PUZZLER Baby presents with fever and liver abnormalities

In the COVID-19 era, is that possible?

Safe return to school

Pediatric Pharmacology
What to recommend in hand sanitizers

Mental Health
Resistance training for adolescents

Respiratory Disorders
A double dose of flu vaccine is the ticket

Dermatology
A bully bullous rash in a toddler

Nutrition
The problems caused by picky eating

Contemporary Pediatrics.com

Contemporary PEDIATRICS

Expert Clinical Advice for Today’s Pediatrician

AUGUST 2020 VOL. 37 NO. 08

Safe return

Infectious Disease

EMVERM PROVIDES A 95% CURE RATE AGAINST PINWORM

PRESCRIBE WITH CONFIDENCE

• The AAP Red Book recommends mebendazole as one of the drugs of choice for pinworm infection
• Mebendazole has been prescribed by physicians for more than 40 years

EMVERM DOSING FOR PINWORM

• Patients should be prescribed 2 tablets. EMVERM can often cure pinworm symptoms in a single dose. However, a second course of treatment may be necessary after 3 weeks to prevent reinfection and to kill any worms that hatched after the first treatment
• Dosing is the same for adults and children
• One 100 mg tablet, for one day
  • Chewable, kid-friendly tablet can also be swallowed whole or crushed and mixed with food

AAP, American Academy of Pediatrics.

SELECT IMPORTANT SAFETY INFORMATION (continued)

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

Please see Brief Summary on pages 3-4. For Full Prescribing Information, visit EmvermHCP.com.

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).

DOSE 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></th>
<th>Pinworm (enterobiasis)</th>
<th>Whipworm (trichuriasis)</th>
<th>Roundworm (ascarasis)</th>
<th>Hookworm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</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>
</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 longer periods 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 emebendazole 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 6,276 subjects who participated in 39 clinical trials for treatment of single or mixed parasitic infections of the gastrointestinal tract. In these trials, the formulations, doses 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>Gastrointestinal Disorders</th>
<th>Gastrointestinal Disorders</th>
<th>Gastrointestinal Disorders</th>
<th>Gastrointestinal Disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Includes mebendazole formulations, dosages and treatment duration other than EMVERM® 100 mg tablet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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>Adverse Reaction(s)</th>
<th>Blood and Lymphatic System Disorders</th>
<th>Blood and Lymphatic System Disorders</th>
<th>Blood and Lymphatic System Disorders</th>
<th>Blood and Lymphatic System Disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Includes mebendazole formulations, dosages and treatment duration other than EMVERM® 100 mg chewable tablets</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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).

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 problems caused by picky eating

Nutrition

The safety of mebendazole was evaluated in 6,276 subjects who participated in 39 clinical trials for treatment of single or mixed parasitic infections of the gastrointestinal tract. In these trials, the formulations, doses and duration of mebendazole treatment varied. Adverse reactions 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 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 Embryofetal Risks
Unintreated 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 (1.6 to 3.9-fold the total daily MRHD, based on mg/m²). In a peri- and post-natal toxicity 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 breastfed 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 breastfed 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 4: Mean Cure Rates and Egg Reductions from Clinical Studies

<table>
<thead>
<tr>
<th></th>
<th>Pinworm (enterobiasis)</th>
<th>Whipworm (trichuriasis)</th>
<th>Roundworm (ascarisis)</th>
<th>Hookworm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure rates mean</td>
<td>95%</td>
<td>68%</td>
<td>96%</td>
<td>99%</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
Advise the patient to read the FDA-approved patient labeling (Patient Information).

Advisne patients that:
• Taking EMVERM® and metronidazole together may cause serious skin reactions and should be avoided.
• EMVERM® can be taken with or without food.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/newmedwatch, or call 1-800-FDA-1088. To report SUSPECTED ADVERSE REACTIONS contact Impax Laboratories, Inc. at 1-877-994-6729.

Please see Full Prescribing Information including Patient Information at www.emvermhcp.com.

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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

Moving into a new season, cautiously.

It has been an unprecedented 6 months for the US, and slowly, we are readying our children to return to normal, a strange new normal that we have never before seen.

We have dealt with, not only COVID-19, but an ancillary disease that has affected children from around the world: Multisystem Inflammatory Syndrome in Children (MIS-C). Earlier this summer, Contemporary Pediatrics held a successful and important webinar to discuss MIS-C. Armed with more information than ever, doctors and parents alike can now better assess and determine the best ways that our children can both finish out summer and prepare for the coming school year. As far as the latter is concerned, the school semester (as of this writing) is still somewhat of an unknown.

There is also still much unknown about how both COVID-19 and MIS-C will play out in the long run. The swell of warmer weather has not shown a drop in cases as originally hoped, and in fact, in many states, infection rates and hospitalizations continue to rise.

Nevertheless, there is room for optimism: from new drug therapies to a variety of clinical trials for vaccines, our medical communities are moving at warp speed to combat and bring these illnesses under control, hopefully forever. ■

Mike Hennessy, Sr.
Chairman and Founder
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in this issue

AUGUST 2020

Contemporary Pediatrics®

Miranda Hester, Editor

A double dose of influenza vaccine reduces burden

Two doses of flu vaccine reduce disease burden

A double dose of influenza vaccine might be best for children.

Miranda Hester, Editor

infectious disease

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This school year will be like no other, and to best prepare children (not to mention teachers, bus drivers, cafeteria workers and all those working within the school system) for a productive—and safe school year—here is what needs to be done.

Donna Hallas, PhD, PPCNP-BC, CPNP, PMHS, FAANP, FAAN; Regena Spratling, PHD, RN, APRN, CPNP, FAANP; Emily T Cupelli, DNP, CPNP, BCB-PMD

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Important information to know about young athletes and resistance training.

Miranda Hester, Editor

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One doctor’s takeaways from practicing televisits in the age of COVID.

Andrew J Schuman, MD

dermatology

33 Bully bullae in a toddler spreads across the body

A healthy 19-month-old boy presents with blisters on his arms and legs, now spread to his face.

Austin Burns, MS3; Bernard A Cohen, MD

in addition

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THE EDITORS ARE PLEASED TO ANNOUNCE the availability of our new parent company’s continuing education activities. We’ve picked this one especially for our Contemporary Pediatrics’ readers. Go to: https://bit.ly/3IhIoXK

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Bad news for SARS-CoV-2 and his pals.


Right now, SARS-CoV-2 is everyone’s top suspect, but respiratory bugs can cause similar, overlapping symptoms. Now you can test for 22 common respiratory pathogens, including SARS-CoV-2, with the BioFire® Respiratory 2.1 (RP2.1) Panel—now available under an FDA Emergency Use Authorization.*

Syndromic testing means all it takes is one test and just 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects. Rapid answers on a broad range of pathogens can inform patient management and alleviate patients and staff alike. What’s your frontline solution into respiratory season and beyond?

To learn more, visit biofiredx.com/Covid-19

*This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bb-3(b)(1), unless the authorization is terminated or revoked sooner.
As the COVID-19 pandemic continues to surge in many states around the United States and as the incidence of disease is significantly increasing in the 10- to 18-year-old population, the subject of whether schools will reopen in the fall for in-person learning is at the top of the minds of a multitude of people including parents, teachers, students, pediatricians, and public health officials. This is a decision that needs a lot of thought in order to ensure that the setting for in-person learning is as safe as it can be for students, teachers, custodians, lunch room workers, school crossing guards, and other personnel that work in the school setting. It is a decision that is not "one size fits all" but needs to be individually adapted to specific school settings. Even though many national organizations including the American Academy of Pediatrics (AAP), the Centers for Disease Control and Prevention (CDC), the National Education Association (NEA), and the National Academy of Sciences (NAS) support the reopening of schools for the many social and psychological benefits of in-person learning, these benefits must be balanced with the threat posed by COVID-19 and schools should not be forced, under any conditions, to reopen in an unsafe manner. One of the key factors that needs to be considered is the level of COVID-19 disease that is circulating in the community at the time that a school district plans to reopen, especially the amount of disease being seen in children 10 to 18 years of age. If these levels are high, it would be unwise to reopen schools at that time. For many school districts, e-learning will be what is rolled out at the beginning of the year. For others, a hybrid model of part in-person and part e-learning will be feasible. The model of all in-person learning will probably comprise a minority of school districts.

