Unexplained pediatric death

Groundbreaking guidance for medical professionals

Infectious Disease
COVID-19: What’s your practice battle plan?

Pediatric Pharmacology
Simplified test for opioids in neonates

Respiratory Disorders
Asthma linked to T1D diagnosis

Nutrition
Antioxidant-rich diet cuts infection risk in kids with ALL

Dermatology
Persistent birthmark on a toddler’s back

Practice Improvement
How to make the most of chronic care management

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TEAM ADHD is a group of psychiatric health care professionals united by an expertise in the field of ADHD treatment.
CHAIRMAN’S LETTER

A pediatric wrinkle in the COVID-19 scenario

Just as we were comforted by the data showing that COVID-19 was sparing our nation’s children, there is news of a disturbing set of complications in some pediatric patients.

First described in the United Kingdom in late April and followed by Spain, Italy, France, and the United States, “Multisystem Inflammatory Syndrome in Children (MIS-C) associated with coronavirus disease (COVID-19)” has been confirmed/suspected in more than 200 children in at least 20 states, with 4 pediatric deaths reported, by late May. The syndrome mimics Kawasaki disease and/or toxic shock syndrome with fever, rash, cardiac/blood vessel inflammation, and abdominal pain, and appears days after children have been exposed to coronavirus infection. Treatment includes intravenous immunoglobulin, blood thinners, and steroids, with most patients recovering.

The Centers for Disease Control and Prevention has advised clinicians to be observant and report confirmed cases to state and local health departments.

Contemporary Pediatrics recently assembled a panel of experts to discuss MIS-C. Listen to this informative webinar on demand at ContemporaryPediatrics.com/MIS-C-webinar.

Mike Hennessy, Sr.
Chairman and Founder
MJH Life Sciences
mental health

18 Groundbreaking guidelines issued for unexplained pediatric death

New consensus guidelines clarify the procedural guidance for investigation, certification, and reporting of sudden unexplained pediatric death to help medical professionals and families through these crises. **Erin Bowen, MD**

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An infant with severe hemophilia A presents with fussiness and inability to sleep for 3 days, crying when laid down. **Supriya Ramanathan, MD; Miriam B Garcia, DO; Neethu M Menon, MD; Lynnette Mazur, MD, MPH**

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Children with acute lymphoblastic leukemia (ALL) can cut their risk of infections by eating more fruits and vegetables. **Miranda Hester, Editor**

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Coding properly for chronic care management (CCM) of patients with multiple conditions will ensure correct reimbursement. **Luis F Seguías, MD**

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35 Persistent birthmark grows on a toddler’s back

Parents ask for advice about a lesion that has grown proportionately with their son. **Michelle A Recto, BA, MS4; James P Senter, MPH, MS4; Bernard A Cohen, MD**

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THE ONLY AVAILABLE FDA-APPROVED PRESCRIPTION TREATMENT INDICATED FOR PINWORM

95% CURE RATE AGAINST PINWORM¹

- EMVERM contains mebendazole, the active ingredient that has been prescribed by physicians for more than 40 years²
- The AAP Red Book recommends mebendazole as one of the drugs of choice for pinworm infections³
- The CDC recommends treating the entire household where more than one member is infected or where repeated, symptomatic infections occur⁴
- Patients should be prescribed 2 tablets. EMVERM can often cure pinworm infection with a single tablet. However, a second tablet may be necessary after 3 weeks to prevent reinfection and to kill any worms that hatched after the first treatment⁵
  - One 100 mg tablet is the same dose for adults and children⁶
  - Chewable, kid-friendly tablet can also be swallowed whole or crushed and mixed with food⁷

ELIGIBLE PATIENTS MAY PAY AS LITTLE AS $5.¹ LEARN MORE AT EMVERMSAVINGS.COM/CP

*Subject to eligibility. Individual out-of-pocket costs may vary. Not valid for patients covered under Medicare, Medicaid, or other federal or state program. Please see full terms, conditions, and eligibility criteria at EmvermSavings.com. AAP: American Academy of Pediatrics.

INDICATION
EMVERM is indicated for the treatment of patients two years of age and older with gastrointestinal infections caused by *Ancylostoma duodenale* (hookworm), *Ascaris lumbricoides* (roundworm), *Enterobius vermicularis* (pinworm), *Necator americanus* (hookworm), and *Trichuris trichiura* (whipworm).

IMPORTANT SAFETY INFORMATION
Contraindication: EMVERM is contraindicated in persons with a known hypersensitivity to the drug or its excipients (mebendazole, microcrystalline cellulose, cornstarch, anhydrous lactose, sodium starch glycolate, magnesium stearate, stearic acid, sodium lauryl sulfate, sodium saccharin, and FD&C Yellow #6).

Warnings and Precautions:
- Risk of convulsions: Convulsions in infants below the age of 1 year have been reported.
- Hematologic effects: Neutropenia and agranulocytosis have been reported in patients receiving mebendazole at higher doses and for prolonged duration. Monitor blood counts in these patients.
- Metronidazole and serious skin reactions: Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) have been reported with the concomitant use of mebendazole and metronidazole.

Adverse Reactions from Clinical Trials*: Anorexia, abdominal pain, diarrhea, flatulence, nausea, vomiting, rash.

Adverse Reactions from Postmarketing Experience with Mebendazole*: Agranulocytosis, neutropenia, hypersensitivity including anaphylactic reactions, convulsions, dizziness, hepatitis, abnormal liver tests, glomerulonephritis, Stevens-Johnson syndrome/toxic epidermal necrolysis, exanthema, angioedema, urticaria, alopecia.

*Includes mebendazole formulations, dosages and treatment duration other than EMVERM 100 mg chewable tablet.

Drug Interactions: Concomitant use of EMVERM and metronidazole should be avoided.

Use in Specific Populations:
- Pregnancy: Mebendazole use in pregnant women has not reported a clear association between mebendazole and a potential risk of major birth defects or miscarriages. However, there are risks to the mother and fetus associated with untreated helminthic infection during pregnancy.
- Lactation: Limited data from case reports demonstrate that a small amount of mebendazole is present in human milk following oral administration. There are no reports of effects on the breastfed infant.
- Pediatric Use: The safety and effectiveness of EMVERM 100 mg chewable tablet have not been established in pediatric patients less than two years of age.
- Geriatric Use: Clinical studies of mebendazole did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects.

Overdosage: In patients treated at dosages substantially higher than recommended or for prolonged periods of time, the following adverse reactions have been reported: alopecia, reversible transaminase elevations, hepatitis, agranulocytosis, neutropenia, and glomerulonephritis.

Symptoms and signs of overdose: In the event of accidental overdose, gastrointestinal signs/symptoms may occur.

Treatment of overdose: There is no specific antidote.

Patient Counseling: Healthcare professionals should advise the patient to read the FDA-approved patient labeling (Patient Information). Advise patients that:
- Taking EMVERM and metronidazole together may cause serious skin reactions and should be avoided.
- EMVERM can be taken with or without food.

To report SUSPECTED ADVERSE REACTIONS contact Amneal Specialty, a division of Amneal Pharmaceuticals LLC at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information at www.EMVERMHCP.com and Brief Summary on following pages.


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PRESRIPTION POWER OVER PINWORM

Emverm® (mebendazole) chewable tablet, USP
100 mg
EMVERM® (mebendazole) 100 mg Chewable Tablets

BRIEF SUMMARY: Complete information about EMVERM® can be found in the Full Prescribing Information.

INDICATIONS AND USAGE
EMVERM® is indicated for the treatment of patients two years of age and older with gastrointestinal infections caused by Ancylostoma duodenale (hookworm), Ascaris lumbricoides (roundworm), Enterobius vermicularis (pinworm), Necator americanus (hookworm), and Trichuris trichiura (whipworm).

DOSAGE AND ADMINISTRATION
The recommended dosage for EMVERM® is described in Table 1 below. The same dosage schedule applies to adults and pediatric patients two years of age and older. The tablet may be chewed, swallowed, or crushed and mixed with food.

Table 1: Dosage of EMVERM® in Adult and Pediatric Patients (two years of age and older)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Dose</th>
<th>Pinworm (enterobiasis) Morning and evening for 3 consecutive days</th>
<th>Whipworm (trichuriasis) Morning and evening for 3 consecutive days</th>
<th>Roundworm (ascarisiasis) Morning and evening for 3 consecutive days</th>
<th>Hookworm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pinworm (enterobiasis)</td>
<td>1 tablet, once</td>
<td>1 tablet morning and evening for 3 consecutive days</td>
<td>1 tablet morning and evening for 3 consecutive days</td>
<td>1 tablet morning and evening for 3 consecutive days</td>
<td></td>
</tr>
</tbody>
</table>

If the patient is not cured three weeks after treatment, a second course of treatment is advised. No special procedures, such as fasting or purging, are required.

CONTRAINDICATIONS
EMVERM® is contraindicated in persons with a known hypersensitivity to the drug or its excipients (mebendazole, microcrystalline cellulose, corn starch, anhydrous lactose, sodium starch glycolate, magnesium stearate, stearic acid, sodium lauryl sulfate, sodium saccharin, and FD&C Yellow #6).

WARNINGS AND PRECAUTIONS
Risk of Convulsions
Although EMVERM® is approved for use in children two years of age and older, convulsions have been reported in infants below the age of 1 year during post-marketing experience with mebendazole, including EMVERM®.

Hematologic Effects
Agranulocytosis and neutropenia have been reported with mebendazole use at higher doses and for more prolonged durations than is recommended for the treatment of soil-transmitted helminth infections. Monitor blood counts if EMVERM® is used at higher doses or for prolonged duration.

Metronidazole Drug Interaction and Serious Skin Reactions
Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) have been reported with the concomitant use of mebendazole and metronidazole. Avoid concomitant use of mebendazole, including EMVERM® and metronidazole.

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

The safety of mebendazole was evaluated in 6276 subjects who participated in 39 clinical trials for treatment of single or mixed parasitic infections of the gastrointestinal tract. In these trials, the formulations, dosages and duration of mebendazole treatment varied. Adverse reactions reported in mebendazole-treated subjects from the 39 clinical trials are shown in Table 2.

