social media sites like Facebook.

Does it seem that you've lost interest in things that you used to really enjoy?

Do you find yourself spending less time with friends?

Would you rather just be by yourself most of the time?

Have you ever tried to kill yourself?

Have you ever had to hurt yourself (by cutting yourself, for example) to calm down or feel better?

Have you started using alcohol or drugs to help you relax, calm down, or feel better?

Do you use safety equipment for sports and/or other physical activities (for example, helmets for biking or skateboarding)?

Have you ever been in a car or motorcycle accident? (What happened?)

Have you ever been picked on or bullied? Is that still a

Have you gotten into physical fights in school or your neighborhood? Are you still getting into fights?

Have you ever felt that you had to carry a knife, gun, or other weapon to protect yourself? Do you still feel that

Have you ever been incarcerated?

Abbreviations: CRAFFT, Car, Relax, Alone, Forget, Friends, Trouble; HEEADSSS, Home, Education and employment, Eating, Activities, Drugs, Sexuality, Suicide/depression, Safety; PHQ-2, Patient Health Questionnaire 2. Adapted from Goldenring JM, et al.2; Goldenring JM, et al.2

TABLE 2 Characteristics of resilient teenagers					
Home	Connected, caring parents or family members Acceptance of responsibility Chores Care of siblings or other relatives				
Education and employment	Better than average school performance Feelings of connection to school Limited employment (<20 hr/wk) Strong participation in extracurricular, school-related activities, including sports				
Activities	Leadership among peers Religious affiliation				
Drugs	Pledge to abstain Refusal skills				
Sexuality	Pledge to abstain Refusal skills Consistently responsible sexual behavior				
Suicidality	No personal history of attempted suicide No family history of attempted or accomplished suicide Access to a confidant Successful coping skills Substance free				
Safety	Seat belt and helmet use Conflict resolution skills Substance free Refusal to ride in cars with potentially intoxicated driver				
Goldenring JM, et al ¹ ;	; Ginsburg KR ¹⁰ ; Resnick MD, et al. ¹⁴				

to those most often considered highly personal. Nothing about the HEEADSSS interview, however, including the order of questioning should ever be treated rigidly. Although teenagers typically feel comfortable progressing in the order of the acronym, be aware of clues from the chief complaint or previous interactions that would modify your approach. For example, the home environment may be much more stressful to some adolescents than any issues they may have about sexuality.

Remember to search for the patient's strengths because positive attributes suggest the presence of resilience.8,10,11 In fact, some experts recommend

first screening for markers of strength and resiliency to use throughout the rest of the visit (Table 2).1,10,14 Consider: "To help me get to know you, tell me something about yourself that makes you proud" or "Tell me how your friends describe you." This may be postponed when patients are anxious to address their psychosocial concerns; however, positive factors may mitigate risks or point to productive interventions or an improved outlook. 10,11,14

While counseling about risks you have uncovered, be certain to assess the patient's readiness to change, the context of the patient's situation, opportunities to praise the patient for significant accomplishments or avoiding risks, and implementation of patient-created solutions and coping strategies (Table 3).1,10,14

Consider starting at Home

Questions about the teenager's home environment are generally expected and are a good beginning for the psychosocial interview. Instead of making assumptions, ask open-ended questions if possible (Table 4).1 It is a mistake, for example, to say "Tell me about your mom and dad," which assumes that the patient lives with 2 parents and that the parents are of different genders. Rather, start by asking "Where do you live?" or "Tell me about your living situation." Then ask: "Who lives with you?" These questions allow the adolescent to describe what is most important in his or her home setting.

Proceed by asking what relationships are like at home and whether there has been a recent change: moving, running away, divorce, or having someone join or leave the household. Such events are often extremely stressful to teenagers, who prefer a stable environment in which to undertake the developmental tasks of adolescence, such as separating from parents, connecting with peers, and developing a positive self-image.

Because media-related morbidity can be reduced by enlisting parental supervision, it is important to screen for the patient's home use (especially bedroom use) of computers, TVs, video games, smart phones, or other media devices.7 (See "Screening for media use and misuse," page 24.)

It is extremely useful to ask in whom the teenager trusts to confide. Connection to supportive

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A strengths-based approach

When talking to adolescents, search for positives in the history. Approaches based on risk factors alone may induce feelings of shame and deter patient engagement. It also sets low expectations—absence of risk factors does not equate to success. Here are some tips:

Identify strengths early so that they can be "built on" when motivating the patient to change or when encouraging ongoing success. An alternative acronym, SSHADESS, accounts for this strategy.¹⁰

2 Look for examples of past difficulties that your patient has successfully overcome. The ability to adapt to and overcome adversity is known as resilience and is highly protective against a wide range of bad outcomes.

Praise when praise is warranted! Many adolescents, **Praise** when praise is warrances...... / especially those at high risk, never hear any praise from adults!

Use reflective listening and pause. This allows the teenager time to confirm and expand on his or her thoughts.

5 Create a comfortable, trusting, nonjudgmental setting that communicates respect. Consider: "I want you to feel comfortable coming to me for health information and comfortable telling me what is going on in your life."

Share your concerns. It is acceptable to gently challenge your patient by saying, for example, "I'm worried that daily marijuana use may be a barrier to your achieving your goal of serving in the military."

Abbreviation: SSHADESS, Strengths, School, Home, Activities, Drugs/substance abuse, Emotion/depression, Sexuality, Safety. Goldenring JM, et al1; Ginsburg KR10; Resnick MD, et al.14

adults-parents or others-is highly protective against many health risks and high-risk behaviors.14 It is also important to remember to praise solid relationships with adults and assumption of responsibilities at home.

E is for **Education** and **Employment**

Most young people expect questions about their education and are seldom threatened by them. A common error is to ask "How are you doing in school?" Invariably, the patient will simply answer "fine" or "good," necessitating additional questioning. Instead, try asking: "Tell me about school. What do you like about it, and what don't you like?"

Search for the patient's degree of connectedness to the school and education; high connectedness predicts lower rates of substance use, early sexual initiation, violence, school absenteeism, and other causes of adolescent morbidity.14 Connectedness is specifically increased not only by educational commitment and adult mentorship but also by peer group belonging and a safe environment.15 Be certain to inquire about involvement in extracurricular activities and occurrences of bullying.

Ask specifically about academic performance (generally measured by grades). Declining academic performance correlates highly with psychosocial problems, such as drug use or suicide risk, and may indicate an underlying learning or attention disorder.