As we continue to address the emerging issues that have been impacted by COVID-19, I want to personally thank all of our pediatric healthcare provider heroes for providing the safest and most comprehensive care to our patients. As the actor Christopher Reeve stated, "A hero is an ordinary individual who finds the strength to preserve and endure in spite of overwhelming obstacles."

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

The articles focusing on Back to School include:

- "Safe Return to School" by Hallas and colleagues, which provide detailed guidance on different areas where protocols need to be developed and in place to ensure that the in-person learning environment is as safe as possible.

- The Pediatric Pharmacology article "Guidelines for the best hand sanitizers" dovetails nicely with the Safe Return to School articles as hand hygiene is critically important in any in-person learning protocol. The biggest obstacle will be the purchase of hand sanitizers, difficult to find in stores.

With warmest regards,
Tina Q. Tan,
Editor-in-Chief
Thick, Rich Derma Problem-Solvers

For samples, visit: www.summers-direct.com/samples
Using only intensive clinical examination for initial identification of early-onset sepsis (EOS) in late preterm and term neonates substantially decreases laboratory testing and antibiotic use with no adverse outcomes. These were the findings of investigators who analyzed the effect of such an approach at their California hospital during a 5-year period.

As part of this approach, late preterm and preterm neonates who appeared well at birth remained with their mothers, even when the infants had perinatal risk factors for EOS. Nurses provided all these babies with enhanced clinical monitoring, and a neonatal hospitalist performed the initial clinical assessment of infants born to mothers with chorioamnionitis. Early in the study period, such chorioamnionitis-exposed infants were admitted to the NICU, but later on these babies instead remained with their mothers for the entire hospitalization if they appeared well.

Antibiotic treatment was administered only if the treating physician decided it was appropriate because the neonate was clinically ill at birth or later developed clinical signs of illness that posed a risk of sepsis. In addition, neonates were not routinely screened using sepsis laboratory testing, and when such testing was performed it was only once antibiotic treatment was started.

Finally, routine evaluation for EOS did not include lumbar puncture for cerebrospinal fluid studies and culture. These tests generally were performed only in the presence of neurologic signs, such as mental status changes or seizures, at presentation or when the blood culture became positive.

Analysis of outcomes in 20,394 neonates ≥35 weeks’ gestation found that the percentage of neonates exposed to ampicillin decreased from 11.1% in the period before the clinical-examination approach was instituted to 4.1% during the intervention period. In addition, C-reactive protein testing declined from 15.3% to 6.3%. Overall, during an almost 5-year period, implementation of the clinical-examination approach reduced the use of antibiotics by 63% and sepsis laboratory testing by 59% (Frymoyer A, et al. J Pediatr. 2020. E pub ahead of print).

This paper is a potentially seminal article in my view. I was taught that at-risk newborns required work-ups and antibiotics, so this would be a drastic change.

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.
Melatonin helps children with ASD overcome insomnia

A nightly dose of pediatric prolonged-release melatonin (PedPRM) administered to children with autism spectrum disorder (ASD) moderated sleep disturbances, a trial in 80 children and adolescents from 2 to 17 years of age with ASD found. Participants had experienced at least 3 months of impaired sleep, defined as sleeping continuously for fewer than 6 hours or taking more than a half hour to fall asleep most nights. Before entering the study, all participants had tried standardized sleep hygiene and behavioral interventions.

The study comprised a 2-week placebo run-in followed by a randomized trial during which participants in the intervention group received a nightly dose of PedPRM (2 mg, 5 mg, or 10 mg) 30 to 60 minutes before bedtime for up to 104 weeks (most children were treated for 2 years). This was followed by a 2-week placebo period to assess withdrawal effects.

PedPRM was associated with improvements in participants’ sleep and caregiver satisfaction with their child’s sleep patterns, quality of sleep, and quality of life, benefits that were maintained throughout the treatment period, though they declined somewhat during the placebo phase. The most common treatment-related adverse events were fatigue (experienced by 6.3% of participants), somnolence (6.3%), and mood swings (4.2%). PedPRM was not associated with any detrimental effects on growth or pubertal development (Malow, BA et al. J Am Acad Child Adolesc Psychiatry. 2020. Epub ahead of print).

Melatonin has been a lifesaver for many parents, markedly improving quality of life, especially those whose children have developmental disabilities. Previously, at times I had been forced to use chloral hydrate. This study, while not exploring some possible side effects (e.g. lab abnormalities), does support that melatonin can be used safely, in high doses, for at least two years.

Smartphone apps for weight control? How to choose

Smartphone applications that address weight reduction have increased along with smartphone app use among pediatric patients. This led a team of pediatric practitioners to develop an evaluation tool (called Ped-WHAT) and rating system for these apps (16 currently are available), with the goal of health care providers a tool for assisting patients and their families in selecting apps that meet their needs and are based on scientific evidence. The Ped-WHAT tool evaluates apps based on whether they address 8 evidence-based behavior modification strategies that target weight management (such as self-monitoring, goal setting, and physical activity support) and 10 behavior strategies outlined by the American Academy of Pediatrics (such as eating 5 fruits and vegetables each day and getting 1 hour of daily physical activity). The team also developed a 5-star rating system to simplify interpretation of the evaluation criteria.

In addition, the team tested an educational in-service training session for practitioners, finding it significantly improved provider knowledge and confidence about using Ped-WHAT (Al-Lami N, et al. J Pediatr Health Care. 2020. Epub ahead of print).

Apps for weight loss are promising, but so far strong evidence that any of them are effective is lacking. This article does not evaluate apps per se, but does give the interested provider guidance in deciding whether a given app might be worth suggesting to a family.
A previously healthy 5-week-old former term newborn male presented to the emergency department with the chief complaint of fever ranging from 101-104°F for 2 days. He also had been fussy and not been eating well. The infant remained febrile despite his mother’s administration of Infant Tylenol every 4 hours at home. His mother denied any cough, rhinorrhea, bleeding or bruising, diarrhea, vomiting, and reported stool and urine had been normal.

Recent past medical history revealed the infant had been discharged 2 days ago after a 24-hour admission for observation following a linear skull fracture of the right parietal bone diagnosed by CT with no associated hemorrhage. These injuries were sustained after his mother fell on the stairs while carrying him. He had an additional prior admission at 9 days of age for fever which resolved after 48 hours of IV antibiotic therapy; no cause was determined as blood, urine and CSF cultures were all negative.

Family history revealed both parents have sensorineural hearing loss from nongenetic causes. The patient had received hepatitis B vaccine at birth. There was no other significant past medical history, family history or surgical history.

\[ \text{FIGURE 1 DIAGNOSIS: Hemophagocytic lymphohistiocytosis.} \]

A. Mild histiocytic hyperplasia in the bone marrow biopsy (20xHE). Bone marrow shows mild increase in clusters of histiocytes mixed with hematopoietic elements.

B. Hemophagocytosis highlighted by CD63 staining (40xIHC). Hemoglobin-haptoglobin scavenger receptor CD163 staining highlights histiocytic infiltration in the bone marrow biopsy. Few hemophagocytosis evident in mid-left of image.