Table 2: Adverse Reactions Reported in Mebendazole-treated Subjects from 39 Clinical Trials*

<table>
<thead>
<tr>
<th>Adverse Reaction(s)</th>
<th>Blood and Lymphatic System Disorders</th>
<th>Immune System Disorders</th>
<th>Nervous System Disorders</th>
<th>Hepatobiliary Disorders</th>
<th>Renal and Urinary Disorders</th>
<th>Skin and Subcutaneous Tissue Disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agranulocytosis, Neutropenia</td>
<td>Adverse Reaction(s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypersensitivity including anaphylactic reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convulsions, Dizziness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis, Abnormal liver tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glomerulonephritis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEN, SJS, Exanthema, Angioedema, Urticaria, Alopecia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Includes mebendazole formulations, dosages and treatment duration other than EMVERM® 100 mg tablet

Postmarketing Experience
The following adverse reactions have been identified in adult and pediatric patients postmarketing with mebendazole formulations and dosages other than the EMVERM® 100 mg chewable tablet. Because these reactions 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 drug exposure.

Table 3: Adverse Reactions Identified During Postmarketing Experience with Mebendazole*

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Adverse Reaction(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rash</td>
<td>Gastrointestinal Disorders</td>
</tr>
<tr>
<td>Anorexia, Abdominal Pain, Diarrhea, Flatulence, Nausea, and Vomiting</td>
<td></td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
<td></td>
</tr>
<tr>
<td>TEN, SJS, Exanthema, Angioedema, Urticaria, Alopecia</td>
<td></td>
</tr>
</tbody>
</table>

*Includes mebendazole formulations, dosages and treatment duration other than EMVERM® 100 mg chewable tablets

DRUG INTERACTIONS
Concomitant use of mebendazole, including EMVERM®, and metronidazole should be avoided.

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
The available published literature on mebendazole use in pregnant women has not reported a clear association between mebendazole and a potential risk of major birth defects or miscarriages [see Data]. There are risks to the mother and fetus associated with untreated helminthic infection during pregnancy [see Clinical Considerations]. In animal reproduction studies, adverse developmental effects (i.e., skeletal malformations, soft tissue malformations, decreased pup weight, embryolethality) were observed when mebendazole was administered to pregnant rats during the period of organogenesis at single oral doses as low as 10 mg/kg (approximately 0.5-fold the total daily maximum recommended human dose [MRHD]). Maternal toxicity was present at the highest of these doses [see Data]. The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

Clinical Considerations
Disease-Associated Maternal and/or Embryo/Fetal Risks
Untreated soil transmitted helminth infections in pregnancy are associated with adverse outcomes including maternal iron deficiency anemia, low birth weight, neonatal and maternal death.

Data
Human Data
Several published studies, including prospective pregnancy registries, case-control, retrospective cohort, and randomized controlled studies, have reported no association between mebendazole use and a potential risk of major birth defects or miscarriage. Overall, these studies did not identify a specific
pattern or frequency of major birth defects with mebendazole use. However, these studies cannot definitively establish the absence of any mebendazole-associated risk because of methodological limitations, including recall bias, confounding factors and, in some cases, small sample size or exclusion of first trimester mebendazole exposures.

Animal Data
Embryo-fetal developmental toxicity studies in rats revealed no adverse effects on dams or their progeny at doses up to 2.5 mg/kg/day on gestation days 6–15 (the period of organogenesis). Dosing at ≥10 mg/kg/day resulted in a lowered body weight gain and a decreased pregnancy rate. Maternal toxicity, including body weight loss in one animal and maternal death in 11 of 20 animals, was seen at 40 mg/kg/day. At 10 mg/kg/day, increased embryo-fetal resorption (100% were resorbed at 40 mg/kg/day), decreased pup weight and increased incidence of malformations (primarily skeletal) were observed. Mebendazole was also embryotoxic and teratogenic in pregnant rats at single oral doses during organogenesis as low as 10 mg/kg (approximately 0.5-fold the total daily MRHD, based on mg/m²). In embryo-fetal developmental toxicity studies in mice dosed on gestation days 6–15, doses of 10 mg/kg/day and higher resulted in decreased body weight gain at 10 and 40 mg/kg/day and a higher mortality rate at 40 mg/kg/day. At doses of 10 mg/kg/day (approximately 0.2-fold the total daily MRHD, based on mg/m²) and higher, embryo-fetal resorption increased (100% at 40 mg/kg) and fetal malformations, including skeletal, cranial, and soft tissue anomalies, were present. Dosing of hamsters and rabbits did not result in embryotoxicity or teratogenicity at doses up to 40 mg/kg/day (1.5 to 3.9-fold the total daily MRHD, based on mg/m²). In a peri- and post-natal study in rats, mebendazole did not adversely affect dams or their progeny at 20 mg/kg/day. At 40 mg/kg (1.9-fold the total daily MRHD, based on mg/m²), a reduction of the number of live pups was observed and there was no survival at weaning. No abnormalities were found on gross and radiographic examination of pups at birth.

Lactation
Risk Summary
Limited data from case reports demonstrate that a small amount of mebendazole is present in human milk following oral administration. There are no reports of effects on the breastfeeding infant, and the limited reports on the effects on milk production are inconsistent. The limited clinical data during lactation precludes a clear determination of the risk of EMVERM® to a breastfeeding infant; therefore, developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for EMVERM® and any potential adverse effects on the breastfed infant from EMVERM® or from the underlying maternal condition.

Pediatric Use
The safety and effectiveness of EMVERM® 100 mg chewable tablets has not been established in pediatric patients less than two years of age. Convulsions have been reported with mebendazole use in children less than one year of age.

Geriatric Use
Clinical studies of mebendazole did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects.

OVERDOSAGE
In patients treated at dosages substantially higher than recommended or for prolonged periods of time, the following adverse reactions have been reported: alopecia, reversible transaminase elevations, hepatitis, agranulocytosis, neutropenia, and glomerulonephritis.

Symptoms and signs
In the event of accidental overdose, gastrointestinal signs/symptoms may occur.

Treatment
There is no specific antidote.

### CLINICAL STUDIES
Efficacy rates derived from various studies are shown in Table 4 below:

<table>
<thead>
<tr>
<th></th>
<th>Pinworm (enterobiasis)</th>
<th>Whipworm (trichuriasis)</th>
<th>Roundworm (ascariasis)</th>
<th>Hookworm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure rates mean</td>
<td>95%</td>
<td>68%</td>
<td>98%</td>
<td>96%</td>
</tr>
<tr>
<td>Egg reduction mean</td>
<td>—</td>
<td>93%</td>
<td>99%</td>
<td>99%</td>
</tr>
</tbody>
</table>

### PATIENT COUNSELING INFORMATION
Advises the patient to read the FDA-approved patient labeling (Patient Information).
Advises patients that:
- Taking EMVERM® and metronidazole together may cause serious skin reactions and should be avoided.
- EMVERM® can be taken with or without food.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Please see Full Prescribing Information including Patient Information at www.emvermhcp.com.

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Bridgewater, NJ 08807
07/2019 PP-XPI-MEB-US-0012
Warm greetings! It is hard to believe that summer is almost upon us.

Over the last 4 months, the spreading COVID-19 pandemic has made us rethink how we practice medicine in order to continue to provide outstanding comprehensive care to all our patients. This is especially important for our patients aged younger than 2 years for whom it is critically important that they receive their recommended vaccines on time and for medically complex patients who require close follow-up for the management of their conditions.

The pandemic has challenged us to be creative in the ways we evaluate patients and provide reassurance to their parents. In this issue of Contemporary Pediatrics, these are must-reads:

- **COVID-19: A battle plan for pediatricians**—This article highlights some strategies that pediatric practitioners can incorporate into their practices to safely and effectively provide care to their patients. **PAGE 21**

- **CDC issues preliminary information on MIS-C**—Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19 was first described in the United Kingdom in late April 2020 and has since been reported in Spain, Italy, France, and the United States. This is a serious condition with some symptoms that overlap those seen in Kawasaki disease and/or toxic shock syndrome. Preliminary data indicate that many individuals who develop this syndrome have either COVID-19 infection or a history of exposure and that MIS-C may be a postinfectious inflammatory process. This article presents the CDC case definition of MIS-C and the need to report MIS-C to local, state, or territorial health departments. **PAGE 24**

- **Updated consensus guidelines issued for unexplained pediatric death**—There is limited medical awareness of SUDC, which is the sudden and unexpected death of a child aged 12 months or older that remains unexplained after a thorough investigation including autopsy. This document provides comprehensive guidance for the pediatric practitioner on the investigation of the event and the important role that they play in serving as liaisons to help families maneuver through the processes that occur after the death. **PAGE 18**

- **Chronic care management: Increase the value of your practice**—Fifteen to 25% of children in the United States have one or more chronic health conditions that require some level of chronic care management. This is an important Practice Improvement article that provides the information to properly code for the management of children with multiple chronic conditions and ensure proper reimbursement. **PAGE 29**

As we continue to work through the COVID-19 pandemic, remember that:

“No matter how hard things may seem, don’t get down and don’t give up. The clouds will clear and there are brighter days ahead.” —Anonymous

Please stay safe and well. I welcome your suggestions, comments, and questions.

With warmest regards,
Tina

Tina Q. Tan, MD, Editor-in-Chief
Can fewer daily doses of cephalaxin treat MSSA?

A pharmacokinetic model suggests that although 4 daily doses of cephalaxin are the standard of care for treating methicillin-susceptible Staphylococcus aureus (MSSA) infections, 2- or 3-dose daily regimens (BID or TID) could achieve similar results.

To develop the model, investigators used data from a pharmacokinetic study in 12 children with bone and joint MSSA infections receiving cephalaxin in 53 concentrations. Seven of these children were male, and median age and weight were 7.6 years and 25 kg, respectively. Samples to determine total cephalaxin concentration in the blood were taken before the drug dose and at 1, 1.5, 2, and 6 hours after it. Investigators performed simulations to determine a BID and TID dosing regimen that would allow 90% or more of children to achieve the pharmacodynamic target for MSSA (when the free drug concentration exceeds the minimum inhibitory concentration [MIC] of the bacteria for at least 40% of the dosing interval).

For BID dosing, a dose of 45 mg/kg BID was required for an MIC of 1 or 2 mg/L and 80 mg/kg for an MIC of 4 mg/L. For both BID and TID dosing regimens, a total daily dose of more than 1 mg/kg was required if the MIC was 4 mg/L.

The probability of reaching the pharmacodynamic target for MSSA was similar for doses of 80 mg/kg BID, 45 mg/kg TID, and the current standard of care, 25 mg/kg 4 times a day. Based on their modeling, investigators developed a table for a proposed BID and TID cephalaxin dosing regimen for MSSA infections based on the child’s weight. They noted that these regimens should be prospectively evaluated to determine their efficacy for common childhood infections (Gwee A, et al. Pediatr Infect Dis J. March 11, 2020. Epub ahead of print.).