When an adolescent lives in a high-risk environment, begin the school section of the interview by ascertaining whether he or she regularly attends school. In some inner-city areas, the absenteeism rate for teenagers ranges from 15% to 40%.16 It also may be helpful to check how many schools and new sets of friends the student has adapted to in recent years. This is particularly important in military families for whom moving is often a way of life.17

The older the teenager, the more you should expect him or her to have some plans for future education or employment. Ask teenagers who are employed part time whether the work is intrusive and if economic circumstances necessitate it. Working more than 20 hours a week has been associated with negative outcomes of emotional distress and substance use.14 When interviewing adolescents who are employed full time, inquire about their strengths and weaknesses on the job, satisfaction level, nature of relationships at work, goals, and recent or frequent changes in employment.

Again, remember to look for and praise successes at school and at work. Such successes include not only academic ones but also leadership and achievement in extracurricular school activities or in the workplace.

TABLE 4 Opening lines, poor and better					
Category	Poor	Better			
Home	"Do you get along with your mom and dad?"	"Where do you live and who lives there with you? (No assumptions made.)			
Education	"How are you doing in school?"	"Tell me about school." OR: "What do you enjoy about school? What do you dislike? (Open-ended; harder to answer "OK.")			
Eating	"What do you eat?"	"Tell me what you think about your weight and shape." OR: "Tell me about what you like and don't like about your body." (Open-ended; can't answer "OK.")			
Activities	"Do you have any activities outside school?"	"What do you and your friends like to do for fun?" (Open-ended.)			
Drugs	"Do you use drugs?"	"What kinds of drugs have you seen around your school or at parties?" OR: "Do any of your friends use drugs or alcohol?" (Less personal; eases into a difficult discussion.)			
Sexuality	"Have you ever had sex?"	"You told me you've been going out with Steve for the past 3 months. Has your relationship become sexual?" (Context makes question seem less intrusive.) OR: "Are you attracted to anyone currently?" (Nonjudgmental.)			
From Goldenring	JM, et al. ¹				

E is also for *Eating*

Adolescents often have unhealthy eating habits, and the prevalence of obesity and eating disorders continues to increase, so questions about nutrition are important. Aim to help all adolescents develop healthy eating (and exercise) habits that can be maintained over a lifetime.

Obesity, which greatly increases the likelihood of developing diabetes and heart disease, is now clearly recognized to begin in childhood and adolescence.18 Sedentary adolescents often snack continually during the time that they spend in front of media devices, compounding their risk. Simple strategies, such as recommending appropriate portion sizes, eliminating sugared soda and fast food, and limiting screen time, can be helpful in improving adolescent eating habits and overall health.7,19

Physicians should also attempt to identify adolescents whose eating habits may signal body image or self-esteem problems, psychologic distress, or depression. Frequent dieting, compulsive exercise, and purging are all of concern. At least half of normal-weight young women surveyed in the United States believe they are overweight.20

Use this question, for example: "As I ask all my patients—does your weight or body shape cause you any stress? If so, tell me about it." Then follow with specific questions about diet, eating habits, nutritional knowledge and beliefs, and pathologic dieting behaviors. Remember how much eating and exercise behaviors are influenced by genetic inheritance and by behavior modeled in the family or media. In 2010, there were at least 100 easily discoverable pro-anorexia websites encouraging and guiding disordered eating behaviors.²¹ Media "apps" for calorie counting are widely available and these can be used to increase health and/or contribute to pathologic behavior.

Remember, of course, to praise good diet and exercise choices whenever you find them.

Looking at peer-related *Activities*

When adolescents or young adults are not at home, in school, or at work, they tend to be with their peers. As a prelude to more sensitive HEEADSSS questions, it is wise to have the patient tell you about what things he or she really enjoys. Adolescents derive much of their identity and self-esteem from peer activities.

Begin by asking: "Tell me what you do with your friends" or "What do you do for fun?" Be concerned about teenagers who cannot readily name friends or describe their activities beyond "hanging out." They may be at higher risk than teenagers who

SCREENING FOR MEDIA USE AND MISUSE

- Improved media access can lead to positive, prosocial outcomes such as empathy, acceptance of diversity, social group acceptability, and respect for the elderly. a.b Clinicians are now also faced with identifying how the concerning aspects of the media age—cyberbullying, sexting, driving while texting, online solicitation, Internet addiction (eg, video games), and media-related depression (eg, Facebook depression), to name a few—are affecting virtually every aspect of adolescent patients' psychosocial and physical wellbeing.
- Adolescents now spend 7 to 11 hours per day with different media, far from the maximum 1 to 2 hours typically recommended.^a One quarter of teenagers are "cell-mostly" Internet users, stating that they mostly go online from their cell phones.^c This suggests an unprecedented level of unsupervised Internet access. One-quarter of adolescents experience electronic bullying and one-third text while driving.de Those bullied online are more likely to report pervasive fear (in multiple environments) than those traditionally bullied. In addition, pornography is available by typing a few key words into a search engine. Failing to identify associated risk behaviors will miss opportunities to improve health outcomes.
- Try to add "media" or "Internet" literacy in discussion with parents and patients. This can include topics such as co-viewing to foster communication and accurate interpretation of content, as well as setting limits (eg, parental controls, time using media, or access to media in one's bedroom).

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talk about specific activities with friends, such as sports, dancing, hobbies, games, or even shopping. Adolescents who say they are "bored all the time" may be depressed.

Ask teenagers about the nature and quantity of their use of television, computers, video games, and mobile media devices. Nearly one-third of high school students surveyed in a large nationwide study played video or computer games for 3 hours or longer on the average school day.²² You may uncover a lack of parental connection and control, an avoidance of homework or family/peer interaction, or addictive behavior. Seek the specifics when interviewing an adolescent who endorses constant text messaging or social media posting. This behavior may be detrimental (eg, leading to sexting, texting while driving, or media-related depression) and/or it may be protective (as when used to connect with a health peer group that is otherwise unavailable).

On to Drugs

The drug history is sensitive. For patients in early adolescence, approach the topic obliquely: "We talked about what you and your friends do to have fun. Do any of your friends use drugs or alcohol (or get drunk or high)?" Young adolescents who would not readily talk about their own drug or alcohol use are often very willing to tell about such behavior by their friends. Next you might ask: "Tell me about a time that you felt pressured by friends to use drugs or alcohol, if any." The answer may lead to a discussion of specific circumstances and types of substances tried.