C. Hemophagocytosis in bone marrow aspirate smear (60xWright-Giemsa stain). One histiocyte with engulfed erythroid cells and red blood cells is near center of image.

D. Bone marrow aspirate with positive staining for Epstein-Barr virus by in situ hybridization (20x).

\[ \text{CONTINUED ON PAGE 12} \]
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.

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- Point-of-care testing

- Less than 1 minute hands-on-time
- Accuracy comparable to laboratory testing methods

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Evaluation and testing
On exam, the patient was nursing and appeared fussy but consolable by his mother. Temperature was 102.5°F. Head circumference, weight and length were all in 80th percentile. Abdominal exam was somewhat difficult to perform but abdominal tenderness was suspected. There was tachycardia and palpable hepatosplenomegaly. The physical exam was otherwise within normal limits.

Laboratory evaluation showed transaminitis with ALT of 325 Units/L (normal 5-45 Units/L), AST of 393 Units/L (normal 20-60 Units/L), total bilirubin of 3.4 mg/dL (normal 0.2-1.3 mg/dL) with direct bilirubin of 0.7 mg/dL (normal 0.0-0.3 mg/dL), decreased albumin of 3.1 (normal 3.4-4.2 g/dL), and lactate dehydrogenase and D-dimer were significantly elevated at 2007 Units/L (normal 500-920 Units/L) and 15,099 ng/ml (normal 215-500 ng/ml) respectively. White blood cell count revealed pancytopenia with WBC count of 3.34x10^9/L (normal 7.7-13.7x10^9/L), RBC count of 2.65x10^6/μL (normal 3.0-4.3x10^6/μL), Hgb of 8.1 g/dL (normal 9.5-13.3 g/dL), platelet count of 56x10^9/L (normal 150-500x10^9/L). Differential count showed 22.1% neutrophils, 54.5% lymphocytes, 19.8% monocytes, 0.3% basophils, 0.3% eosinophils and 3% immature granulocytes. Reticulocyte count was mildly elevated at 5.43% (normal 0.90-3.80%). PT was elevated at 13.3 seconds (normal 9.6-12.5 seconds). Blood, urine and cerebrospinal fluid cultures were all negative. Triglycerides were normal at 118 mg/dL (normal 40-160 mg/dL), and all other labs were without significant abnormality. CXR was normal. Repeat head CT confirmed previously described skull fracture without intracranial hemorrhage. Abdominal ultrasound showed splenomegaly without hepatomegaly.

Pathophysiology Of HLH
Hemophagocytic lymphohistiocytosis (HLH) can be a primary disease driven by homozygosity or compound heterozygosity for verified HLH mutations, or a secondary disease occurring in the presence of chronic viral illness, autoimmune disease or lymphoma. Both forms are thought to require a triggering event involving either immune activation, most commonly Epstein-Barr infection, or an immune deficient state like human immunodeficiency virus infection. Regardless of the underlying etiology, HLH involves excessive activation of hyperplastic histiocytes resulting in excessive cytokine release. Additionally, there is often natural killer cell and cytotoxic lymphocyte abnormalities present, which result in decreased elimination of damaged or infected host cells. Elevated amounts of cytokines such as IL-6 result in characteristic fever as well as broad tissue damage and multiple organ failure. Though the liver and central nervous system are most often described as being involved, any organ system may be affected.

**Continued investigation over the next week included consultations from oncology and infectious disease services. Additional testing revealed elevated serum ferritin of 11,100 ng/mL (normal 14-647 ng/mL) and soluble CD-25 of 79,500 pg/mL (normal 0-1,033 pg/mL). Histopathology of a bone marrow biopsy revealed mild histiocytic hyperplasia with increase in histiocytes with occasional hemophagocytosis. Epstein Barr Virus was positive by in situ hybridization (Figure 1: Images A-D).**

**TABLE 1 DIFFERENTIAL DIAGNOSIS: FEVER, PANCYTOPENIA, LIVER ABNORMALITIES AND SPLENOMEGALY**

<table>
<thead>
<tr>
<th>Malignancy</th>
<th>Leukemia, Lymphoma, Solid tumors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral Infection</td>
<td>EBV, CMV, HIV</td>
</tr>
<tr>
<td>Rheumatologic</td>
<td>Systemic rheumatoid arthritis</td>
</tr>
</tbody>
</table>

Author created.

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**Hemophagocytic lymphohistiocytosis is a rare syndrome characterized by excessive immune activation.**
Clinical Presentation of HLH
The clinical presentation of hemophagocytic lymphocytosis is consistent with a hyperinflammatory or dysregulated immune state. Most commonly the patient is less than 18 months old and presents with fever > 101.3°F splenomegaly, and peripheral blood cytopenia with at least two of either hemoglobin <10g/dL, platelets <100,000 microliter or absolute neutrophils <1,000 microliter5. Further study typically reveals high ferritin levels as well as elevated CD255. There may also be hypofibrinogenemia and hypogammaglobulinemia5. Hemophagocytosis may be present in bone marrow, lymph nodes, liver and spleen, and reflects macrophages in a hyperactive state5. There may also be a late finding of hypertriglyceridemia after the disease has damaged the liver. As many as 30% of patients may present with a variety of neurological abnormalities such as mental status changes and encephalitis, seizures, hemiparesis, nuchal rigidity and ataxia reflective of central nervous system involvement6. Additionally, nonspecific findings in cerebrospinal fluid of increased protein and decreased glucose may be present in 50% of cases5. Fever and pancytopenia in the presence of either elevated liver function tests or central nervous system involvement and without other explanation should prompt consideration of HLH workup.

Differential Diagnosis
There are a number of conditions that may present in an infant with a clinical picture of persistent fever, pancytopenia, liver abnormalities and splenomegaly including malignancies, rheumatoid disorders, and infections like Epstein-Barr virus (EBV) (Table 1). The additional findings of hyperferritinemia, elevated CD25 and hemophagocytosis are extremely suggestive of HLH.

DIAGNOSIS OF HLH:
Diagnosis is based on fulfillment of 5 or more of 8 established criteria (Table 2) or on an HLH gene panel comprised of verified HLH mutations in cases where 5 criteria are not met. Additional findings that may support a diagnosis of HLH include spinal fluid pleocytosis with or without elevated spinal fluid protein and liver biopsy findings consistent with chronic persistent hepatitis by histology5. As swift initiation of treatment in cases of HLH is imperative for a good patient outcome, modified diagnostic criteria may also be used (Table 3) to determine if HLH treatment should be initiated5.

MANAGEMENT:
Treatment of HLH is guided by the HLH 2004 treatment protocol. Initial therapy consists of 8 weeks of chemoimmunotherapy consisting of etoposide, dexamethasone, and cyclosporine A. In cases with CNS involvement at diagnosis, systemic therapy alone should be employed. After 2 weeks of therapy if CNS symptoms have worsened or not improved (based on repeat MRI showing new, increased or unchanged CNS involvement such as increased parenchymal lesions, leptomeningeal enhancement or global edema, and repeat lumbar puncture with cerebrospinal fluid analysis showing increased pleocytosis or other abnormality associated with HLH) intrathecal meth-
As many as 30% of patients may present with neurological abnormalities such as mental status changes and encephalitis, seizures, hemiparesis, nuchal rigidity and ataxia reflective of central nervous system involvement.

Potrexate and prednisolone should be added. Severity of serum ferritin elevation prior to treatment may correlate directly with severity of disease and overall probability of mortality. In patients without familial disease or with negative genetic testing who achieve complete resolution after initial therapy, no further treatment is necessary although close follow-up is imperative; patients with HLH are at risk of recurrence or development of secondary hematologic malignancy such as leukemia or lymphoma. We recommend follow-up every 3 months to assess for new history of fever, lymph node enlargement and hepatosplenomegaly. Patients should be monitored for neurologic changes as well as hematologic abnormalities suggestive of malignancy (especially leukemia). Patients with positive genetic testing or otherwise known familial disease or unresolved disease after initial treatment should undergo a hematopoietic stem cell transplant (HSCT) as soon as possible. In such patients, HSCT may be curative.