I have been treating impetigo and urine infections twice a day with cephalaxin for some time now with good results. This study, which will need some clinical correlation, suggests that this dosing should work for more worrisome infections, such as cellulitis. Anything that reduces the number of doses needed daily and improves compliance is a big plus in my book.

Dr. Farber, section editor for Journal Club, is a pediatrician in Woodbridge, Virginia. Ms. Freedman is a freelance medical editor and writer in New Jersey. 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 these articles.
Children who take proton pump inhibitors (PPIs) are at increased risk of having fractures compared with those who have no PPI exposure, according to a retrospective review of information in the Pediatric Hospital Information System database. Further, likely fracture location differs between those who are exposed to PPIs and those who are not.

Data was obtained from about 32,000 health care encounters with documented PPI use. Median age was 4 years, with children aged younger than 1 year accounting for almost one-third of patients and females representing almost one-half. Investigators selected a propensity matched control group and evaluated patients from both groups for hospitalizations resulting from fracture during a 2-year period.

Of the 808 patients who experienced fractures during the study period, 437 were in the PPI group and 371 in the control group. The total number of fractures, including multiple fractures, was 581 in the PPI group compared with 453 among controls. In both groups, fractures were most often in the upper extremities, but the PPI group was more likely to have lower extremity, rib, and spinal fractures than was the control group. Investigators found no correlation between fracture risk and individual PPIs (Fleishman N, et al. J Pediatr Gastroenterol Nutr. March 12, 2020. Epub ahead of print.).

Proton pump inhibitors usually are not that effective for reflux. Earlier studies have shown they can increase the risk of allergies when the child is older. Now we can add fractures to the potential long-term adverse effects. Try not to treat spit-up with medicine and, if you do and the medicine is not clearly working for a given child, please discontinue it.
With kids home and parents looking for things to do that include “social distancing,” more families will take to the outdoors. The only thing, ticks don’t play by the same rules, so Lyme disease could end up on the rise. When patients aren’t feeling well, anxiety levels could be especially high – and now more than ever they’ll ask to be tested. Sofia 2 Lyme FIA uses a finger-stick whole blood sample to provide accurate, objective and automated results in as few as 3 minutes, getting practitioner and anxious patient on a path to treatment much sooner.

- IgM and IgG differentiated results
- CLIA waived
- Point-of-care testing
- Less than 1 minute hands-on-time
- Accuracy comparable to laboratory testing methods

For more information contact Quidel Inside Sales at 858.431.5814 or go to our website at Sofia2Lyme.com
Epidural bleeding in an infant with hemophilia

A 7-month-old male with severe hemophilia A (less than 1% factor VIII [FVIII] activity) presented to his pediatrician with fussiness and inability to sleep for 3 days. He had received his influenza vaccine 3 days earlier. His mother attributed the fussiness to introducing lentils into his diet.

The infant was born to a 32-year-old primigravida mother via cesarean delivery after a normal pregnancy. Severe hemophilia A was diagnosed due to bleeding after a circumcision done at birth. There were no subsequent bleeding episodes and he was not on FVIII replacement therapy.

The infant’s review of systems was positive for atopic dermatitis, intermittent constipation, mild gastroesophageal reflux, and co-sleeping. His growth and development were normal. He was not on medications and his immunizations were up-to-date, including his influenza vaccine 3 days prior to this presentation. There was no history of fever, cough, cold, vomiting, diarrhea, or trauma. The child was treated initially with reflux precautions, dietary advice, and observation but the fussiness worsened. He continued to feed well and smiled when held but started crying when laid down. He slept only in his mother’s arms and awakened screaming at night.

Clinical course and evaluation

The mother called the hematologist for worsening fussiness and was advised to take the patient to the emergency department (ED). The Hematology service was consulted in the ED. The patient’s vital signs and physical exam were normal. Abdominal imaging (X-ray and abdominal ultrasound [US]) showed no evidence of constipation or intussusception.

The patient saw the pediatrician for a follow-up visit. He was afebrile, fussy, and tired appearing with normal vital signs and a normal physical exam other than crying when laid on the examination table that stopped when he was picked up. Rapid tests for respiratory syncytial virus (RSV) and influenza were negative. He was evaluated at the Hemophilia Clinic the next day when he had a complete blood count (CBC) and a head computed tomography (CT), which were normal.

He followed up again with the pediatrician. His mother reported continuing fussiness, increased flatulence, and pasty stools with straining and crying. On examination, the patient appeared uncomfortable and curled up when laid down. A repeat abdominal X-ray was normal. He was put on an elemental formula and advised polyethylene glycol 1 teaspoon per day in water. The family was advised to return to the ED if the fussiness continued.

The patient returned to the pe-
The patient was noted to be intermittently fussy but had normal vital signs and continued to feed well. He was noted to arch his back during episodes of fussiness. He showed a preference to turn his head to the left. Neck exam showed no asymmetry or evidence of muscle bleed. He did not awaken to an abdominal exam when asleep. The occupational therapist recommended gentle neck exercises for his neck stiffness that was thought to be related to his preferred sleep position in the parents’ arms for several days. His arching was attributed to gastroesophageal reflux. After 2 days, he was discharged.

**Differential diagnosis for fussiness**

Fussiness in infants is a common pediatric outpatient complaint and has many causes that range from trivial to life threatening. Both hematologic and nonhematologic causes of fussiness were considered in the differential diagnosis for this infant with hemophilia (Table 1). At the onset of fussiness, the patient appeared well, and nonorganic causes were considered such as his recent influenza vaccination, recent introduction of a new food, co-sleeping with parents, frequent awakening at night, and the onset of teething. His exam was negative for thrush, corneal abrasion, or musculoskeletal trauma. Infections appeared unlikely due to the lack of fever, cold symptoms, ear pain, or rash. Because of his history of mild gastro-intestinal reflux, intermittent constipation, and fussiness, he was treated with reflux precautions, polyethylene glycol, and a trial of elemental formula.

The patient was simultaneously evaluated for signs and symptoms of hemophilia (Table 2). He demonstrated no obvious bruising, tenderness, swelling, or deformity. Additionally, he had no hemarthroses. He did exhibit worrisome signs such as refusal to lay on his back, turning to 1 side, and curving forward. Hence,
The child was evaluated for intracranial and intra-abdominal hemorrhage, which were ruled out based on clinical exam, laboratory evaluation, and imaging studies.

A worsening exam
During the follow-up with his pediatrician on the day after discharge from the hospital, the patient’s mother reported worsening fussiness with “his hands numb from pain.” On examination, he had torticollis with a head tilt to the left and a partial ptosis of his left eyelid. Tone and spontaneous movements of his trunk and upper extremities were decreased and he reached for a toy with his feet.

Unable to sit, he curved his spine forward when placed in a seated position. He was unable to lift himself up from the prone position. Grasp reflex was absent, and he appeared to have no sensation in his palms. The pediatrician advised the parent to return to the ED and called the hematologist about the new neurologic findings. The child was intubated in the ED and an imaging study confirmed the diagnosis.

Diagnosis
The patient was diagnosed with spinal epidural hematoma (SEH) with cord compression presenting with Horner syndrome.

Magnetic resonance imaging (MRI) of the patient’s spine showed multiple epidural hematomas extending from C2 down to S1 with significant cord compression. This was especially pronounced from C6 to T4 where the spinal cord was severely compressed and displaced anteriorly and to the left. Multiple septations suggested that the hematomas could be subacute or chronic. (Figures 1 and 2 present preoperative T1- and T2-weighted sagittal and axial images of the spine.)

Factor VIII replacement was given immediately after the MRI and perioperatively per standard guidelines for hemophilia. He underwent multiple partial hemilaminectomies for decompression of epidural hematomas. His neurologic exam improved the next day with increased spontaneous movements of his upper extremities.

One week postoperatively, another spinal MRI showed significant improvement (Figure 3). The patient was found to have a low titer inhibitor (0.8 BU) during the admission that self-resolved on follow-up testing. Postoperatively, further bleeding complications were successfully prevented with recombinant FVIII product, 200 units/kg/dose given every 6 hours that was gradually spaced out. He was discharged after 3 weeks with residual right-sided hemiparesis and left-sided ptosis.

Three months later, a central line was placed to facilitate the admin-

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TABLE 2
HEMOPHILIA SIGNS AND SYMPTOMS

<table>
<thead>
<tr>
<th>SITE</th>
<th>SYMPTOMS</th>
<th>SIGNS</th>
<th>FURTHER WORKUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joint</td>
<td>Warmth and discomfort on movement followed by swelling</td>
<td>Tenderness, effusion, reduced range of motion</td>
<td>X-ray to rule out fracture; no test needed to confirm bleed</td>
</tr>
<tr>
<td>Muscles</td>
<td>Muscle ache worse on stretching or contracting the muscle</td>
<td>Tension and tenderness on palpation; swelling</td>
<td>Assess NV bundle, especially with deep muscles; Hemoglobin as needed to check for blood loss</td>
</tr>
<tr>
<td>Iliopsoas with risk of NV compromise</td>
<td>Pain in lower abdomen, groin, lower back</td>
<td>Pain on extension but not on rotation of hip joint</td>
<td>USG/CT/MRI to diagnose and monitor extent of bleed; Hemoglobin</td>
</tr>
<tr>
<td>Head</td>
<td>Sudden severe headache</td>
<td>Focal neurologic deficits</td>
<td>CT/MRI</td>
</tr>
<tr>
<td>Spine</td>
<td>Sudden severe back pain</td>
<td>Focal neurologic deficits</td>
<td>CT/MRI</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Hematochezia, melena, hematemesis</td>
<td>Sudden unexplained pallor, tense and distended abdomen, shock</td>
<td>USG/CT/MRI</td>
</tr>
<tr>
<td>Renal</td>
<td>Painless hematuria often triggered by NSAIDs, trauma or exertion; Pain once clots form</td>
<td></td>
<td>Rule out other causes of hematuria such as infection, stones, neoplasm</td>
</tr>
</tbody>
</table>

Abbreviations: CT, computed tomography; MRI, magnetic resonance imaging; NSAIDs, nonsteroidal anti-inflammatory drugs; NV, neurovascular; USG, ultrasonography. From Srivastava A, et al.3
Administration of the recombinant FVIII product every other day. Six months later, he transitioned to an extended half-life (EHL) FVIII product (50 units/kg/day every 4 days). He received physical and occupational therapy with steady improvement and was enrolled in Early Intervention services for children.