You may be able to ask older adolescents about drugs more directly. To elicit the most information, you need to know the latest trends of substance use within the patient's specific community. Substances used may include, for example, new synthetic cannabinoids, caffeine-containing energy drinks, anabolic steroids, and prescription medications such as opioids, benzodiazepines, and stimulants.

Also, ask specifically about tobacco and cigarettes, including electronic cigarettes (inhaled doses of nicotine), because many teenagers do not consider chewing tobacco or smoking to be a form of drug use. Be sure to find out whether the adolescent drives while under the influence of drugs or alcohol and/or rides with drivers who are intoxicated.

Explaining harms—without also evaluating readiness to change, acknowledging perceived benefits to substance use, using motivational interviewing techniques, and establishing trust and rapport—will likely not suffice to induce behavioral change. CRAFFT (Car, Relax, Alone, Forget, Friends, Trouble) is a brief, validated, office-friendly screening test useful in initially assessing the substance-using teenager (Table 5).²³

The goal of obtaining a drug history is usually to have the adolescent reveal the nature of problematic substance use to his or her parents or guardians (with your facilitation, if the patient desires) so that these caregivers can provide the patient with a more robust support system and foster additional treatment. Alternatively, substance use can remain confidential as long as there is no clear and immediate threat to the patient.

Sexuality

The sexual history may be the most sensitive part of the interview. It may benefit rapport to seek permission before proceeding: "Do you mind if I ask you a few more personal questions to learn how I can best assist you?" It is also helpful to expressly acknowledge the discomfort most patients feel about discussing this topic. Say, for example: "I know that this may be embarrassing for you, but I ask these questions of all my teenaged patients to make sure I can give my best advice."

Especially with younger adolescents, you might observe: "Tell me about any of your friends who are starting to be in romantic relationships." To older adolescents, simply say: "Tell me about any romantic relationships you've been involved in." The openendedness of such questions allows adolescents to tell whether they are having relationships with people of the same sex, the opposite sex, or both.

From asking about relationships, it is a short step to asking about sexual relationships: "Since sexual activity can affect your health, please tell me whether any of your relationships involved kissing or touching." If so, inquire about other sexual behaviors. Whether to screen for sexually transmitted infections, pregnancy, abuse, and other sequelae of sexual activity depends on the details.

Ask patients about their knowledge of fertility,

TABLE 5 The CRAFFT questions

Two or more "Yes" answers suggest high risk of a serious substance-use problem or a substance-use disorder.

Have you ever ridden in a Car driven by someone who was high or had been using drugs or alcohol?

Do you ever use alcohol or drugs to Relax, feel better about yourself, or fit in?

Do you ever use drugs or alcohol when you are Alone?

Do you **Forget** things you did while using drugs or alcohol?

Do your family and **Friends** ever tell you that you should cut down your drinking or drug use?

Have you ever gotten into **Trouble** while using drugs or alcohol?

Abbreviation: CRAFFT, Car, Relax, Alone, Forget, Friends, Trouble. Knight JR, et al.25

contraception, and sexually transmitted infections, given that many teenagers use the Internet and social media as their primary sex educators. You might add: "Many people do not have anyone knowledgeable to talk to about sex. We're always happy to answer any questions you have." And remember, adolescents may forgo contraceptive or reproductive services if they think (rightly or wrongly) that parental notification is mandatory. 12,13

Do not assume that adolescents who are having sexual experiences are comfortable about it. You may say: "Some of my patients tell me they feel pressured or coerced into having sex. Have you ever felt this way?" Sometimes, you can serve as a trustworthy adult who gives adolescents permission to avoid sexual activity until they are more comfortable with engaging in it. A history of abuse (if any) may not come out in the first interview, but the very fact that you show interest establishes rapport and may lead the patient to reveal the facts at a later time.

In today's Internet-linked world, sexual materials of all kinds are easily available. You may wish to ask teenagers about what sexual information and materials they have accessed online and how much and how often. Again, some experimentation with this is likely normal, but excessive use of such sites or accessing unusual or violent sexual content may

TABLE 6 Patient Health Questionnaire 2 A score of 3 or greater has good sensitivity and specificity for detecting major depression in adolescents.					
OVER THE PAST 2 WEEKS, HOW OFTEN HAVE YOU BEEN BOTHERED BY ANY OF THE FOLLOWING?	NOT AT ALL	SEVERAL DAYS	MORE THAN HALF THE DAYS	NEARLY EVERY DAY	
Little interest or pleasure in doing things	0	1	2	3	
Feeling down, depressed, or hopeless	0	1	2	3	
Richardson LP, et al. ²⁵					

indicate a risky behavior.7

Sometimes the greatest impediment to obtaining an adequate sexual history is a physician's own discomfort with sexuality. With practice, these questions become easier to ask without appearing judgmental. You can offer advice and personal opinions, but only if the teenager solicits them and only if you clearly label them as such.

Screening for Suicide and depression

Adolescents should be screened for depression when systems are in place to ensure accurate diagnosis, psychotherapy, and follow-up.24 Teenagers often exhibit depression as boredom, irritability, anxiety, moodiness, sleep disturbance, and social withdrawal. Many are more willing to admit to "stress" than to overt depression or sadness. The Patient Health Questionnaire 2 (PHQ-2), a 2-item survey, may be used as an initial screening tool for depression in adolescents at each visit (Table 6).25

When depression seems likely, ask directly and clearly about self-harm. Asking about suicidal behavior does not precipitate or trigger it, and clinicians should not be reluctant to question patients unambiguously: "You've told me that you've been feeling bad lately. Have you felt so bad that you've thought seriously about harming yourself?" Adolescents attempt suicide more often than we realize, so physicians should not be surprised if a teenager has contemplated or even attempted it. Past suicide attempts are a strong risk factor for future attempts and future suicide. The clinical question is: How serious is the ideation, planning, or actual behavior?

Pay attention to sexual orientation. A recent study

found that lesbian, gay, and bisexual (LGB) adolescents were more likely than heterosexual teenagers to have attempted suicide in the previous 12 months (21.5% vs 4.2%, respectively).26 The likelihood of attempting suicide was 20% higher for LGB teenagers in unsupportive environments than in supportive environments. Sexual minority adolescents benefit greatly from clinician-provided support, as well as a safe place for asking questions.