**Patient Outcome**

Our patient was found to meet all 8 of the diagnostic criteria previously discussed and underwent 8-week induction therapy and HLH genetic screening. Gene testing showed him to be a compound heterozygote with two different mutations on opposite copies of the UNC13-D gene. Though he is currently in remission and doing well, because he has been determined to have familial HLH, he is currently on continuation therapy and with plans to undergo a HSCT very soon.

**Lessons for the clinician**

Hemophagocytic lymphohistiocytosis is a rare syndrome characterized by excessive immune activation. Typically considered a disease of infancy and childhood, the condition may be observed in males and females at any age. Most commonly, presentation includes febrile illness and multiorgan involvement especially of the liver and/or the central nervous system. The combination of persistent fever, pancytopenia, splenomegaly and liver function abnormalities should prompt thoughts of possible HLH diagnosis as early detection and treatment are imperative if there is to be a positive outcome for patients with HLH.

**TABLE 3 MODIFIED DIAGNOSTIC CRITERIA USED TO MAKE PRELIMINARY DIAGNOSIS OF HLH FOR INITIATION OF TREATMENT**

<table>
<thead>
<tr>
<th>ANY 3 OF FOLLOWING</th>
<th>PLUS ANY ONE OF FOLLOWING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>Hemophagocytosis</td>
</tr>
<tr>
<td>Splenomegaly</td>
<td>Elevated ferritin</td>
</tr>
<tr>
<td>Multiple cytopenias</td>
<td>Hypofibrinogenemia</td>
</tr>
<tr>
<td>Hepatitis</td>
<td>Absent or decreased natural killer cell activity</td>
</tr>
</tbody>
</table>

**COMMENTS?** E-mail them to llevine@mjlifesciences.com

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The authors have nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.
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Safe return to school: a call to action

On the topic of ‘return to school’ this year, anxiety abounds for parents and children, as well as teachers, school staff and nurses, nurse practitioners, departments of health and legislators.1 Since school is considered “the work of children,”2 we must carefully consider all aspects of ‘return to school’ in light of the current, unprecedented COVID-19 pandemic. Many compelling questions emerge, but first and foremost the question to address is: Can children return to school and be in classroom environments that assure health and well-being for all?

The National Parent Union conducted an online COVID-19 survey of 500 parents with children from kindergarten through 12th grade on May 4 and 5, 2020.1 Lowe’s data revealed a significant level of anxiety among parents concerning return to school for their children. A New York Times article reported that 6 of 10 parents are considering continuing with home learning rather than sending their children to school in Fall 2020.3 Some of the parental anxiety and decision making by parents may be attributed to uncertainty as the pandemic remains a viable threat throughout our country.

Planning, testing and masks are a critical component for safe return to school

Guidance from the CDC for opening schools was posted on the CDC website on March, 19, May 19, June 3, and July 23, 2020.4-6 The guidance emphasizes the importance of school officials and administrators collaborating with local health officials for decision making regarding return to school and decisions about closing schools, while the most recent statement did stress the importance of reopening schools. The initial interim CDC guidelines4-6 did not address two major issues, masks and testing, that must be resolved either locally, or nationally by implementation of best available scientifically based health safety measures prior to any child’s/adolescents return to school. However, the CDC guidance on July 23, 2020 does recommend masks for children and staff in school settings, except those under 2 years old, and those with some medical conditions. Since wearing masks has been met with controversy, the work of health care professionals (HCPs) is to gain the support of parents, children and school personnel to wear masks during school. And, while recommendations presented in this paper are consistent with CDC guidelines and supports wearing masks, it also provides more stringent considerations for testing school personnel and children. All HCPs realize the ever evolving and changing health care recommendations as the pandemic moves across the country and the world. Thus, what is considered best practice today based on the available evidence, may be shown to be incorrect tomorrow. Making reasonable changes to tackle the twists and turns that emerge every day in this pandemic is a major challenge. HCPs at the local, state, regional,
TEST. TRACK. TREAT. REPEAT.
TEST. TRACK. TREAT. REPEAT.
TEST. TRACK. TREAT. REPEAT.

Testing without TRACKING is not enough!

Bringing our lives back to “normal” begins with TESTING and TRACKING.

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RSV FIA
Strep A+ FIA
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and national levels have a major role in helping non-HCPs make sensible decisions based on scientific data to protect all individuals. Return to school decisions must be based on the science with the overall goal of the health and well-being of the children/adolescents, the school personnel and the community as a whole. One size and one decision will not fit all.

The CDC guidance on COVID-19 from July 23, 2020 supports using “cloth face coverings” to prevent the spread of the COVID-19 virus, and includes in their practical recommendations that schools put “cloth face coverings on school supply lists and provide cloth face coverings as needed to students, teachers, staff, or visitors who do not have them.”

Indeed, the scientific evidence from COVID-19 public health measures supports wearing masks as the new norm for all adults and for all children older than 2 years. Thus, we believe that wearing masks is an essential component of safe return to school. However, children with chronic illnesses, including pulmonary conditions, and those with disabilities may be advised by their physicians and NPs, not to wear face masks. Thus, some protection for children, who are too young to tolerate wearing a mask or are unable to wear masks, may be provided by other children and school personnel who can safely wear face masks in school settings.

The CDC guidance of July 23, 2020 also states that “[The CDC] does not currently recommend universal symptom screenings to be conducted by schools.” School nurse practitioners (NPs) and school nurses are educated on public health screening measures and are ideally suited to appropriately screen students and all school personnel prior to entering school for the purpose of preventing exposure of individuals with COVID-19 or any communicable disease symptoms from spreading the virus to contacts at the school. The value of having a school nurse for every school was supported by the AAP policy statement in June 2016. In this pandemic, the school nurse is an essential part of the healthcare team (e.g., private practice physicians, school based health centers, community clinics, and the department of health) overseeing the health of the children and school personnel and should be employed in every school (See Safe Return to School: Call to Action Part 2 online at contemporarypediatrics.com/safe-return-to-school-part-2.)

Another major concern identified in the original CDC guidance is the recommendation to close schools for 2 to 5 days when there is a confirmed case of COVID-19 in the school system. Opening and closing schools for 2 to 5 days will be disruptive to everyone. Testing prior to return to school may prevent schools from opening and closing in a chaotic fashion.

Plans to reopen schools must be based on local and state public health data as well as primary and secondary prevention strategies that minimize the potential for viral spread, and avoid a cycle of frequent opening and closing of school systems due to outbreaks of COVID-19. The authors believe that testing of students and school personnel prior to reopening schools is the cornerstone of primary and secondary prevention strategies.

When the pandemic began, data from other countries led healthcare providers (HCPs) to believe that children were less affected by COVID-19 but may be asymptomatic carriers. However, as the pandemic spread in the United States and Italy, there were reports of chronically ill children hospitalized with severe symptoms. The most troubling occurrence is the new presentation of the COVID-19 complication of the syndrome, Multisystem Inflammatory Syndrome in children (MIS-C). The etiology of MIS-C remains unclear. According to reports from the CDC, children who developed MIS-C may have been infected weeks before the appearance of MIS-C symptoms, and/or were symptomatic carriers.

Thus, based on these presentations of COVID-19 in children, testing strategies for children must be considered on all levels to protect all children, school personnel, and the communities in which they live. As of this writing, data for widely testing children for COVID-19 in the U.S. is non-existent.

Innovation is an outcome of a crisis. New, non-invasive methods for testing for COVID-19 in children should be developed. Saliva sample testing may be a reasonable solution that can be developed, and, as of this writing, is under investigation as a point-of-care test.