**Discussion**

Hemophilia, an X-linked bleeding disorder, is the most common hereditary bleeding disorder in the United States. Its incidence is estimated to be approximately 1 in 5000 live male births. Hemophilia A, the condition affecting this patient, results from deficiency in FVIII. Central nervous system bleeding in patients with hemophilia is a rare complication with an incidence between 2% and 8%. Fewer than 10% of these hemorrhages occur within the spinal canal.

This case highlights the importance of recognizing infancy as a high-risk age group for the occurrence of SEH. Infants may be predisposed to epidural bleeding as their cervical musculature begins to develop between ages 4 and 6 months. Increased cervical motion in the developing muscle body (due to acceleration and deceleration of the head mass in babies with poor head control) leads to cervical spine injury and the potential for hemorrhage.

Spontaneous SEH can be either venous or arterial in origin. In venous SEH, absence of valves in the venous plexus allows for venous backflow and sudden increases in pressure (from an infant’s crying, straining, coughing, or sneezing), inducing spontaneous rupture of these fragile vessels. In arterial SEH, it is hypothesized that the higher pressure of arterial bleeding could result in cord compression with a rapid onset in patients who previously performed strenuous activities without incident. Young infants with hemophilia also are at higher risk for hemorrhage because they typically do not begin prophylactic factor replacement until after age 1 year or following their first joint or muscle bleed once ambulatory.

Babies with SEH have nonspecific symptoms such as unexplained irritability, inconsolable crying, poor feeding, or refusal to bear weight without history of trauma, making it difficult to recognize. The classic clinical triad of SEH—radicular pain, severe localized spinal pain, and sensorimotor deficits—may initially be difficult to perceive in a nonverbal infant. However, a diligent physical exam demonstrating specific neurologic signs such as decreased neck range of motion, diminished arm reflexes, or decreased strength, tone, and sensation in the upper extremities should prompt diagnostic imaging.

Review of literature revealed 2 previous cases describing torticollis as a presentation of SEH in hemophilia A. Similar to this case, a 10-month-old infant with a cervicothoracic epidural hematoma presented initially with irritability and a normal neurologic exam but developed torticollis approximately 48 hours later that progressed to diffuse hypotonia, flaccid upper extremity paralysis, and respiratory distress requiring emergent decompressive laminectomy. Another 10-month-old boy developed torticollis 48 hours...
puzzler

after an incident of repeated neck overextension and went on to develop flaccid upper extremity paralysis.12 There are no previous cases of SEH in hemophilia presenting with Horner syndrome. However, a similar presentation was found in a 72-year-old woman receiving anticoagulant therapy for atrial fibrillation.13

Early diagnosis and treatment of SEH in hemophilia patients is necessary to prevent progression of neurologic deficits leading to long-term sequelae. Magnetic resonance imaging is the diagnostic modality of choice for SEH. However, spinal ultrasonography is a reasonable screening tool should MRI not be readily available.14 Empirical factor replacement, even prior to imaging, is the initial therapy in cases of suspected central nervous system bleeding and is dosed to achieve factor levels of 100%. The role of surgical intervention is less clear. Prompt surgical decompression with or without laminectomy should be considered.15 However, surgery may be deferred in the presence of a stable neurologic exam with successful correction of the underlying coagulopathy.5,16

Kiehna and colleagues reviewed 24 cases of spontaneous epidural hemorrhage in children with hemophilia and found that prompt conservative treatment with FVIII and correction of coagulopathies was critical in patient outcomes. Aggressive medical management without surgery provided for full neurologic recovery in hemodynamically and neurologically stable patients.4 Importantly, these authors and other proponents of conservative management (under the appropriate circumstances) recommend a multidisciplinary approach to the treatment of these patients with a team consisting of a pediatric hematologist, neurosurgeon, and pediatric intensivist.8,16

A high index of suspicion for spinal hemorrhage and recognition of subtle neurologic signs of cord compression, which can be difficult in a nonverbal and nonambulatory child, are essential in order to obtain the correct imaging and make the diagnosis in a timely way.

Horner syndrome or oculosympathetic paresis is a classic neurologic syndrome whose signs include ptosis, miosis, and anhydrosis due to a lesion along the sympathetic pathway that supplies the head, eye, and neck. Children with new onset Horner syndrome and upper extremity weakness suggested cord compression from cervical spinal hemorrhage in this patient.

Patient outcome

The patient at age 6 years has no neurologic deficits and his general health is very good. His cognition and speech are excellent. He has had no further bleeding episodes. He recently transitioned from EHL FVIII product to a new prophylactic agent called emicizumab given subcutaneously once a week. ■

COMMENTS? E-mail them to cradwan@mjhlifesciences.com

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The death of a child is devastating for everyone involved, including families and medical professionals alike. It defies the natural order of life that we expect. When the death is sudden and unexpected, families are overwhelmed with trauma, shock, and grief as the medicolegal death investigation begins. Sudden unexplained death in childhood (SUDC) is the sudden and unexpected death of a child aged 12 months or older that remains unexplained after a thorough investigation including autopsy. According to the Centers for Disease Control and Prevention (CDC), SUDC affects approximately 400 children aged 1 to 18 years annually. The death investigation system in our country is variable, comprising coroner and medical examiner systems in most areas. It is faced with challenges that include a lack of resources, a shortage of forensic pathologists, and, until recently, lack of procedural guidance, particularly for pediatric deaths. The lack of standardization for death investigation has far-reaching implications, including the resultant effects on the family as well as public health ramifications. Without standardization, accurate surveillance of these deaths is elusive.

Education regarding the death investigation system is limited in our pediatric training curriculum and, consequently, pediatricians may have difficulty providing appropriate guidance to families in the aftermath of these deaths. In sudden unexpected deaths of children aged 12 months and older, there is the additional challenge of minimal awareness of this category of death. Although SUDC is the fifth-leading category of death in children aged 1 to 4 years, there is no targeted federal funding to support research. The SUDC Foundation (sudc.org) is the only organization whose mission is to promote awareness, advocate for research, and support those affected by the sudden loss of a child.

New consensus guidelines clarify the procedural guidance for investigation, certification, and reporting of sudden unexplained pediatric deaths to help medical professionals and families through these crises.

ERIN BOWEN, MD

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Groundbreaking guidelines issued for unexplained pediatric death

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EDITOR’S NOTE: Dr. Erin Bowen herself experienced the sudden unexpected death of a child—her 17-month-old son Conor—in 2016. In her family’s search for answers and support for their grief, she turned to the SUDC Foundation and found a mission. To read Dr. Bowen’s own story, go to ContemporaryPediatrics.com/pediatrics/kisses-conor
After the sudden and unexpected death of a child, there are a multitude of medical professionals who enter the families’ lives, including first responders, law enforcement, emergency department physicians, nurses, social workers, child protection agencies, and pediatricians. The family’s pediatrician is often the one professional who has a pre-existing relationship and who should serve as a liaison between professionals during this overwhelming time.

Professionals should maintain unbiased nonaccusatory communication to prevent further trauma.

Hospitals should establish trauma-informed protocols in conjunction with their local medicolegal death investigator.

When permitted by death investigation officials, families should have the opportunity to see and hold the child in supervised conditions. There have been studies showing that in situations wherein parents were unable to hold their child, there were heightened grief and trauma responses, with effects lasting for years afterward.2

Memorial keepsakes should be offered to families (handprints/footprints/lock of hair).

Open and timely communication with a single point of contact is recommended to foster positive long-term bereavement outcomes.

Offer a face-to-face meeting with the family within 2 weeks to assess for grief response and to address necessary mental health and medical screening and/or referrals. Maintain ongoing communication, recognizing that grief is not linear and the families’ needs may change over time.

Refer families to the SUDC Foundation early if there has been a sudden and unexpected death of a child. Even if the cause of death later becomes explained, the SUDC Foundation provides services to all families of unexpected deaths in childhood.

Be aware of the local medicolegal death investigation system and be prepared to provide the family with a realistic timeline and contact information.

Act as a liaison between the medicolegal death investigator and the family, providing updates and establishing a conference once the investigation is complete to assist with communication of the results.

Ensure adequate screening and support of siblings, who often are referred to as the “forgotten mourners” as they grieve the direct loss of their sibling and the indirect emotional loss of their parents to the grieving process. Screen siblings at annual physicals, as well as around possible trigger times, such as the anniversary of the death or their sibling’s birthday. Provide age-appropriate resources, including recommendations for books, strategies for parents on how to discuss death with their surviving child or children, referrals for sibling support groups, and, when necessary, mental health referrals.

Approach the care of siblings with sensitivity for the families’ unique needs, recognizing that parents may fear for the health of their surviving and subsequent children. Balance the need for providing compassionate care with not overmedicalizing these children.

Medical referrals for the siblings will vary, but may include cardiology, genetics, neurology, and others as clinically indicated. Cardiac referral is recommended for all first-degree relatives of sudden unexpected death, regardless of age. Genetic testing may be complicated by financial limitations of the medicolegal death investigation system and/or the family. In these circumstances, research opportunities may be beneficial for families to seek further answers.

Refer families for research opportunities such as the SUDC Registry and Research Collaborative (SUDCRRC), which provides a thorough case review by a multidisciplinary team, including neuroimaging, neuropathology, and whole exome sequencing of both biologic parents and the deceased child, at no charge to families: sudc.org/research-medical-info/sudc-registry-research-collaborative

Multidisciplinary case reviews of child fatalities should be utilized for public health research and advocacy.

Home visits should be considered to assess families’ needs and to facilitate support and provide them with resources.

Medical professionals should seek appropriate self-care.

Education of medical professionals should provide specific training around death communication.
How new guidelines will help

In recognition of the need for consistency in approaching sudden pediatric deaths, the SUDC Foundation funded a grant for a collaboration between the National Association of Medical Examiners (NAME) and the American Academy of Pediatrics (AAP). In January 2020, this expert panel of more than 30 multidisciplinary contributors from across the country published the first national consensus guidelines for sudden unexplained pediatric deaths: Unexplained Pediatric Deaths: Investigation, Certification and Family Needs. Available at sudpeds.com, the publication discusses the evolution of our understanding and practice in the area of pediatric death investigation; outlines procedural guidance for death investigation, autopsy, and ancillary testing as well as certification and reporting of these deaths; and promotes consistent classification of deaths in order to understand how often they occur.