Some adolescents who are not contemplating suicide nevertheless harm themselves. Teenagers who engage in cutting describe it as a mood-stabilizing behavior; in these situations a careful risk assessment is important.

S for Safety

Injuries, suicide, and homicide—the major causes of morbidity and mortality in adolescents—are a constant environmental reality for many young people. Antecedents such as bullying, domestic and school violence, gang involvement, sexual abuse, online solicitation, and access to weapons must be identified in the psychosocial history. Family violence, which increases the risk for teenaged violence several-fold, occurs in all social and economic classes, as does dating violence, which is reported by as many as 25% of teenaged and young adult women.^{27,28}

Proceed to questions about the threats most prevalent in the patient's community. In some settings, these threats may be school violence and guns; in other settings, these may be sports injuries, sexual violence, or risk taking related to motor vehicles. Then ask about any other threats. Avoid letting assumptions based on the patient's racial, ethnic, or socioeconomic status lead you to skip taking parts of the history.

Find out what strategies the patient uses for selfprotection, conflict resolution, and avoidance of violence. (No gangs? How about local bullies? Is there an abusive partner or parent?) Know the school-based and community organizations in your area that offer programs on conflict resolution and violence avoidance so that you can make specialized referrals. Many young people respond to violence with violence because that is all they know from their homes, streets, and media. Before offering concrete solutions, ask adolescents whether they can think of ways to avoid violence using their reported strengths.

Wrapping it up

You may end the psychosocial interview by asking adolescents to tell you in whom they can trust and confide if they have problems. Emphasize that your approach is nonjudgmental and that you welcome

future visits. You may say: "I'm here for you, and I want you to feel comfortable confiding in me. If you have something personal to talk about, I'll try to give you my best advice and answer your questions."

Many adolescents do not recognize dangerous behavior patterns as dangerous because they see their activities not as problems but as solutions. Your challenge is to explore these behaviors and the context in which the adolescent lives, and to develop realistic solutions with patient buy-in.^{10,11} Depending on the nature of the risk factors identified and the intervention to be established, you can either extend the initial visit or arrange a follow-up.

Finally, by now you may be overwhelmed by the amount of issues to be covered in this interview and wonder how to do this in a limited time. Of course, you cannot cover every aspect in a single visit, but your goal is to establish an effective

A **CONTEMPORARY PEDIATRICS** RESOURCE CENTER

HEEADSSS 3.0: THE PSYCHOSOCIAL INTERVIEW FOR ADOLESCENTS UPDATED FOR A NEW CENTURY FUELED BY MEDIA

As part of our commitment to providing the pediatric practitioner with practical clinical information and tools that are immediately applicable to incorporate into daily practice, Contemporary Pediatrics is launching a series of topic-specific Resource Centers. Resource Centers comprehensively cover a single clinical topic and include articles, tools, videos, links to CME, and more.

Since HEEADSSS, the psychosocial exam for adolescents, is such a critical part of the field of adolescent medicine and for the training of pediatric residents, the Contemporary Pediatrics **HEEADSSS Resource Center** is dedicated to imparting clinicians with the considerations, rationale, and clinical flexibility of this assessment in a single site that can serve as a starting point for students, residents, and teachers alike. Access this Resource Center's tools, videos, and articles in support of the HEEADSSS goal of fostering patient-physician rapport, at

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relationship in each case and leave the remaining questions for a later visit. You should feel free to add or remove priority questions based on the needs of your patient population. In other words, make HEEADSSS your own.

Try getting into the HEEADSSS of your adolescent patients. Your effort may have a lifelong impact. CP

Dedication

This manuscript is dedicated to the memory of David Rosen, MD, and Eric Cohen, MD, for their significant contributions to previous versions of the HEEADSSS psychosocial history and to the field of adolescent medicine.

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Narrow-spectrum and broad-spectrum antibiotics effective for inpatient pneumonia

nvestigators compared outcomes in hospitalized children with community-acquired pneumonia who were treated with a narrow-spectrum antibiotic (ampicillin/penicillin) versus a broad-spectrum agent (ceftriaxone/cefotaxime), each by a parenteral route. The retrospective review included data for more than 15,000 children, aged 6 months to 18 years, who were admitted to 43 children's hospitals from 2005 to 2011.

To control for severity of disease on admission, patients with chronic conditions, complicated pneumonia, those requiring intensive care, and those hospitalized for fewer than 2 days were excluded from the study. No significant differences in length of stay, costs, or need for intensive care or readmission were seen between children treated with narrow-spectrum and broad-spectrum therapies.

The vast majority of children (89.7%) received broad-spectrum therapy rather than narrow-spectrum therapy (10.3%). Median length of stay was 3 days in both groups, and 1.1% of patients receiving broad-spectrum therapy and 0.8% of those receiving narrow-spectrum therapy were admitted to intensive care. Readmission rates also were similar for the broad-spectrum and narrow-spectrum groups: 2.3% and 2.4%, respectively. Although median hospitalization costs were higher among children receiving narrow-spectrum therapy (\$4,375) than among those receiving broad-spectrum treatment (\$3,992), these differences were not statistically significant in adjusted analyses (Williams DJ, et al. *Pediatrics*. 2013;132[5]:e1141-e1148).

COMMENTARY

The researchers estimate that 150,000 US children are admitted with pneumonia each year. If, as in this study, nearly 90% of these children receive broadspectrum antibiotic coverage rather than the more

targeted coverage recommended by the Pediatric Infectious Diseases Society and the Infectious Diseases Society of America (*Clin Infect Dis.* 2011;53[7]:e25-e76), a change in practice could go a long way toward suppressing development of antibiotic resistance. This could be accomplished with no measurable impact on clinical outcome for these children.

—Michael Burke, MD

UNINTENTIONAL INGESTION OF COUGH AND COLD MEDICINES HAS DECLINED

Restrictions on the sale of over-the-counter (OTC) cough and cold medications for children aged younger than 2 years and subsequent labeling changes in these products have led to a decline in their unintentional ingestion, therapeutic errors, health care facility referrals for ingestions, and serious medical outcomes in these children, a retrospective database study showed.