Once testing policies and methods are in place, only then can we proceed with developing other policies.
that address a safe school environment for children and adolescents, and all school personnel that work every day to educate and care for our children/adolescents.

Screenings are critical to safely reopen schools

Children have been out of school since March 2020 and may not have had their usual access to healthcare throughout this pandemic. Screenings to identify problems in physical, emotional, social, and behavioral health are a critical strategy for the design and implementation of effective strategies for healthy children. Thus, we encourage all HCPs, including school nurses, to assume a leadership role in the design and implementation of screenings for the identification of children and school personnel who may present with problems that may have arisen during stay-at-home orders (e.g., anxiety, school phobia, etc.).

Screening is a critical part of the process for prevention of transmission of COVID-19 within school systems. An innovative, reliable method for screening children and school personnel prior to going to school each day should be implemented. Some health care systems and other clinical practices have already implemented the use of a web-based application or ‘app’ that can be used to screen for temperature and emerging symptoms one-hour before reporting to work each day. This screening tool asks the individual how they are feeling and if they have any symptoms of COVID-19. The tool also asks if the individual has any recent contact with individuals who are known to have COVID-19.

Screenings are critical for the identification of children and school personnel who may present with problems that may have arisen during stay-at-home orders (e.g., anxiety, school phobia, etc.).
infectious disease

THE NEW NORM FOR CLEANING CLASSROOMS

- Equip rooms with disease-transmission reducing capabilities such as routine cleaning of ventilation ducts
- Consider installing air filter or purifier systems
- Classroom should be cleaned on a schedule, whenever students are in common spaces and/or outside of the classroom

BATHROOMS

Based on the literature and WHO recommendations we recommend the following:

- Children must sanitize hands upon arrival at school with either a hand sanitizer or soap and water, and frequently during the school day
- Parents or schools should either supply each child (based on age) with a personal hand sanitizer that is 60% alcohol based OR
- Schools should have hand sanitizer no-touch hand washing stations throughout the buildings
- Urinals should be replaced with separate toilets with touchless entry
- Children should have scheduled bathroom time at least 2-3 times during the school day, and more often in the younger grades
- In classrooms with young children that have a bathroom in the classroom, personnel who can monitor the use and cleanliness of the classroom is highly recommended
- Appropriate adult supervisions should be available at all time
- It is recommended that a registered professional nurse (RN) be present in every school for provision of care if there are associated concern
- The RN must have a private bathroom for use by children who might become ill at school, and appropriate staff for disinfection after each use
- Seat covers should be used on all toilets that close prior to flushing

Call to Action for Educational Equality

COVID-19 brought to the forefront nationwide educational inequality. As HCPs, we know the importance of being lifelong learners and the importance of early childhood education and continued excellence in education throughout the K through 12 years. It was distressful to hear many parents report that their children did not have access to computers, tablets, and Wi-Fi. Therefore, we encourage schools and parents to take proactive steps to ensure that all children have access to the tools and resources they need to succeed. This includes providing access to computers, tablets, and Wi-Fi, as well as ensuring that the classroom environment is safe and hygienic. By taking these actions, we can help to ensure that all children have the opportunity to succeed, regardless of their socioeconomic status.
and/or the internet at home to continue their education virtually. To achieve meaningful societal change, social justice and educational parity, we encourage educators, parents, and all community members to analyze the local educational needs and to plan accordingly to meet the needs of all students.

**Conclusion**

As Erik Erickson said, “School is the work of children.” We value the education our children receive throughout the US each year preparing the children to develop into healthy, kind, valuable, innovative and productive members of society in whatever careers and professions they choose. The immediate closing of schools at the onset of the COVID-19 pandemic has further enlightened everyone on the value of educators and the school systems. All HCPs want children to return to school safely and free of the threats of contracting COVID-19 within the school environment. Thus, our recommendations are based on the best available evidence as of this date and time. Screening, non-invasive testing, masks for all children over 2-years old, eye protection, social distancing, cleaning, transportation, and bathroom use are critical to the health and well-being of the children, all school personnel, their parents, family members and the community in which they live and grow.

For references and more tables, go to [ContemporaryPediatrics.com/Safe-return-to-school](https://www.contemporarypediatrics.com/Safe-return-to-school).

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**Survey shows primary care physicians not ready for next COVID-19 surge**

More than a third of respondents said they are not ready.

KEITH A. REYNOLDS

More than one third of primary care physicians in the United States are not ready for another wave of COVID-19, according to a survey.

The survey is the 15th part of a series by The Larry A. Green Center, the Primary Care Collaborative, and 3rd Conversation aimed at gauging how the COVID-19 pandemic has impacted primary care physicians. More than 30 percent of respondents said that their practices felt unready or spent from the demands of the pandemic, while more than 40 percent said they were not ready for another wave of the disease. Personal protective equipment (PPE) shortages continued to plague practices as 45 percent of respondents reported that they are were out of PPE, while 61 percent reported that they were reusing it, according to the survey.

“While new federal, state and health plan virtual health policies have helped primary care, these turned out to be necessary, but not sufficient support,” Ann Greiner, president and CEO of the Primary Care Collaborative, said in a news release. “Plus, more financial support from the Provider Relief Fund is needed as is testing and PPE. You can draw a straight line between lack of primary care support and bad patient outcomes, particularly for patients of color.”

Cash was also a factor in practice distress as less than 50 percent of respondents reported they had enough cash to stay open and one third said they had laid off or furloughed staff within the past four weeks. Compounding this issue, 53 percent of respondents said their patients were not scheduling well visits or chronic care visits, the survey says.

Primary care physicians’ stress, about 70 percent of respondents said they were not ready for reduced or terminated payment for audio and video visits which the Centers for Medicare & Medicaid Services (CMS) will terminate when the national emergency is declared over unless Congress intervenes, the survey said.

“Primary care is holding on by a thread as our country faces a surge in COVID-19 cases,” Christine Bechtel, patient advocate and co-founder of 3rd Conversation, says in the release. “Anyone—whether a policy maker, an insurer or patient—should be totally alarmed. This surge is a preview of what’s to come during the impending second wave, and this data tells us that we are in deep trouble. I don’t know how much longer we can shout at the wind, but I’ll say it again—health care is only going to get more expensive and less available from here on out, unless policy makers and insurers act fast to prevent even larger economic and health catastrophes resulting from the imminent collapse of primary care.”

This article originally appeared in our sister publication, *Medical Economics*. 
Vyvanse is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients ages 6 and above. Vyvanse is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Vyvanse for the treatment of obesity have not been established.

Vyvanse is proven to help treat pediatric patients (ages 6-17) with ADHD

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IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE
- CNS stimulants (amphetamines and methylphenidate-containing products), including Vyvanse, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

- Contraindications
  - Known hypersensitivity to amphetamines or other ingredients of Vyvanse. Anaphylactic reactions, Stevens-Johnson Syndrome, angioedema, and urticaria have occurred.
  - Use with monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.