There are also recommendations for prevention strategies and future research. Guidelines are provided for working with family members and other professional team members. The cornerstone of these guidelines is the provision of comprehensive and compassionate care, recognizing that the two are not mutually exclusive, but rather intimately connected for thorough investigations dedicated to high-quality care of survivors.

More research is needed

Currently, SUDC is unpredictable and unpreventable. For some families, the lack of explanation for their child’s death can be crippling. Although finding a cause does not mitigate their grief, in some cases it can allow them to better understand the death of their child and the implications for other family members. Pursuing appropriate medical screening may elucidate a cause for some of these deaths. However, we know that studies into the causes of sudden unexplained deaths in children aged older than 12 months are limited.

A recently published study from JAMA Network Open showed an increased rate of febrile seizures in these children. Similarly, the grief responses and needs of families after the death of older children have not been studied as extensively as infant death. With more research into these areas, we can build upon these guidelines to provide improved, data-driven approaches to the care for families affected by SUDC.

Although we may not be able to provide answers for all these deaths, we can ensure that we adequately support families after these tragedies and connect them with the appropriate resources. It is important to remember that your role as the child’s pediatrician does not end with their death.

In conclusion

Pediatric deaths are, thankfully, relatively rare. Consequently, pediatricians may feel ill equipped to manage the needs of bereaved families, particularly when these deaths are sudden and unexpected. Creating protocols that incorporate these new recommendations in conjunction with all the agencies and professionals involved can minimize confusion, prevent further trauma, and ensure optimal care for families during an already overwhelming and traumatic time.

COMMENTS? E-mail them to cradwan@mhliifesciences.com

For references, go to ContemporaryPediatrics.com/unexplained-pediatric-deaths-guidelines-2020
Four months ago, we all were aware there was a novel coronavirus causing an epidemic in the Wuhan region of China, but many experts expected it would be limited in scope and spread, not unlike the severe acute respiratory syndrome (SARS) epidemic and Middle East respiratory syndrome (MERS) outbreaks that occurred years ago.

And then COVID-19 began its march around the world, finally arriving on our shores on January 20th.1 We underestimated the tenacity of the virus and were caught without adequate supplies of personal protective equipment (PPE), had no antivirals with which to combat the virus, and had extremely limited testing capability. Clearly, our government and health care system were woefully ill prepared to deal with COVID-19.

Fast forward to mid-March. Advisories to “stay at home” were issued in a cascading fashion by state governors, and nonessential businesses were closed. Now, weeks later, pediatricians still are utilizing telehealth (TH) for ill and health-maintenance visits, seeing fewer patients in our offices, and dealing with the financial impact of the pandemic on our practices. As mitigation efforts begin to diminish novel coronavirus infections, we continue our efforts to care for our patients as well as ourselves.

Although we remain optimistic about eventually emerging from seclusion, the reality of the situation is that, at best, local communities will gradually relax restrictions, but some degree of social distancing will last for weeks if not months. During this time, we need to do our best to keep our practices open and accessible. We also need to plan ahead for accommodating patients in our offices once we start the recovery process.

Ultimately, I expect that our response to the novel coronavirus pandemic will be the development of a novel practice model that will allow our practices to survive adversity in the “here and now” and prosper once PPE, toilet paper, and hand sanitizer become plentiful once again.

Assume all patients and parents may be capable of transmitting the novel coronavirus. We know that patients can shed the virus days before they become symptomatic or while remaining asymptomatic carriers. Parents and patients should be screened for COVID-19 risk factors and children should be accompanied by one guardian. Your parking lot is now considered your waiting room. You call the parent in their vehicle when they are ready to be roomed.

Dr Schuman, section editor for Practice Improvement and Editorial Advisory Board member of Contemporary Pediatrics, is clinical assistant professor of Pediatrics, Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire. He also is CEO of Medgizmos.com, a medical technology review site for primary care physicians.
infectious disease

- Use services such as the Comprehensive Health and Decision Information System (CHADIS; Total Child Health Inc.; Baltimore, Maryland) so patients and parents can fill out the Modified Checklist for Autism in Toddlers (MCHAT), Parents Evaluation of Developmental Status (PEDS), the Ages and Stages Questionnaire (ASQ), the Patient Health Questionnaire (PHQ), and other forms online with automatic scoring to expedite well visits provided by TH.

- Increase daily visit volume by turning phone calls involving “advice” questions into TH visits for which patients and insurance companies get charged, and your practice generates revenue.

- It is probably prudent to consider utilizing full PPE for all patient visits and not just ill visits. If your PPE is in short supply, you can reuse PPE according to Centers for Disease Control and Prevention (CDC) guidelines (www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html) thoroughly following well visits and “extra thoroughly” following visits involving coughing or febrile patients. Although I have not seen official recommendations from the CDC, and understanding that the novel coronavirus is aerosolized following a cough or sneeze, I personally suggest that offices spray a room in which a febrile coughing child was seen with an air sanitizer such as Lysol Spray or similar product. Patients aged 2 years and older and parents should wear masks whenever possible.

- Take copays via credit card over the phone and try not to take cash. Although the novel coronavirus is unlikely to be spread by exchanging cash, it is a possibility that must be considered.

- Take the opportunity to renovate your medical home. Whereas some patients may seek TH care via urgent care facilities, largely because of ease of access, during the pandemic you are just as accessible as community clinics. You should call patients back following an acute illness to check on their status and to arrange follow-up visits when appropriate. Consider starting a newsletter for patients distributed electronically. Also, as you get more comfortable with TH, consider holding Zoom meetings for patients or parents with similar medical problems such as attention-deficit/hyperactivity disorder (ADHD), or just to address concerns regarding the pandemic.

- Be creative in arranging for immunizations via drive-through arrangements or administered in the office at nursing visits.

- Considering partnering with community mental health providers to provide TH mental health services.

- Encourage parents of newborns to purchase baby scales (or provide these by partnering with hospitals and other community resources). Using these

How to initiate telehealth visits

Pediatricians need to rapidly implement TH care of ill patients, directing them to emergency departments or to our offices for further evaluation and treatment. On April 15, 2020, the American Academy of Pediatrics (AAP) recommended that pediatricians conduct well visits via TH if in-office well visits were not otherwise feasible based on local circumstances.

There are dozens of TH platforms from which to choose and it is advisable to trial several before settling on your platform of choice. One of my favorite TH platforms is Doxy.me Pro (Rochester, New York). It costs $35 per provider per month for a high-resolution video TH service that is accessible via a web-based portal. With Doxy.me Pro, providers can quickly create an ad hoc video visit for a patient by sending a link to either a parent’s or patient’s email address or phone number. Clicking on the link directs the parent or patient into a waiting queue and the provider clicks on the name in the queue to start the video call.

Unlike competitors, Doxy.me Pro does not have an integrated scheduler, but one can simply utilize the scheduler integrated into your electronic health record (EHR) and notify parents of patients that they will be called at a specific time. If you’d like to use a HIPAA-compliant scheduler to complement Doxy.me, consider Cogsworth (Sydney, New South Wales, Australia), which costs as little as $39 per year. Android is already integrated.

Another TH tool that I recommend is the HIPAA-compliant Doximity Dialer Video application (Doximity; San Francisco, California) that is integrated into the Doximity application on IOS and Android phones. Although not promoted as a TH platform, the Doximity Dialer Video application provides users with a Business Associates Agreement (BAA) and encrypts data, so essentially it is a bare-bones TH application that allows physicians to initiate TH visits with patients with only a few clicks. Doximity Dialer Video visits are free, high quality, and very easy to use from the patient’s and provider’s perspective. Providers use the app to send a message containing a URL link to a parent’s or patient’s phone number. (You can mask the call, so the recipient “sees” the office phone number rather than your own). Patients simply click on the link and the video visit begins. —Andrew J. Schuman, MD
Considerations for the future

Patients are likely to remain “coronaphobic” for some time following the pandemic. There is uncertainty whether the novel coronavirus will become a seasonal event like the flu. This means that, like it or not, TH is now a routine part of your practice. Stockpile PPE once the supply shortage has been eliminated and safeguard the financial health of your practice by saving money and/or securing a line of credit from your local bank.

As patients get accustomed to paying for TH services, practice revenue will likely increase as an unintended consequence of the COVID-19 crisis. Pediatricians have campaigned to be reimbursed for phone calls (the earliest form of TH) for decades, and it has taken no less than a global pandemic to make reimbursement for these types of interactions possible.

Communicate with your state AAP chapter to see how it can support pediatric practices and patients. Now is the perfect opportunity to join with other like-minded pediatricians to campaign for health care reform. We need to reform the US Food and Drug Administration (FDA), pharmaceutical companies, and insurance companies if we are to ensure that Healthcare 2.0 will be the best it can be.

Please send suggestions for other ways practices can cope with COVID-19 to:
andrew.schuman@ymail.com

For reference, go to ContemporaryPediatrics.com/Covid19-battle-plan

Tips for prescribing (or not prescribing) antibiotics at telehealth visits

As I write this, I have been performing telehealth (TH) visits for ill children with regularity for 7 weeks and have prescribed surprisingly few antibiotics. Here are some helpful considerations regarding prescribing antibiotics at the conclusion of your TH visit with a patient.

The decision to prescribe antibiotics is straightforward in cases of conjunctivitis and impetigo. Obviously, there are many patients whose parents call regarding sore throats and ear pain. Given that most children are currently sheltering in place and are not in school, strep infections are infrequent unless another household member is a carrier or has a strep infection. Even without treatment, strep infections will resolve on their own.

Rheumatic heart disease, which is a sequela of untreated strep pharyngitis, is very rarely encountered in the United States. Whereas some pediatricians utilize the Centor Score for assessing the likelihood of a strep infection, there are many experts who find this tool of little use. In my own experience, exudate is a rare sign of strep infection (at least in my community) as is cough. A scarlet fever rash obviously makes a diagnosis of strep pharyngitis much more likely.

Regarding ear pain, consider having the patient perform a Valsalva maneuver, or blow into a whistle or a party horn depending on the age of the child. If there is fluid in the middle-ear space, this procedure will exert pressure on the tympanic membrane, causing pain. If fluid is absent or the patient has otitis externa, there will be no discomfort. Also, be aware of other signs of ear infection such as reduction in hearing acuity or purulent discharge from the ear associated with rupture of the tympanic membrane.