Ingestions of these medications also declined in 2- to 5-year olds, according to a comparison of OTC cough and cold medication ingestions reported to US poison centers between 2005 to 2006 (before restrictions and labeling changes were implemented) and 2009 to 2010 (after implementation). Initiatives in 2007 and 2008 to limit the use of OTC cough and cold medications in young children included the US Food and Drug Administration's (FDA's) advice not to use these drugs in children aged younger than 6 years; the Consumer Healthcare Products Association's (CHPA's) voluntary withdrawal of products marketed for use in children aged younger than 2 years; and CHPA warnings about use of these medications in children aged younger than 4 years.

Data comparisons of the preimplementation and postimplementation periods in children up to the age of 12 years showed that unintentional ingestions declined by 33.4% and therapeutic errors by 46.0% in all age groups. These declines were greatest in children aged younger

MS FREEDMAN is a freelance medical editor and writer in New Jersey. **DR BURKE**, section editor for Journal Club, is chairman of the Department of Pediatrics at Saint Agnes Hospital, Baltimore, Maryland. He is a contributing editor for *Contemporary Pediatrics*. The editors 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.

than 2 years. Referrals to health care facilities for unintentional general ingestions also decreased 28.9% in children aged younger than 2 years between the preintervention and postintervention time periods. For children aged 2 to 5 years, the decrease was 19.9%. Health care facility utilization for therapeutic errors decreased 59.2% in children aged younger than 2 years while no significant change was seen in children aged from 2 to 12 years. Moderate and severe adverse outcomes for unintentional ingestions decreased by 32.4% in children aged younger than 2 years and by 21.3% in 2- to 5-year-olds (Mazer-Amirshahi M, et al. J Pediatr. 2013;163[5]:1372-1376).

COMMENTARY

These improvements are the result of hard work by pediatricians and other child advocates in mobilizing both the FDA and pharmaceutical companies as well as in educating parents in the office to avoid these ineffective, potentially harmful medications in young children. There is still work to be done, however. In a 2010 survey of caregivers for children aged younger than 2 years, 63% believed that cough and cold medications were effective in young children and 57% thought that these medications were safe. At the time of that survey, just 31% of caregivers were aware of the FDA guidelines for cough and cold medications (Pediatr Emerg Care. 2012;28[9]:883-885). -Michael Burke, MD

PARENTS OFTEN ARE NOT **AWARE OF AVAILABLE ENHANCED ACCESS SERVICES**

Do parents know whether their pediatric provider offers enhanced access services—such as answering questions by telephone while the office is open or urgent queries after the office is closed; availability of same-day and evening sick visits; and having questions answered via e-mail? Is access to such services associated with fewer visits to an emergency department (ED)? Investigators conducted an Internet-based national survey of 820 parents to answer these questions and determine the prevalence of such enhanced access services in pediatric primary care.

Most parents reported that their child's primary care provider offered access to advice by telephone during office hours (80%), same-day sick visits (79%), and telephone advice outside office hours (54%). Fewer than half of parents reported access to their child's provider on weekends (47%), after 5 PM on any night (23%), or by e-mail (13%). In addition, substantial proportions of parents did not know if enhanced services were available, with 27% of parents being unaware if they could contact their child's primary care office by phone with urgent questions outside office hours and 22% not knowing if their child could be seen in the office on the weekend. Half of parents were not aware of whether the office was ever open after 5 pm, and 57% did not know if they could use e-mail or an office website/ patient portal to communicate with the office.

As to whether any enhanced services made a trip to the ED less likely, offering office hours after 5 PM on 5 or more nights a week was most consistently associated with decreased ED use (Zickafoose JS, et al. J Pediatr. 2013:163[5]:1389-1395).

COMMENTARY

Some parents will bypass their child's medical home and head for the ED or an urgent care center even if they are aware of weekend and evening hours and access to a provider by phone or computer. But *no* parent who is unaware of these services will use them. If you provide any of these resources for your patients, make sure that their parents know. -Michael Burke, MD

Also of Note

Brief primary care interventions can reduce media viewing and exposure to violence. Compared with controls, parents of 2- to 12-year-olds who received either of 2 brief interventions during a well-child visit were more likely to report decreased media time and exposure to violent media as well as more reading and active time. In 1 intervention, parents viewed a 5-minute video that illustrates the recognized risks of children's exposure to violent media and recommends limiting children's media viewing. In the other intervention, parents read the American Academy of Pediatrics handout, "Pulling the Plug on TV Violence," which also recommends limiting media exposure and not having a TV in the child's bedroom (Neely JA, et al. Acad Pediatr. 2013;13[6]:531-539).

WHAT'S YOUR DX?



SAMRAT U DAS, MD, AND PISESPONG PATAMASUCON, MD

THE CASE

The worried mother of a 4-week-old boy brings her son to you for evaluation of a rash that appeared 3 weeks ago on his left eyebrow and chest, then spread to his back, arms, and legs despite treatment with topical steroids. What's your diagnosis?

FOR DISCUSSION SEE PAGE 35



What dermatology mysteries have you solved in your practices? How did you reach your diagnoses? We'd like to hear from you. Share your stories with us and with your colleagues.

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DR DAS is assistant professor, Department of Pediatrics, University of Nevada School of Medicine, Las Vegas. **DR PATAMASUCON** is professor, Department of Pediatrics, University of Nevada School of Medicine, Las Vegas. DR COHEN, the section editor for Dermatology: What's Your DX?, is director, Pediatric Dermatology and Cutaneous Laser Center, and associate 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.

DIAGNOSIS:

Infantile nodular scabies

CLINICAL FINDINGS AND ETIOLOGY

Scabies is a contagious disorder caused by the itch mite Sarcoptes scabiei that infests infants and children as well as adults. The eruption in scabies presents with distinctive pruritic papules, vesicles, and linear burrows.1 Unfortunately, many patients do not present this classic picture but rather a mixture of primary lesions intermingled with or camouflaged by excoriations, eczematization, crusting, and/or secondary infection. The severe itching accompanying scabies takes 4 to 6 weeks to develop and is believed to be related to a type 4 hypersensitivity reaction. Before sensitization occurs, scabies burrows may not be brought to the attention of the practitioner because symptoms may be minimal.

In infants and young children, the distribution may include palms, soles, head, neck, and face.2 The burrow, considered a pathognomic sign of scabies, unfortunately is demonstrable in only 7% to 13% of adults. In newborns and infants who are not particularly effective scratchers, nonspecific symptoms such as poor feeding or increased fussiness may not raise clinical suspicion.