- Warnings and Precautions
  - Prior to and during treatment assess for the presence of cardiac disease. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems. Sudden death, stroke and myocardial infarction have been reported in adults with CNS stimulants at recommended doses, as well as sudden death in children and adolescents with structural cardiac abnormalities and other serious heart problems while taking CNS stimulants at recommended doses. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias while taking Vyvanse.
  - CNS stimulants cause increases in blood pressure (mean increase about 2-4 mm Hg) and heart rate (mean increase about 3-6 bpm). Monitor all patients for tachycardia and hypertension.
  - Exacerbation of Pre-existing Psychosis: May exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. Induction of a Manic Episode in Patients with Bipolar Disorder: May induce a mixed/manic episode in patients with bipolar disorder. Prior to initiating treatment, screen for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms, or a family history of suicide, bipolar disorder, and depression). New Psychotic or Manic Symptoms: At recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients with no prior history of psychotic illness or mania. Discontinue if symptoms occur.
Study 301 Review Clinical Study

In a clinical study of children aged 6-12 years with ADHD, Vyvanse (lisdexamfetamine dimesylate) demonstrated a significant reduction in ADHD-RS-IV* total score1-3

**PRIMARY ENDPOINT:** Change from baseline to endpoint in ADHD-RS-IV total score1,2

Vyvanse provided a 56% average reduction in ADHD-RS-IV total score (from 43.9 to 19.5) for all doses combined vs a 14% average reduction for placebo (from 42.4 to 36.6); P<.0001 for Vyvanse versus placebo.1,3

**Study Design**

Randomized, double-blind, parallel-group, placebo-controlled, 4-week study with forced-dose escalation to assess the efficacy and safety of Vyvanse 30, 50, and 70 mg/day compared with placebo in 290 children aged 6-12 years with ADHD (as defined by DSM-IV-TR®).1,2

*ADHD-RS-IV=Attention-Deficit/Hyperactivity Disorder Rating Scale, Version IV, a validated investigator-rated measure that consists of 18 items designed to reflect symptomatology of ADHD based on DSM-IV-TR® criteria.

1Last post-randomization treatment week for which a valid ADHD-RS-IV total score was obtained.

2DSM-IV-TR®=Diagnostic and Statistical Manual of Mental Disorders, 4th ed, text revision.

**Adverse Reactions**

The most common adverse reactions (≥5% and at least twice the rate of placebo) reported in clinical trials were:

- **Children aged 6 to 12:** decreased appetite, insomnia, upper abdominal pain, irritability, vomiting, decreased weight, nausea, dry mouth, and dizziness;
- **Adolescents aged 13 to 17:** decreased appetite, insomnia, and decreased weight;
- **Adults:** decreased appetite, insomnia, dry mouth, diarrhea, nausea, anxiety, and anorexia.

**Pregnancy and Lactation**

Vyvanse may cause fetal harm. Breastfeeding is not recommended during Vyvanse treatment.

Please see Brief Summary of Full Prescribing Information, including Boxed WARNING regarding Potential for Abuse and Dependence, on following pages.
CONTRAINDICATIONS
VYVANSE is contraindicated in patients with:
• Known hypersensitivity to amphetamine products or other ingredients of VYVANSE. Anaphylactic reactions, Stevens-Johnson Syndrome, angioedema, and urticaria have been observed in postmarketing reports.
• Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.

WARNING: ABUSE AND DEPENDENCE
VYVANSE has a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

Serotonin Syndrome
Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Discontinue treatment with VYVANSE and any concomitant serotoninergic agents immediately if symptoms of serotonin syndrome occur, and initiate supportive symptomatic treatment. Concomitant use of VYVANSE with other serotoninergic drugs or CYP2D6 inhibitors should only be used if the potential benefit justifies the potential risk. If clinically warranted, consider initiating VYVANSE with lower doses, monitoring patients for the emergence of serotonin syndrome during drug initiation or titration, and informing patients of the increased risk for serotonin syndrome.

ADVERSE REACTIONS

Clinical Trial Experience
Based on data from 4-week parallel-group controlled clinical studies of VYVANSE in pediatric and adult patients with ADHD.

Adverse Reactions Associated with Discontinuation of Treatment
In the controlled trial in patients ages 6 to 12 years, 8% (18/218) of VYVANSE-treated patients discontinued due to adverse reactions compared to 1% (7/72) of placebo-treated patients. The most frequently reported adverse reactions leading to discontinuation (1% or more and twice rate of placebo) were ECG voltage criteria for ventricular hypertrophy, tic, vomiting, psychomotor hyperactivity, insomnia, decreased appetite and rash [2 instances for each adverse reaction, i.e., 2/218 (1%)].

In the controlled trial in patients ages 13 to 17 years, 3% (7/233) of VYVANSE-treated patients discontinued due to adverse reactions compared to 1% (7/77) of placebo-treated patients. Most frequent adverse reactions leading to discontinuation were irritability (3/233; 1%), decreased appetite (2/233; 1%), and insomnia (2/233; 1%).

In the controlled adult trial, 6% (21/358) of VYVANSE-treated patients discontinued due to adverse reactions compared to 2% (1/62) of placebo-treated patients. The most frequently reported adverse reactions leading to discontinuation (1% or more and twice rate of placebo) were insomnia (8/358; 2%), tachycardia (3/358; 1%), irritability (2/358; 1%), hypertension (4/358; 1%), headache (2/358; 1%), anxiety (2/358; 1%), and dyspnea (3/358; 1%).

Adverse Reactions Occurring at an Incidence of ≥5% or More Among VYVANSE-Treated Patients with ADHD in Clinical Trials
Most common adverse reactions (incidence ≥5%) and at a rate at least twice placebo reported in children, adolescents, and/or adults were anorexia, anxiety, decreased appetite, decreased weight, diarrhea, dizziness, dry mouth, irritability, insomnia, nausea, upper abdominal pain, and vomiting.

Adverse Reactions Occurring at an Incidence of 2% or More
Adverse reactions reported in the controlled trials in pediatric patients ages 6 to 12 years, adolescent patients ages 13 to 17 years, and adult patients treated with VYVANSE or placebo:

Adverse Reactions Reported by ≥2% of Children (Ages 6 to 12 Years) with ADHD Taking VYVANSE and at Least Twice the Incidence in Patients Taking Placebo - VYVANSE (n=218), Placebo (n=72):
Decreased Appetite (39%, 4%), Insomnia (22%, 3%), Abdominal Pain Upper (12%, 6%), Irritability (10%, 0%), Vomiting (9%, 4%), Weight Decreased (9%, 1%), Nausea (6%, 3%), Dry Mouth (5%, 0%), Dizziness (5%, 0%), Affect lability (3%, 0%), Rash (3%, 0%), Pyrexia (2%, 1%), Somnolence (2%, 1%), Tic (2%, 0%), Anxiety (2%, 0%), Anorexia (2%, 0%).

Adverse Reactions Reported by ≥2% of Adolescent (Ages 13 to 17 Years) Patients with ADHD Taking VYVANSE and at Least Twice the Incidence in Patients Taking Placebo - VYVANSE (n=233), Placebo (n=77):
Decreased Appetite (34%, 3%), Insomnia (13%, 4%), Weight Decreased (9%, 0%), Dry Mouth (4%, 1%), Palpitations (2%, 1%), Anorexia (2%, 0%), Tremor (2%, 0%).

Adverse Reactions Reported by ≥2% of Adult Patients with ADHD Taking VYVANSE and at Least Twice the Incidence in Patients Taking Placebo - VYVANSE (n=358), Placebo (n=62):
Decreased Appetite (27%, 2%), Insomnia (27%, 8%), Dry Mouth (26%, 3%), Diarrhea (7%, 0%), Nausea (7%, 0%), Anxiety (6%, 0%), Anorexia (5%, 0%),
Feeling Jittery (4%, 0%), Agitation (3%, 0%), Increased Blood Pressure (3%, 0%), Hyperhidrosis (3%, 0%), Restlessness (3%, 0%), Decreased Weight (3%, 0%), Dyspnea (2%, 0%), Increased Heart Rate (2%, 0%), Tremor (2%, 0%), Palpitations (2%, 0%).

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

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

DRUG INTERACTIONS

Clincially Important Interactions with Amphetamines

MAO Inhibitors (MAOI)

Clinical Impact: MAOI antidepressants slow amphetamine metabolism, increasing amphetamines effect on the release of norepinephrine and other monoamines from adrenergic nerve endings causing headaches and other signs of hypertensive crisis. Toxic neurological effects and malignant hyperpyrexia can occur, sometimes with fatal results.