Cough with fever should make one suspicious of bacterial pneumonia, once novel coronavirus infection has been ruled out. It is reassuring to observe a child via a TH visit and see that the child is not showing signs of respiratory distress such as elevated respiratory rate, wheezing, retractions, and so on. Without the benefit of auscultation or a chest X-ray, I would err on the side of caution and consider antibiotics for a possible pneumonia in such cases. — Andrew J. Schuman, MD
The Centers for Disease Control and Prevention (CDC) has issued an official Health Advisory for Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19. The condition was first reported by clinicians in the United Kingdom on April 26, 2020. Kawasaki disease-like symptoms were reported in children who previously had been healthy. The children had tested positive for current or recent infection by SARS-CoV-2. They presented with persistent fever and a variety of symptoms including elevated inflammatory markers, multiorgan involvement, and hypotension. Not all cases had respiratory symptoms. Cases of MIS-C were reported to the New York City Department of Health and Mental Hygiene in early May, and as of May 12, 2020, there were 102 children identified. The current case definition for MIS-C is:

- A patient aged younger than 21 years who presents with fever, laboratory evidence of inflammation, and evidence of clinically severe illness that requires hospitalization along with multisystem organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic, or neurologic); and
- No alternative diagnoses that are plausible; and
- Testing positive for current or recent SARS-CoV-2 infection by reverse-transcriptase polymerase chain reaction, serologic assay, or antigen test, or the patient had exposure to a COVID-19 case within the 4 weeks prior to onset of symptoms.

The CDC says that clinicians who have cared for or are caring for patients aged younger than 21 years who meet the MIS-C criteria should report the suspected cases to local, state, or territorial health departments. Patients who meet full or partial criteria for Kawasaki disease also should be reported if they meet the case definition for MIS-C. In pediatric deaths with evidence of COVID-19, MIS-C should be considered.

Currently, it is unknown whether MIS-C is specific only to children after exposure to COVID-19 or if it also occurs in adults.

The CDC’s emergency announcement was distributed to state and local health officers, epidemiologists, laboratory directors, public information officers, and clinicians across its Health Alert Network.

**COMMENTS?** E-mail them to cradwan@mjhlifesciences.com

**CDC issues preliminary information on MIS-C**

The Centers for Disease Control and Prevention (CDC) has issued official guidance for Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19. **MIRANDA HESTER, EDITOR**

The Centers for Disease Control and Prevention (CDC) has issued an official Health Advisory for Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19. The condition was first reported by clinicians in the United Kingdom on April 26, 2020. Kawasaki disease-like symptoms were reported in children who previously had been healthy. The children had tested positive for current or recent infection by SARS-CoV-2. They presented with persistent fever and a variety of symptoms including elevated inflammatory markers, multiorgan involvement, and hypotension. Not all cases had respiratory symptoms. Cases of MIS-C were reported to the New York City Department of Health and Mental Hygiene in early May, and as of May 12, 2020, there were 102 children identified.

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**COMMENTS?** E-mail them to cradwan@mjhlifesciences.com

**For reference, go to**

ContemporaryPediatrics.com/CDC-health-advisory-MIS-C

**MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (MIS-C):**

A new wrinkle in COVID-19 infection

First described in the United Kingdom in late April and since reported in Spain, Italy, France, and here in the United States, “Multisystem Inflammatory Syndrome in Children (MIS-C)” has been confirmed/suspected in more than 200 children in at least 20 states, with 4 pediatric deaths reported. These serious infections mimic symptoms of Kawasaki disease and/or toxic shock syndrome and arise days after some children have experienced possible coronavirus exposure. Contemporary Pediatrics assembled a panel of experts in Infectious Disease for a webinar to discuss MIS-C and its ramifications for children.

The webinar is available on demand at ContemporaryPediatrics.com/MIS-C webinar

**YOU WILL LEARN:**

- What MIS-C is and how it may mimic some of the findings in Kawasaki disease and/or toxic shock syndrome.
- How to recognize and treat MIS-C.
- How MIS-C is potentially related to COVID-19.

Don’t miss this informative discussion with **Tina Q. Tan, MD**, Feinberg School of Medicine, Northwestern University, and Ann & Robert H. Lurie Children’s Hospital of Chicago, Illinois, and Editor-in-Chief of Contemporary Pediatrics; **Stanford T. Shulman, MD**, Feinberg School of Medicine, Northwestern University, and Ann & Robert H. Lurie Children’s Hospital of Chicago; and **Leonard R. Krilov, MD**, New York University (NYU) Winthrop University Hospital, Mineola, New York, and State University of New York (SUNY) Stony Brook School of Medicine, Stony Brook, New York.
Simpler test assesses neonates for opioid exposure

A simplified assessment could determine the need for medications to treat opioid withdrawal in neonates more quickly.

RACHAEL ZIMLICH, RN, BSN

Researchers have shortened the assessment tool used to determine pharmacologic treatment options for newborns exposed to opioids in the womb and say the changes could help increase the tool’s clinical utility.

In a study published recently in *JAMA Network Open*, researchers investigated whether the Finnegan Neonatal Abstinence Scoring Tool (FNAST), used to gauge signs of opioid exposure and withdrawal at birth, could be simplified.1

According to the report, medical and nonmedical opioid use have increased significantly, from 1.5 per 1000 live births in 1999 to 6.5 per 1000 live births in 2014. Exposure to opioids in the womb, from mothers with Opioid Use Disorder (OUD), resulted in a five-fold increase in babies born with problems from opioid exposure. These problems, labeled neonatal abstinence syndrome (NAS), are rooted in the passive maternal transfer of opioids during pregnancy, followed by withdrawal symptoms at birth when that transfer ends. It can be difficult to assess and therefore treat neonatal withdrawal as these infants can’t communicate their symptoms, and there is a wide variation in expressions of these symptoms. “Every neonate exposed to opioids in utero is somewhere along the continuum of withdrawal,” the report notes. “Although some neonates have mild signs and normal physiologic functions, others have more severe NAS that requires pharmacologic treatment to avoid major complications. Differences in the expression of NAS are associated with many factors, including the type of opioid exposure, co-exposure with other illicit drugs and/or psychotropic medications, genetic and epigenetic variability, the gestational age and sex of the neonate, breastfeeding, and parental engagement.”

For decades, observational assessments have been used to determine the severity of NAS and guide treatments with pharmacologic therapy. These observations are subjective, however, and variations between how different clinicians rate symptoms have been shown to result in significant differences in the initiation and duration of medications for NAS, the length of time required in the hospital, and health care utilization rates.

The FNAST is the most commonly used test for assessing infants with NAS. However, this 21-item assessment has some sections with 2 to 4 subcategories each, plus multiple scoring tools for those subcategories. Although complex and lengthy, the FNAST has shown reliability among various observers despite differences in observations. Several attempts have been made to condense the FNAST, but there have been limited data on the success of those attempts.

The goal of this study was to make the FNAST shorter and simpler by only focusing on withdrawal symptoms that required timely clinical intervention. The study team developed a set of questions to test their simplified FNAST, trialing the new tool in a cohort of 424 neonates born with opioid exposure. The infants in the study had a gestational age of at least 36 weeks and were followed from birth to hospital discharge. The team found that the simplified tool worked...
nearly as well as the original FNAST at discriminating between infants who did and did not receive treatment.

Lead study author Lori Devlin, DO, MHA, FAAP, associate professor of Pediatrics and director of the Neonatal Fellowship Program at the University of Louisville School of Medicine in Kentucky, says the simplified FNAST focuses on 8 measures instead of 21, highlighting those that highly correlate with the receipt of pharmacologic therapy.

“These items are dichotomized—present or absent—and able to discriminate between infants who receive pharmacologic therapy and those who do not almost as effectively as the original FNAST,” Devlin says. “This shorter and dichotomized assessment tool could simplify clinical assessment by focusing on components of the original FNAST that are relatively consistent across multiple sites. After prospective validation of the tool, it could be widely used and standardize the approach to neonates with NAS.”

Condensing the criteria
Specific changes made to the FNAST were the removal of convulsions, a high-pitched cry, and a hyperactive Moro reflex from the assessment. Convulsions were not observed in the study group, and the other 2 symptoms were determined to be too variable in nature. Two items dealing with tremors were combined into 1, and only 8 of the remaining 17 test items were independently associated with pharmacologic treatment.

The study team concluded that pharmacologic treatment for NAS may be able to be determined using just 8 criteria from the FNAST. Condensing this tool could allow for a more streamlined assessment of when a neonate needs pharmacologic therapy for NAS and enhance the clinical utility of the FNAST.

“The goal of our research was to determine if a simplified Finnegan Scoring Tool could discriminate the receipt of pharmacologic therapy as effectively as the original FNAST,” Devlin says.

As to whether Devlin and her team are advocating a change in clinical practice, she says it may be too soon.

“Our research focused specifically on the development of a simplified tool to assess for NAS,” she says. “We are not proposing changes in intervention or treatment protocols, as prospective clinical studies are needed to answer to such questions.”

A commentary that accompanied the study was in agreement, noting that there just isn’t enough data on the long-term effects of NAS and its treatments.2 Acknowledging the benefits of a shortened tool and the efforts of Devlin’s team, the commentators questioned whether limiting assessment categories could result in missing rare and complicated expressions of NAS.

“The simplicity of this tool is attractive. However, before it can be embraced in clinical care, several questions remain to be answered,” wrote Ju Lee Oei, MD, of the University of New South Wales in Kensington, Australia, and Trecia Wouldes, PHD, of the University of Auckland, New Zealand.

“The rare or uncommon items, such as seizures, were removed, but this may have limited the ability of the scale to detect severe but rare manifestations of withdrawal that require urgent treatment rather than continued observation,” the commentary notes.

Where the commentators did agree was with the researchers’ call for more study on NAS and assessment tools such as the FNAST. Devlin says her team is already working on additional studies. ■

RECENT FDA APPROVALS
Here’s a recap of several recent FDA drug approvals for children.

FDA approves toenail fungus treatment in kids
The US Food and Drug Administration (FDA) has approved efinaconazole topical solution, 10%, for children with toenail fungal infections.

ContemporaryPediatrics.com/ FDA-approval-for-efinaconazole

FDA approves drug for neurofibromatosis type 1
Pediatric patients aged 2 years and older now have an FDA-approved drug to treat plexiform neurofibroma, a rare tumor.

ContemporaryPediatrics.com/ FDA-approval-neurofibromatosis-type-1

3 drug labels updated for pediatric dosage
The National Institutes of Health has updated drug labels for doxycycline, clindamycin, and caffeine citrate for usage and dosage in infants and children.