Many infants and young children who develop scabies also develop persistent reddish brown infiltrated nodules, or nodular scabies, in skin creases and covered parts of the body (the axillae, shoulders, groin, buttocks, and genital area).1 These lesions represent a hypersensitivity reaction to the scabies mite and may persist for months despite therapy. Nodular scabies may be mistaken for persistent scabies infestation, resulting in unnecessary treatment with scabicides. Skin biopsy of these lesions may be misdiagnosed as incontinentia pigmenti, insect bite hypersensitivity, contact dermatitis, histiocytosis, or lymphoma. The diagnosis is mainly clinical and based on finding scabies among the patient's family, identification of burrows, and finding viable mites on microscopic examination of skin scrapings.

TREATMENT

The management of scabies usually involves application of topical scabicide cream to all areas except the face and removal in 8 to 48 hours depending on the agent. The agent of choice for infants, young children, and pregnant or nursing women is 5% permethrin cream (not approved for children aged younger than 2 months) applied to the entire head, neck, and body of the infant.1 All family members should be treated simultaneously. Two (or more) applications, each about a week apart, may be necessary to eliminate all mites, particularly when treating crusted (Norwegian) scabies.2

Although lindane 1% cream is still available in the United States, the US Food and Drug Administration recommends against its use in children and the elderly, and it is banned in California. Failure rates with topical 10% crotamiton cream are unacceptably high. Offlabel studies with oral and topical ivermectin suggest that this agent may be an effective and safe alternative, especially for crusted scabies.²⁻⁴ Single application for 5% permethrin cream has been shown to have a cure rate between 89% and 92% per various studies.4 Antibiotics may be necessary to treat secondary infection.3

Clothing and bedding should be machine washed in hot water.^{1,2} Insecticidal powder or aerosols should be reserved for materials that cannot be washed.1 Pruritus usually persists for 4 to 6 weeks after successful treatment with a scabicide and may be relieved by bland emollients, bedtime oral antihistamine, or tapering topical steroids. Children should be allowed to return to child care or school after treatment has been completed.

OUR PATIENT

Our patient was admitted to the hospital for fever and concern for disseminated herpes simplex virus and bacterial infection, and started on parenteral antibiotics and acyclovir. His parents and siblings were subsequently noted to have an itchy rash, and scabies was suspected. After 3 days of negative cultures, our patient and his family were treated with 5% permethrin cream. Antibiotics and acyclovir were discontinued and he was discharged home.



For references, go to ContemporaryPediatrics.com/scabies

>>> PEDIATRICS V2.0 ANDREW J SCHUMAN, MD, SECTION EDITOR

Improve your practice: Keep it simple!

"Make everything as simple as possible, but not simpler." —Albert Einstein

here is an immense amount of enjoyment that can be had in doing a good day's work in a pediatric office. Many days, things go smoothly—you fit in extra patients without much hassle; all forms are signed; and most patients smile and are appreciative. The secret karma to having mostly good days in a pediatric practice should be no secret at all. Merely by analyzing your office workflow, you can determine the simplest and most efficient way to achieve most tasks. Those who regulate health care and those pediatricians who never leave their practices on time would do well to learn the lesson of simplicity. Last year we discussed ways to improve office workflow. Now we are revisiting this topic with the emphasis on the well-known KISS (Keep It Simple, Silly) philosophy that is a surefire way to improve any pediatric practice.

A simple environment

A family's impression of your office begins and ends with the waiting room. It needs to be well organized and welcoming with a few select kid-friendly toys that can be cleaned easily at the end of each day. Interactive wall or table play areas can be so inviting that even nervous children feel right at home. I prefer the sealed play tables with toys that can be moved via attached magnets. Play cubes and playhouses are also a great idea. Keep the play area modest because you don't want to have staff burdened with picking up and organizing dozens of small toys at the end of the workday. Keep the area safe and disaster proof, and remember to childproof all electrical outlets. Medical grade carpet can easily be cleaned after accidents. Plastic chairs versus upholstered are always an excellent bet because plastic chairs can be cleaned and sanitized quickly and easily.



Anatex Play Cube Activity Center: Five exposed sides feature puzzles and mazes that occupy children.

DR SCHUMAN is adjunct associate professor of pediatrics at the Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire. He is also section editor for Pediatrics V2.0 and an editorial advisory board member for Contemporary Pediatrics. He has nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.

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I also encourage practices to consider playing soft music in the background. Studies have consistently shown that office workers stay focused and are more productive when there is music in the background. I think parents and nervous children can also be calmed by the right type of music. Instrumental or classical always works best.

It is also a good idea to provide guest Internet access in your waiting area. Teenagers can access their social media and parents can check e-mails if they'd like. Providing Internet access is also a great opportunity to simplify the check-

in process. After the receptionist confirms checkin and collects the copay, parents can be handed a tablet with your practice's web portal loaded (see "Patient portals," page 39). Parents can then use their waiting-room time to update their demographic and insurance information via the tablet and fill out a visit-specific questionnaire or respond to a survey.



Funlandia Magic Cube: Four play sides occupy several children at once. In the spirit of keeping things simple, all questionnaires should be brief and focused. The information collected on the tablet is either transmitted wirelessly to your electronic health record (EHR) system or the tablet is handed to the medical assistant or nurse when the patient is roomed.

Simplify patient communication

If possible, always have a person answer your office phone and avoid automated phone answering systems. This is the most efficient way to

facilitate appointment booking or resolve patient queries. Patients will always prefer a practice where they can depend on a person answering their phone calls. If you must use a phone response system, keep the message short and sweet and ensure that patients are not kept on hold very long. Have the manpower to accommodate high-volume calling times, such as the



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TABLE The "simple" approach to improving office workflow						
Office workflow	Complicated	Simple				
Waiting room	Lots of small toys that must be picked up, cleaned, and organized each day	Interactive play tables or cubes with self-contained nondetachable toys				
Appointment booking	Automated phone answering system	Friendly receptionist				
Check-in	Lots of forms to fill in	Tablet check-in system				
Rooming	Separate measurement and vision screening/ hearing screening areas	All rooms equipped with measuring/vital signs equipment; portable screening devices				
Examination	History followed by exam	Performing exam while history is obtained				
Instructions	Verbal instructions and printed instructions	Written instructions sent to patient portal				
Checkout	Patient instructed to go for testing or specialty care and given paperwork. Printed after visit summary. Follow-up appointment card given.	Orders for labs, x-rays, referrals done electronically. After- visit summary and follow-up appointment sent via patient portal with follow-up visit reminders.				

first hour of the morning and the hour following school closure. Receptionists that are responsible for checking in patients should always be available to greet patients and should not be responsible for answering phone calls. These responsibilities should be handled by others. Make sure that phone calls are returned promptly and encourage patients to enroll in your patient portal so questions can be answered electronically.