Intervention: Do not administer VYVANSE during or within 14 days following the administration of MAOI [see Contraindications]

Examples: selegiline, isocarboxazid, phenelzine, tranylcypromine

Serotonergc Drugs

Clinical Impact: The concomitant use of VYVANSE and serotonergic drugs increases the risk of serotonin syndrome.

Intervention: Initiate with lower doses and monitor patients for signs and symptoms of serotonin syndrome, particularly during VYVANSE initiation or dosage increase. If serotonin syndrome occurs, discontinue VYVANSE and the concomitant serotonergic drug(s) [see Warnings and Precautions].

Examples: selective serotonin reuptake inhibitors (SSRI), serotonin norepinephrine reuptake inhibitors (SNRI), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John’s Wort

CYP2D6 Inhibitors

Clinical Impact: The concomitant use of VYVANSE and CYP2D6 inhibitors may increase the exposure of dextroamphetamine, the active metabolite of VYVANSE compared to the use of the drug alone and increase the risk of serotonin syndrome.

Intervention: Initiate with lower doses and monitor patients for signs and symptoms of serotonin syndrome particularly during VYVANSE initiation and after a dosage increase. If serotonin syndrome occurs, discontinue VYVANSE and the CYP2D6 inhibitor [see Warnings and Precautions and Overdosage].

Examples: paroxetine and fluoxetine (also serotonergic drugs), quinidine, ritonavir.

Alkalizing Agents

Clinical Impact: Urinary alkalizing agents can increase blood levels and potentiate the action of amphetamine.

Intervention: Co-administration of VYVANSE and urinary alkalizing agents should be avoided.

Examples: Urinary alkalizing agents (e.g. acetazolamide, some thiazides).

Acidifying Agents

Clinical Impact: Urinary acidifying agents can lower blood levels and efficacy of amphetamines.

Intervention: Increase dose based on clinical response.

Examples: Urinary acidifying agents (e.g., ammonium chloride, sodium acid phosphate, methamphetamine salts).

Tricyclic Antidepressant

Clinical Impact: May enhance the activity of tricyclic or sympathomimetic agents causing stricking and sustained increases in the concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated.

Intervention: Monitor frequently and adjust or use alternative therapy based on clinical response.

Examples: desipramine, protriptyline

Drugs Having No Clinically Important Interactions with VYVANSE

From a pharmacokinetic perspective, no dose adjustment of VYVANSE is necessary when VYVANSE is co-administered with guanfacine, venlafaxine, or omeprazole. In addition, no dose adjustment of guanfacine or venlafaxine is needed when VYVANSE is co-administered.

From a pharmacokinetic perspective, no dose adjustment for drugs that are substrates of CYP1A2 (e.g. theophylline, duloxetine, melatonin), CYP2D6 (e.g. atomoxetine, desipramine, venlafaxine), CYP2C19 (e.g. omeprazole, lanosprazole, clobazam), and CYP3A4 (e.g. midazolam, pimozide, simvastatin) is necessary when VYVANSE is co-administered.

USE IN SPECIFIC POPULATIONS

The limited available data from published literature and postmarketing reports on use of VYVANSE in pregnant women are not sufficient to inform a drug-associated risk for major birth defects and miscarriage. Adverse pregnancy outcomes, including premature delivery and low birth weight, have been seen in infants born to mothers dependent on amphetamines. Monitor infants born to mothers taking amphetamines for symptoms of withdrawal such as feeding difficulties, irritability, agitation, and excessive drowsiness.

Lactation

Lisdexamfetamine is a pro-drug of dextroamphetamine. Based on limited case reports in published literature, amphetamine (d-or l-) is present in human milk, at relative infant doses of 2% to 13.8% of the maternal weight-adjusted dosage and a plasma: milk ratio of about 0.8-1.5. There are no reports of adverse effects on the breastfed infant. Long-term neurodevelopmental effects on infants from amphetamine exposure are unknown. It is possible that large doses of dextroamphetamine might interfere with milk production, especially in women whose lactation is not well established. Because of the potential for serious adverse reactions in nursing infants, including serious cardiovascular reactions, blood pressure and heart rate increase, suppression of growth, and peripheral vasoconstriction, advise patients that breastfeeding is not recommended during treatment with VYVANSE.

Pediatric Use

Safety and efficacy in pediatric patients below the age of 6 years have not been established.

Geriatric Use

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

Renal Impairment

Due to reduced clearance in patients with severe renal impairment (GFR 15 to <30 mL/min/1.73 m²), the maximum dose should not exceed 50 mg/day. The maximum recommended dose in ESRD (GFR <15 mL/min/1.73 m²) patients is 30 mg/day.

Lisdexamfetamine and d-amphetamine are not dialyzable.

Gender

No dosage adjustment of VYVANSE is necessary on the basis of gender.

DRUG ABUSE AND DEPENDENCE

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

OVERDOSAGE

Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice for treatment of overdose. Individual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses. Manifestations of amphetamine overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, convulsions, hallucinations, panic states, hyperpyrexia, and rhabdomyolysis. Serotonin syndrome has been reported with amphetamine use, including VYVANSE. Fatigue and depression usually follow the central nervous system stimulation. Other reactions include arrhythmias, hypertension or hypotension, circulatory collapse, nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

Lisdexamfetamine and d-amphetamine are not dialyzable.

Manufactured for: Shire US Inc., Lexington, MA 02421 Made in USA
For more information call 1-800-828-2088

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US Pat No. 7,105,486, 7,223,735, 7,655,630, 7,659,253, 7,659,254, 7,662,787, 7,662,788, 7,671,030, 7,671,031, 7,674,774, 7,678,770, 7,678,771, 7,687,466, 7,687,467, 7,713,936, 7,718,619, 7,723,305

Last Modified: 01/2018 US-LIS-0317v1.0 06/20
Early in the COVID-19 pandemic, the US supply chain was stretched thin on many necessary products, including hand sanitizer. In response to this shortage, many health systems, manufacturers, and non-traditional institutions (e.g., distilleries) sought to compound hand sanitizer to meet this need. To ensure safe compounding practices, in March 2020 the Food and Drug Administration (FDA) released guidance for the temporary compounding of certain alcohol-based hand sanitizer products during the public health emergency.1 In addition, the United States Pharmacopeia (USP) provided recommendations on compounding alcohol-based hand sanitizer during the COVID-19 pandemic.2 These guidance documents provided recommendations regarding ingredients, facilities, and labeling in accordance with the World Health Organization’s (WHO) recommended recipe.3 These documents support the use of two formulas that result in either an ethanol antiseptic topical solution containing ethanol 80% (v/v) or an isopropyl alcohol antiseptic topical solution with a final concentration of 75% (v/v).1,2,3 According to the USP guidance, compounded hand sanitizers have a beyond use date of 30 days which is significantly shorter than commercially available products.2 The FDA does not recommend the public manufacture their own hand sanitizers due to risk for poor efficacy if made incorrectly and reports of skin burns.4 The hand sanitizer should be labeled with the alcohol percentage and can be stored at controlled room temperature.1

The CDC recommends using alcohol-based hand sanitizer only when soap and water are unavailable. Therefore, it is crucial that the final concentration of hand sanitizer is at least 60% alcohol (ethanol or isopropyl alcohol) to avoid getting sick and spreading germs to others.5 Hand sanitizer should be used by covering all hand surfaces and rubbing one’s hands together, for approximately 20 seconds, or until they feel dry.6 Soap and water should be used whenever possible and always during food preparation, wound care, using the restroom, or caring for pets.6

Hand sanitizer, when used by children, must be under the direct supervision of adults to prevent accidental ingestion.5

**NOTE FROM DR LEE:** Numerous brands and types of hand sanitizers have emerged in the marketplace and they are NOT regulated by the FDA. It is extremely important to review all contents and their concentration to assure its effectiveness and safe use. The CDC and FDA are excellent resources for updated information for hand sanitizers.