ContemporaryPediatrics.com/ drug-label-changes-for-children
Asthma linked to later T1D diagnosis in children

A new study connects an asthma diagnosis to type 1 diabetes (T1D) development later in life but also shows that the opposite may not be true.

MIRANDA HESTER, EDITOR

Children who have asthma may be more likely to develop type 1 diabetes (T1D), according to a new report, but children with diabetes aren’t necessarily at a higher risk of developing asthma.

The study, published in *JAMA Network Open*, examined the association between asthma and diabetes using data from nearly 1.3 million children in Sweden. The goal of the study was to further research the long-debated association between atopic and autoimmune disease.

Asthma is the most common chronic disease in childhood, affecting about 11% of children aged 6 to 7 years worldwide. It has been linked in some studies to T1D—one of the most common autoimmune diseases in children. Why this association occurs is unclear, with studies suggesting a range of genetics, involvement of T cells, or environmental factors.

In evaluating the cohort for possible associations, the study team found that 9.5% had asthma and 0.3% had T1D at the onset of the study. The children with asthma had been diagnosed around age 3 years, and those with diabetes were diagnosed at about age 6 years. A small portion of the study group—just 494 children—were diagnosed with both asthma and T1D. These children accounted for 0.4% of all asthma cases and 13% of all T1D cases in the cohort, according to the report. Additionally, the report found nearly 900,000 siblings with similar disease prevalence.

A one-way relationship

As far as their relationship to one another, the research team found that asthma and T1D were positively associated at about age 6 years. A small portion of the study group—just 494 children—were diagnosed with both asthma and T1D. These children accounted for 0.4% of all asthma cases and 13% of all T1D cases in the cohort, according to the report. Additionally, the report found nearly 900,000 siblings with similar disease prevalence.

The report also revealed that full siblings with one disease were at an increased risk of developing the other, and there were similar trends—albeit at lower levels—among cousins. Although there was some link between the 2 diseases in both directions, the research team concluded that the order in which the diseases appeared was important. One theory for the association was that subsequent development of diabetes after an asthma diagnosis could be due in part to the use of inhaled corticosteroids during asthma treatment.

More research is needed to develop clinical guidelines based on the study. Yet the research team shares hope that the study will help clinicians understand the possible association between these 2 diseases.

“An understanding of the comorbidity could be beneficial in terms of avoiding diagnostic delay by recognizing symptoms of asthma that may otherwise be overlooked by caregivers and physicians in the more acute management of patients with T1D,” the study notes.

Previous studies have shown similar associations, including a Finnish report from 2018. That report also showed a relationship between the 2 diseases based on the sequence in which they developed.
Antioxidant-rich diet can reduce infection in kids with ALL

Children who have acute lymphoblastic leukemia (ALL) can significantly reduce their risk of infection by consuming a diet rich in fruits and vegetables.

MIRANDA HESTER, EDITOR

A diet packed with fruits and vegetables is a solid foundation for a healthy life. However, that same diet could prove even more beneficial to children and teenagers who have acute lymphoblastic leukemia (ALL), according to a new study in the Journal of Clinical Oncology.1

Investigators enrolled 794 children in a prospective clinical trial for the treatment of ALL. They used a food frequency questionnaire to examine the dietary intake of the participants. There were 614 completed dietary surveys at diagnosis and 561 completed surveys at the end of the trial.

Among the 513 children who provided a dietary survey at both diagnosis and the end of the study, 120 children had a bacterial infection at the induction phase and 87 had a bacterial infection in the postinduction phase. Twenty-two children had mucositis during the induction phase and 55 had mucositis in the postinduction phases. Researchers found that an increased intake of dietary antioxidants was linked to significantly lower rates of infection and mucositis. There was no association between supplementation and toxicity, relapse, or survival.

In a press release for the study, lead author Kara M. Kelly, MD, pediatric oncologist, the Waldemar J. Kaminski Endowed Chair of Pediatrics at Roswell Park, and chair of the Roswell Park Oishei Children's Cancer and Blood Disorders Program, Buffalo, New York, said: “This is the first study to suggest that a high-quality diet, rather than taking supplements, during ALL treatment may be beneficial in reducing these common toxicities.”

Kelly adds, “It really backs up what my research team has been promoting: that you can’t get these benefits by just taking a dietary supplement. There are protective components in whole foods that you don’t get when you take a supplement.”

“[Y]ou can’t get these benefits by just taking a dietary supplement. There are protective components in whole foods that you don’t get when you take a supplement.”

—KARA M. KELLY, MD

For reference, go to ContemporaryPediatrics.com/antioxidant-diet-for-ALL

COMMENTS?

E-mail them to cradwan@mjlifesciences.com

Antioxidant-rich diet can reduce infection in kids with ALL

Children who have acute lymphoblastic leukemia (ALL) can significantly reduce their risk of infection by consuming a diet rich in fruits and vegetables.
Previously, the perceived quality of health care had declined and had opened the door for a value-based care model. The “value” principle is derived from measuring health quality and outcomes against the cost of delivering the care. Quality of care is a composite of traditional treatment outcomes that includes patient quality of life, safety, prevention of emergency department (ED) visits, and hospital admissions.

In acknowledgment of the value of chronic disease management and the impact that it has on health care expenses and outcomes, the Centers for Medicare and Medicaid Services (CMS) had compromised to reimburse for chronic care management (CCM) services on a regular basis.

The Final Rule of the 2015 CMS Physician Fee Schedule included the new Current Procedural Terminology (CPT 99490) and is defined as (Table 1).1

This unique physician fee schedule service was created to pay separately for non-face-to-face care coordination services provided to patients with multiple chronic conditions. In early 2017, CMS revised the care planning element for Complex CCM adding CPT

TABLE 1 FINAL RULE OF THE 2015 CMS PHYSICIAN FEE SCHEDULE WITH NEW CURRENT PROCEDURAL TERMINOLOGY (CPT 99490) FOR CHRONIC CARE MANAGEMENT (CCM)

“Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements; multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.”

Abbreviation: CMS, Centers for Medicare and Medicaid Services.

From American Medical Association.1
peer-reviewed

TABLE 2 CHRONIC CARE MANAGEMENT (CCM) CPT CODE AND REIMBURSEMENT RATES

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
<th>INITIAL TIME</th>
<th>ADDITIONAL TIME</th>
<th>REIMBURSEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>99490</td>
<td>Establishing, implementing, revising, or monitoring a care plan by “clinical” staff member on Complex CCM (2 or more chronic conditions) and Non-Complex CCM (1 chronic condition).</td>
<td>20 min</td>
<td></td>
<td>$42/mo (RVUs=1.17)</td>
</tr>
<tr>
<td>99491</td>
<td>Establishing, implementing, revising, or monitoring a care plan by “clinical” staff member on Complex CCM.</td>
<td>30 min</td>
<td></td>
<td>$83/mo (RVUs=2.33)</td>
</tr>
<tr>
<td>G2058</td>
<td>Non-Complex CCM applies in conjunction with CPT 99490 Each additional 20 min</td>
<td></td>
<td></td>
<td>$37 (up to 2 charges/mo)</td>
</tr>
<tr>
<td>99487</td>
<td>Comprehensive care plan must be established or substantially revised on Complex decision-making patients</td>
<td>60 min</td>
<td>Each additional 20 min</td>
<td>$92 (RVUs=2.58)</td>
</tr>
<tr>
<td>99489</td>
<td>Applies in conjunction with CPT 99487</td>
<td>Each additional 30 min</td>
<td></td>
<td>$46 (RVUs=1.29)</td>
</tr>
<tr>
<td>G0506</td>
<td>Applies in conjunction with E/M code visit for CCM comprehensive care plan elaboration</td>
<td>Unspecified</td>
<td></td>
<td>$64</td>
</tr>
</tbody>
</table>

Abbreviations: CCM, chronic care management; CPT, Current Procedural Terminology; E/M, evaluation and management; HCPCS, Healthcare Common Procedure Coding System; RVUs, relative value units.

Centers for Medicare and Medicaid Services.13

codes 99487 and 99489. Both are available in the cases that require the establishment and implementation of a coordinated comprehensive care plan. In the same month, providers may bill for either CCM (99490) or Complex CCM (99487/99489) according to individual patient needs. Payment fee schedule of the above codes is primarily intended to reimburse for clinical staff time spent on CCM services, rather than physician time.

Effective January 1, 2020, CMS created an add-on code as well for Non-Complex CCM, Healthcare Common Procedure Coding System G2058, with the intent to incentivize private practitioners to embrace this type of management program.2

Care coordination
Care coordination has been defined as “the deliberate integration of patient care activities between 2 or more participants involved in a patient’s care to facilitate the appropriate delivery of health care services.”3

Tertiary medical centers have developed Pediatric Care Coordination or Complex Care Programs that provide individualized CCM where all medical decisions are family centered. These programs are practically unachievable without a strong primary care system.

Pediatric CCM programs are relatively inexpensive to operate compared with the overall cost of patient care. The most recent Florida Department of Health (DOH) data, where I do practice, revealed that from the 4.1 million children that live in our state, only 2% (~80,000) meet complexity criteria yet they utilize one-third of our pediatric annual budget (Figure).4 A similar expenditure percentage was published by Cohen and colleagues on a large retrospective study in Ontario, Canada.5

Traditional vs nontraditional health care outcomes
A CMS evaluation contractor, Mathematica, reported substantial expenditure reduction in acute care utilization of $74 per-beneficiary-per-month (PBPM) during an 18-month period surveillance on adults.6 In contradiction, recent evidence in 2 randomized trials on adult complex “super-utilizer” populations that were enrolled on an “intensive” outpatient monitoring registered no decline on readmission rates. However, an overwhelming “positive” patient experience—96% of the survey participants—was reported in one of the studies.7,8 No well-controlled studies have been
published in pediatric literature addressing treatment CCM outcomes despite that this subset of children accounts for approximately 25% of the total hospital days.9

Pediatric CCM programs focus as well on nontraditional quality-of-care markers such as family “fulfilling” experience and patient functionally. In very complex cases, implementing the “integrative” palliative care (IPC) mindset model of “being with” instead of “doing to” seems congruent.10 It is expected that our complex care pediatric practice will benefit as payment models move away from fee-for-service (FFS) to a risk-based model adjusted to each patient “hierarchical” condition category (HCC).