Simplify rooming

There are always choices to be made when equipping your office. To simplify and streamline office workflow, bottlenecks must be avoided. Some practices use specific rooms for measuring patients and taking vital signs. This may work for young practices that are trying to conserve funds, but it's bothersome to have parents and patient brought to an exam room and be moved to one or more rooms for measuring and vision and

hearing screening, then returned again to the exam room. It is much better to room the patient and have all the equipment in the room for taking vital signs as well as height and weight, thus avoiding unneeded movement of parent and child through a busy office. When possible, simplify the process of vision and hearing screening, as well as point-of-care testing, by using portable testing devices that can be brought into the patient's exam room.

Keep parents focused

It is not uncommon for parents to present a laundry list of concerns and problems to the pediatric staff. When the nurse rooms the patient and records the chief complaints, it is reasonable to prioritize those issues, and determine which problems the parents wish to have resolved by the conclusion of the visit. There is a limit to what can be accomplished in a brief 15-minute visit booked to evaluate a cough. By informing the parent that some issues may not be addressed, your staff provides realistic expectations, so the pediatrician will not look like a villain if some concerns may need to wait. It is also important to address at the reception window or during rooming when a parent brings another ill, unscheduled child who suddenly got sick enough on the way to the office to warrant a visit, so an additional slot can be booked and vital signs obtained. Always be on the lookout for the sibling with a prominent cough, or who looks as if he or she might soon throw up!

Expedite the visit

The skilled pediatrician will expedite an acute care visit by engaging the parent and patient in conversation and begin to examine the patient soon after the initial questions have been answered. The pediatrician will continue to ask questions while the examination is being performed. Because your staff will have performed a urine collection with dipstick urinalysis when a child has dysuria or a rapid strep test when symptoms warrant, you won't need to delay your diagnosis waiting for these results. In the case of an acute illness, in the majority of situations, an experienced pediatrician will either arrive at a firm diagnosis or at least have established a plan of action for further evaluation shortly after completing the examination. Subsequently, the pediatrician can sit down and discuss the findings and recommendations with the parent.

If your EHR has a good template system, you can quickly document the visit while talking with the patient because many of the items such as chief complaint, allergies, and medications have already been entered by your staff. Orders can be placed in the EHR and prescriptions sent electronically, if your office has that capability. There are situations when the diagnosis and plan of care have not been established by the end of the visit. If tests need to be done off-site, then the patient will need to be contacted with these results by the pediatrician or nurse with a discussion of a plan of care.

Preventive health visits can be handled in a manner similar to the acute care visit. Nurses will have resulted all screening tests in the EHR prior to the physician's arrival and will prioritize parental concerns if any. It is always best to reinforce your discussion by providing patients (via your web portal, if possible) with written instructions included in an after-visit summary generated by your EHR. When you leave the exam room, the nurse will have already prepared the immunizations that you ordered electronically to be given at the conclusion of the visit. When you leave the room, she is called to enter and will administer vaccines and cover the wounds with Band-Aids. Then the child can depart with the parent promptly to minimize tear time.

Quick and easy checkout

Your skilled receptionist will help parents make their follow-up appointments and, when possible, assist in scheduling appointments with specialists or arranging diagnostic studies. This information is recorded on the



PATIENT PORTALS

- No doubt you've heard that web-based "patient portals" can leverage parents' comfort level with the Internet and mobile computing to facilitate secure communication. If you have an EHR, a web portal may be included in the purchase price. These, however, may not be as "full featured" as some of the independent patient portals currently available. Simply google "patient portals" and you will quickly locate web companies that supply EHR-independent web portals that provide a bit more versatility and functionality compared with many EHR-integrated patient portals.
- Many of these independent portals are also able to communicate with your EHR. Take a look at Bridge Patient Portal (www.bridgepatientportal.com) and you'll see how nifty these patient portals have become. Via the Bridge Patient Portal, parents can request appointments, arrange an electronic visit when appropriate, pay bills, and update their medication lists as well as family history and allergies. Patients can fill in registration as well as previsit forms. They can request prescriptions and appointments all via a secure and HIPAA-compliant web interface. The Bridge Patient Portal is very affordable and can be obtained via a "software as a service" model for as little as \$150 per physician per month with additional interfacing costs available upon request.
- Other portals worth investigating include the iHealthSpot ezPatientPortal (www.ezpatientportal.com) and konciergeMD (www.konciergemd.com).

after-visit summary that has already been populated with instructions provided by nurses and physicians, as well as a list of the tests performed at the visit, the prescriptions generated, and the immunizations given. If you have a patient portal, the after-visit summary can be transmitted electronically. If you don't have a portal, present the patient with a printed version, with key follow-up items highlighted in yellow.

One would think that it is easy to take the "simple road" to optimize office workflow, but it does take time and effort to analyze your current workflow to reduce unnecessary steps, avoid redundancy, and improve patient movement through the office. Always listen to your staff because they will have good suggestions that can improve your practice. Remember: When in doubt, keep it simple!

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>>> PUZZLER

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	fferential diagnosis of suria in a young adult male
Category	Cause
Infectious	Urinary tract infection Gonococcal urethritis Nongonococcal urethritis; Chlamydia trachomatis; Trichomonas vaginalis; Ureaplasma urealyticum; adenovirus; herpes simplex virus Schistosomiasis Prostatitis Epididymoorchitis Genital tuberculosis
Malignancy/ Tumor	Bladder carcinoma Prostatic tumors Pseudotumor of bladder Papilloma of bladder
Urolithiasis	Calcium oxalate, calcium phosphate are predominantly the most common kinds of calculi
Anatomical	Urethral stricture
Medications/ Herbal remedies	Ticarcillin, penicillin G, cyclophosphamide, saw palmetto, pumpkin seeds, dopamine, cantharidin
Trauma and/or foreign bodies	Mechanical trauma from catheterization, instrumentation
Rheumatologic disorders	Reiter syndrome, Behcet disease
	RG, et al¹; Jacob JT, et al²; Tamada T, et al³; Xu D, et al⁴; A, et al⁴; Buowari YD²; Ellison JM, et al⁵; Bremnor JD, et al.º

chlamydia was given and safe sex was discussed. Because of the CVID and an inability to make antibodies, a human immunodeficiency virus (HIV) DNA and HIV RNA were sent. The clinicians discussed whether or not to treat empirically for syphilis because dark-field microscopy is not easily available.