The current Medicare Physician Fee Schedule (MPFS) conversion factor is $36.0391 per relative value unit. Applying the national average MPFS values (actual payment varies by geographic location), payment for CCM services ranges from $42.17 for code 99490 to $92.98 for code 99487 (Table 2).11 A noteworthy example is that if 100 patients are enrolled to CCM services, an additional amount of $42,000 a year will be generated. Per CMS rules, billing practitioners cannot submit code 99491 in the same calendar month as CPT codes 99487, 99489, or 99490.

**Strategy to Implement CCM**

Understanding the regulatory elements is key to implementing an effective plan. All CCMs require compliance with the following (Table 3)12:

<table>
<thead>
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<th>TABLE 3</th>
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<tbody>
<tr>
<td><strong>WHICH PATIENTS ARE ELIGIBLE FOR CHRONIC CARE MANAGEMENT (CCM)?</strong></td>
</tr>
</tbody>
</table>

To be enrolled in a Complex CCM program, the child must meet the following required elements:

1. Multiple (2 or more) chronic conditions expected to last at least 12 months, or until the death of the patient.
2. Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.
3. Need a comprehensive care plan that requires moderate or high-complexity Medical Decision-Making (MDM).

To be enrolled in a Non-Complex CCM program, the child must meet the following required element:

- One chronic condition.2

From Centers for Medicare and Medicaid Services2; Simon TD, et al.12

1. Multiple (2 or more) chronic conditions expected to last at least 12 months, or until the death of the patient.
2. Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.
3. Needs a comprehensive care plan that requires moderate or high-complexity medical decision making (MDM).

The CMS maintains a Chronic Condition Warehouse with 27 chronic condition-defined categories, the great majority of them are compiled from adult morbidity data. No such statistics exist for the child-aged population. However, it is not an exclusive list to qualify for the CCM pediatric program.11

**ADVANCE PATIENT CONSENT**

In the event of an audit, documentation of a beneficiary consent is crucial. Oral consent to enroll is acceptable until a personal explanatory encounter is set, when the parent and/or patient should sign the appropriate written consent. Once the initial visit is completed, a comprehensive person-centered plan for CCM will be developed and shared with family and patient.

**ELIGIBLE PRACTITIONERS AND CLINICAL STAFF**

The CPT manual defines a “clinical staff member” as “a person who works under the supervision of a physician or other qualified health care professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service, but who does not individually report that professional service.” There are no specific credentialing requirements for staff personnel. They could be directly employed by the clinician or a contracted third party. The American Medical Association (AMA) has developed an online training module “Implementing Health Coaching” for physicians who want to incorporate health coaches into their practices.

The “incidence to” billing rules apply, and the clinician is not required to be on the premises providing direct supervision. The provider must have
accessibility 24 hours a day.

VALIDATED DOCUMENTATION
Any non–face-to-face care management and coordination service provided on behalf of an enrolled beneficiary by a provider or clinical staff member counts.

The following are acceptable documentation categories:
- Telephone calls/messages and emails with the family or patient.
- Laboratory and imaging reports.
- Medication reconciliation.
- Medication refills.
- Chart documentation.
- Remote monitoring of physiological data.
- Referring to and consulting with subspecialists.
- Post-hospitalization or emergency department (ED) follow-up contact.
- Home care plan elaboration, revision, and review with family and/or patient.

Our institution’s electronic medical record (EMR) team helped us to develop a Patient Outreach Navigator tool that enormously facilitates our staff to calculate the time spent and create an electronic descriptive report. In addition, we had used this instrument for Transition of Care Management (TCM) billing CPT codes 99495 and 99496 after hospital admissions or ED visits.

ELECTRONIC CARE PLAN
The following 3 requirements are necessary to submit a claim for CCM:
1. Using a certified EMR.
3. Ensuring beneficiary access to the care plan.

Our EMR offers worldwide interoperability allowing patients to view and share their electronic chart with any clinician worldwide using their mobile Internet devices (smartphone or tablet).

Our EMR Comprehensive Plan of Care includes:
1. A problem list with descriptive overview.
2. Planned interventions to address patient chronic health conditions.
3. Measurable goals and a time frame to achieve the goals.
4. Beneficiary’s agreement with the goals and plan.

MEDICAID VS PRIVATE INSURANCE
State Medicaid agencies and Medicaid Managed Care Organizations (MCOs) have the option of providing CCM as part of an enhanced benefit package. In our experience, CCM reimbursement on patients with commercial insurance is a challenge and it would be advisable to involve your institution’s billing department or, in rare cases, seek for advocacy from the American Academy of Pediatrics (AAP) coding resources.

Conclusion
The CMS had recognized that CCM is a critical component of primary care that promotes outstanding quality service, improves patient satisfaction, and reduces overall health care costs. For all these reasons, a distinctive non–face-to-face physician fee service was created to incentivize practitioners to adopt this type of management programs.

An effective CCM scope entails a timely and comprehensive exchange of the patient plan of care among the team. It is key to understanding the regulatory elements to implement an effective billing plan. Confidently, with the emergence of new clinician EMR navigator tools designed to capture and share information, pediatric outcome data will be available in the near future. At the end, fee-for-value will be accepted as the best model for lowering health care costs while increasing quality care resulting in healthier patients.

COMMENTS? E-mail them to cradwan@mjlifesciences.com

For references, go to ContemporaryPediatrics.com/ CCM-in-pediatric-practice

FIGURE DEMOGRAPHICS:
PEDIATRIC COMPLEX CARE IN FLORIDA, USA (2011-2012)

<table>
<thead>
<tr>
<th>COMPLEX</th>
<th>TOTAL</th>
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<tbody>
<tr>
<td>~2%</td>
<td>~30%</td>
</tr>
</tbody>
</table>

Pediatric Population ~4.1 million
Complex Care ~80,000 children

Budget Utilization

Adapted from Florida Health;2017:37^1
anomaly of that tissue.\textsuperscript{5}

The involvement of the arrector pili muscle is responsible for the characteristic “pseudo-Darier sign” in which the lesion becomes indurated or elevated upon stimulation of that muscle layer through stroking of the lesion.\textsuperscript{1,3-6} The patient may report a similar presentation when exposed to cold.\textsuperscript{3,5} The presence of this sign is suggestive of retained functional activity of the smooth muscle fibers and can distinguish SMH from similarly appearing lesions such as a congenital melanocytic nevus, potentially obviating the need for removal of this benign malformation.\textsuperscript{3} On histology, SMH appears as disseminated proliferation of smooth muscle cells in large, randomly oriented bundles usually located in the reticular dermis.\textsuperscript{3,5}

The prevalence of SMH has been estimated at between 1 in 1000 and 1 in 2700 live births, with a reported male predominance in its development.\textsuperscript{3,5} It often presents with hypertrichosis and/or hyperpigmentation, although these features tend to diminish with age.\textsuperscript{2,6}

Smooth muscle hamartoma usually presents as a solitary lesion, although it has occasionally been reported in a diffuse pattern associated with other complications as part of the Michelin tire baby syndrome (MTBS).\textsuperscript{3}

\section*{Differential diagnosis}

Smooth muscle hamartoma can be confused with congenital melanocytic nevus, which also can present as a raised lesion with hyperpigmentation and hypertrichosis, especially when the pseudo-Darier sign is absent.\textsuperscript{3} On dermoscopy, the patterns found in pigmented nevi are not present. Biopsy of the lesion should be performed prior to excision because selective congenital melanocytic nevi may need to be removed for their malignant potential whereas SMH is fully benign,\textsuperscript{2,5} and SMH is easily distinguishable from congenital melanocytic nevus on histopathology.\textsuperscript{3}

Smooth muscle hamartoma also can masquerade as Becker melanosis and have a similar clinical and histologic appearance to those lesions.\textsuperscript{1,3} Although hypertrichosis, hyperpigmentation, and smooth muscle proliferation are seen in both lesions, smooth muscle proliferation is dominant in SMH whereas Becker melanosis has more robust hypertrichosis and hyperpigmentation, which both tend to worsen with age unlike in SMH.\textsuperscript{1,3} The 2 lesions can be differentiated by long-term follow-up to see whether worsening or improvement in the hypertrichosis and hyperpigmentation occurs.\textsuperscript{1}

\section*{Treatment and management}

Patients with clinically ambiguous lesions should have an evaluation by a dermatologist, and some lesions may require a biopsy to make a specific diagnosis.\textsuperscript{1,3-4} Parents should be reassured that the SMH lesion is benign and does not require treatment. They also should be advised that any hypertrichosis or hyperpigmentation will improve over time.\textsuperscript{2,3} If cosmetic therapy is desired by the parents or patient, treatment can include laser therapy to reduce the burden of hypertrichosis and hyperpigmentation or surgical excision.\textsuperscript{3}

\section*{Patient outcome}

The patient’s parents were reassured that the finding was a common benign lesion and had no malignant potential. They were advised that the lesion would likely continue to grow proportionately with the child, that it could be removed if it became bothersome, and that routine monitoring would be sufficient for now.

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\section*{COMMENTS?} E-mail them to cradwar@mjhlifesciences.com

\section*{For references, go to ContemporaryPediatrics.com/dermcase-0620}
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Persistent birthmark grows on a toddler’s back

MICHELLE A RECTO, BA, MS4; JAMES P SENTER, MPH, MS4; BERNARD A COHEN, MD

The parents of a healthy 20-month-old boy ask for advice about a birthmark on his lower back (Figure 1). The lesion is asymptomatic and has grown proportionately with their son.

**Clinical findings**
The child is noted to have a soft, partially compressible, nontender, skin-colored smooth plaque measuring approximately 5.5 cm by 3 cm with overlying hypertrichosis extending from the midline lower lumbar back to the middle-right lower lumbar back. Upon stroking the lesion, it becomes more raised and indurated transiently (Figure 2). There are no other similar growths anywhere else on the body. An ultrasound performed at an outside hospital revealed no underlying spinal abnormalities.

**Etiology/Epidemiology**
Smooth muscle hamartoma (SMH) is an innocent cutaneous lesion that can be categorized into congenital or acquired types. The congenital form of SMH is generally sporadic, although a familial case has been described. Smooth muscle hamartoma is occasionally referred to as “arrector pili hamartoma” because the malformation arises from disorganized proliferation of the smooth muscle cells in the arrector pili muscle. The etiology of SMH is unclear, but it likely arises secondary to a developmental

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**FIGURE 1** A persistent atrophic, fibrotic plaque has been growing on a toddler’s lower back for 3 months.
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