Table 1 outlines the other possible differential diagnosis.¹⁻⁹ Sexually active young men are also prone to nongonococcal urethritis from infections including mycoplasma and ureaplasma. For diagnosis, specific tests will need to be ordered to detect these agents. Viruses such as adenovirus can cause dysuria in association with hemorrhagic cystitis. Herpes typically would be associated with characteristic painful lesions or discharge.

Prostatitis would be associated with a tender prostate

and pain in genitalia. Epididymoorchitis would be associated with a swollen, tender scrotum. These features were absent in the patient.

A less likely infectious possibility includes genital tuberculosis, a rare, unusual, extrapulmonary manifestation of tuberculosis that can be associated with dysuria, sterile pyuria, or a painless testicular mass. Genital tuberculosis will typically manifest with other features such as fever and weight loss, which were absent in this case.2

Schistosomiasis^{6,7,9} is also less likely because there is no history of travel to an endemic area. An additional point that helps the clinician with this diagnosis is the presence of hematuria associated with blood eosinophilia.

Mechanical trauma⁸ is an underlying possibility for dysuria, but the patient denies any recent history of catheterization, instrumentation, or foreign bodies. By the same token, urethral stricture, which would need some previous history of trauma or chronic inflammation, can also be excluded.

Urolithiasis⁵ can be associated with dysuria and hematuria, but a typical presentation would involve excruciating flank pain or groin pain (ie, "renal colic"), which was lacking in this case. The patient does not have a history of hematuria that may be associated with urolithiasis.

Malignant as well as benign tumors (papilloma and pseudotumor of the bladder), although rare, have been documented in young adults and are associated with hematuria and dysuria. Diagnosis requires imaging, cystoscopy, and confirmatory biopsy.3,4

Dysuria can also be associated with urethritis in Reiter syndrome1 where other features such as conjunctivitis and arthritis are also present. Similarly, dysuria can also be a feature of Steven-Johnson syndrome and Behcet syndrome, in which skin and mucocutaneous lesions will be more obvious manifestations of the disease process. Any obvious skin lesions were absent in the patient.

The patient is also not taking any medications that are known to cause dysuria.

Is CVID the culprit?

Common variable immunodeficiency disease is comprised of a group of primary hypogammaglobulinemias. It is characterized by decreased serum immunoglobulin levels, inability to make antibodies, and recurrent bacterial infections. It is often accompanied by autoimmune disease. Renal involvement is rare in CVID, despite widespread involvement of other organ systems. Although there have been case reports of renal failure in CVID, there is currently no evidence that CVID itself can lead to dysuria.10

A surprising development

The patient comes back with his urine specimen and announces, "I think I passed a stone." He reported no pain but hands over a urine sample with a visible stone. He then recalled that this "happens to my mother occasionally."

The urine specimen reveals 3+ glucose, 1+ blood, no white blood cells, no nitrate, and no leukocyte esterase. The analyses for gonorrhea and chlamydia were negative and the HIV test was negative. The analysis of the stone revealed calcium oxalate and calcium phosphate.

When the patient was followed up in a week's time, his symptoms had completely resolved without any further treatment. His dysuria was gone as soon as the stone passed. He was referred to urology for further evaluation.

Discussion

Six months earlier, a 15-year-old girl with CVID, also in the practice's care, presented to the emergency department with severe flank pain. The work-up revealed urolithiasis and extensive renal calculi analyzed to be calcium oxalate. Were these cases a reminder that even those with chronic disease can suffer common illnesses, or is there a connection?

Urolithiasis is a fairly common disease in adults with an estimated prevalence of 3% to 5%.⁵ In economically developed countries, urolithiasis has been regarded as an uncommon condition in children. Recent studies from the United States suggest an increase in its incidence and prevalence, with 1 study demonstrating a nearly 5-fold increase in the incidence in the last decade.^{5,11}

A number of factors may be contributing to this increase. Many theories are plausible and such theories include the increasing childhood obesity epidemic, a changing sex predilection, climate change, alterations in dietary habits, and improving diagnostic modalities.¹²

The classic adult presentation of urolithiasis is acute, severe flank pain that radiates to the groin, and adolescents present similarly. Younger children, particularly those aged younger than 5 years, have varied presentations including nonspecific pain localized to the abdomen, flank, or pelvis. Approximately 10% of calculi can present with dysuria and urinary frequency and are usually localized to the lower urinary tract. Some UTIs may

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TABLE 2 Result of the patient's urinalysis

Test name	Result	Flag	Reference
Urine appearance	Clear		
Color	Yellow		
Glucose	3+	Α	Negative
Bilirubin	Negative		Negative
Ketones	Negative		Negative
Specific gravity	1.023		1.005-1.030
Blood	1+	Α	Negative
рН	7.0		5.0-8.5
Protein	Negative		Negative
Urobilinogen	Negative		0.0-1.0
Nitrite	Negative		Negative
Leukocyte esterase	Negative		Negative
RBCs	2-5/HPF		<2
WBCs	<5/HPF		<5
Epithelial cells	<5/HPF		<5
Cast	None/LPF		None
Crystals	None/HPF		None
Mucus	Negative/HPF		Negative
Bacteria	None/HPF		None
Sperm	None seen/ HPF		NSE

Abbreviations: HPF, high power field; LPF, low power field; NSE, neuron-specific enolase; pH, potenz power/hydrogen; RBC, red blood cell; WBC, white blood cell.

complicate nephrolithiasis, although pyuria may also be present without bacteriuria or infection.

In the United States, approximately 40% to 65% of calculi are comprised of calcium oxalate; 14% to 30% of calcium phosphate; 10% to 20% of struvite; 5% to 10% of

cystine; and 1% to 4% of uric acid. Rarely, stones may also be comprised of xanthine, or 2, 8-dihydroxyadenine.^{5,13}

The initiation and growth of calculi requires the super saturation of certain ions in the urine. All types of calculi are less likely to form in dilute urine.

It is possible that in patients with CVID who receive monthly immunoglobulin transfusions, periods of inadequate hydration may predispose these patients to urolithiasis. Further studies in this area are needed to determine if a correlation exists between CVID and renal stones.

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