—Carlton Lee, PHARMD, MPH, FASHP, FPPAG
Impact of picky eating in early childhood

Picky eating is an all-too-common hallmark of childhood. A new investigation looks at the impact of picky eating. MIRANDA HESTER, EDITOR

Picky eating is common in children and may be a source of anxiety for parents. An investigation in Pediatrics examines how picky eating habits can impact a child’s life.¹

The investigators looked at 317 low-income mother-child pairs who provided anthropometry and reported picky eating behavior and maternal feeding behaviors. The mothers completed a questionnaire when the child was aged 4, 5, 6, 8, and 9 years. Mothers were asked about demographics and child emotional regulation.

There were 3 different picky eating trajectories: persistently high, persistently medium, and persistently low. Children in the high picky-eating trajectory were at risk of higher child emotion lability and lower child emotional regulation. Overall picky eating was linked with low restriction in the low picky eating trajectory and high demandingness in the high picky eating trajectory. Medium and high picky eating trajectories were linked with lower body mass index (BMI) z scores. Researchers concluded picky eating is traitlike during childhood and highly picky children could be protected against higher BMI z scores, but further research is needed.

COMMENTS? E-mail them to llevine@mjhiflsciences.com

For references, go to ContemporaryPediatrics.com/view/impact-picky-eating-early-childhood

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Jill Overcash MD
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RESPIRATORY DISORDERS

2 doses of flu vaccine reduce disease burden

Every flu season, many children get the flu vaccine. The yearly recommendations for the vaccine state that children should receive 2 doses during their first vaccination season. A new study in *JAMA Pediatrics* looks at whether improving adherence to the initial 2-dose series could reduce the burden of influenza in young children, one of the most vulnerable populations for the disease.¹

Investigators conducted this test-negative case-control study in outpatient clinics and emergency departments during the 4 influenza seasons from 2014-2015 through 2017-2018. Children were aged 6 months to 8 years and presented to outpatient care within 7 days of onset of acute respiratory tract illness with cough. Each child was tested with real-time, reverse-transcriptase polymerase chain reaction (PCR) for influenza.

The sample included 7533 children. In the enrollment season, 3912 children were unvaccinated; 2924 children were fully vaccinated; and 697 were partially vaccinated.

The adjusted vaccine effectiveness against any influenza was 51% in fully vaccinated children and 41% in partially vaccinated children. Among the 1519 vaccine-naive children aged 6 months to 2 years, the vaccine effectiveness for 2 doses in the enrollment season was 53% and 23% for 1 dose. Children who had 2 doses were found to be less likely to test positive for influenza compared with children who only had 1 dose.

The researchers concluded that children who received the recommended number of doses, which was consistent with current vaccine policy, saw higher vaccine effectiveness than children who only received partial vaccination in all 4 influenza seasons studied.

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

**REFERENCES**

AAP addresses resistance training

Many young athletes are interested in resistance training, and a policy statement update from the American Academy of Pediatrics (AAP) addresses how they can safely participate.

MIRANDA HESTER, EDITOR

For many young athletes and children who are interested in physical fitness, resistance training has become increasingly popular over the years, and many parents want to ensure that their child is engaging in a safe program. The American Academy of Pediatrics has updated its 2008 policy statement on resistance training for children and adolescents.1

The revised policy statement highlights that some children may require additional consultation before starting resistance training, such as children with poorly controlled hypertension or seizure disorders. Children who had cancer treated by anthracycline chemotherapy should be cautious when starting training because they are at increased risk of cardiotoxicity and acute congestive heart failure during resistance training. Children with pulmonary hypertension, Marfan syndrome, and hypertrophic cardiomyopathy should be counseled against resistance training.

The policy statement also offers the following recommendations:

1. When children with complex congenital cardiac diseases come in for consultation, a pediatric cardiologist should be consulted to give guidance on safety and any possible modifications.
2. Resistance training should be added to aerobic training and other skill-related fitness components in order to form a comprehensive fitness program.
3. Recommend basic resistance exercises over a more aerobic fitness program for children and adolescents who are overweight or obese.
4. Make sure that children and adolescents are using dynamic warm-up exercises and less intense stretching in the cool down.
5. Discuss and encourage adequate fluid intake and proper nutrition.
6. Assess the resistance training regimen and give feedback to minimize the risks from resistance training.
7. Ensure that all major muscle groups are used in the resistance training. For children and adolescents who have sport-specific goals, additional exercises can be added to complement the initial training regimen.
8. Count resistance training as part of the total training program and monitor the amount of time spent to reduce the risk of overuse injuries.
9. Evaluate any sign of injury or overuse before allowing the child or adolescent to resume the exercise program.
10. Weightlifting exercises can be incorporated under the direction of a qualified professional.
11. Discuss the risks of performance-enhancing substances as well as anabolic steroids.
12. Make sure the resistance training is overseen by professionals who are qualified, trained, and aware of the unique aspects of children and adolescents.

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

For references, go to ContemporaryPediatrics.com/view/aap-addresses-resistance-training
COVID-19: Keep Smiling!

This article is dedicated to recently retired Catherine Radwan, who had been the managing editor of Contemporary Pediatrics for the last decade. She will be missed by this author, our readers, and the Contemporary Pediatrics staff. She always made us smile! ANDREW J SCHUMAN, MD

For patients, parents and pediatricians,
the COVID-19 pandemic has been a surreal experience. In March of this year our society changed abruptly. Families were advised to stay home, and pediatricians quickly altered their practices to help safeguard staff and patients.

For over two months I’ve been practicing telehealth exclusively at home. I did so with the support of my partners, as I have risk factors which predispose me to more severe consequences from SARS-CoV-2 infection. Just recently, I emerged from seclusion, fearful, but eager to return to office practice. Following my return to the office, I’ve made some observations about pediatric practice worth sharing with our readers.

For months, as healthcare workers, we have been doing our best to care for patients in the midst of a pandemic. Without a means to diagnose COVID-19 at the point of care, treat suspected COVID-19 cases with a proven antiviral, and lacking an effective vaccine, we could do little to help patients with the crisis. Our battle plan included modifying our routine to implement telehealth services, triaging patients, using personal protective equipment (PPE) to see patients, and seeking loans to keep our offices afloat financially.

Telehealth during a pandemic: lessons learned
While practicing telehealth at home, I quickly realized that parents and children were quite worried. Schools were closed, parents lost jobs, and life was now unsettling. While most parents did their best to reassure children, I discovered that face-to-face video visits were a welcome experience for everyone. Sheltering in place, it seems, makes one keen for human interaction, and families appreciate when words of encouragement come from someone familiar. I knew my patients and their interests, and our telehealth visits were fun. I could joke about a patient’s long hair and ask how they were doing with their online classes. Like most pediatricians, I easily recalled the nuances of the lives of my patients and families. It was easy to ask about hobbies, parents’ jobs, and the whereabouts of older brothers and sisters who had aged out of the practice. During the visit I could smile at parents and patients, and receive warm smiles in return, while reassuring them that together we would get through the pandemic, and perhaps be better in many ways for the experience. No matter if the virtual visit was for an ADHD evaluation, or an acute visit for a fever and cough, the telehealth visit was effective, and in many ways better than an office-based visit. After all, there was no travel involved, patients did not need to be roomed by a nurse, and as vaccinations were never administered, visits were pain free. I was in my “safe space” and the patient was in theirs. I usually wore pajamas, and a hat to cover my too-long-hair-needing-a-haircut, and my patients and parents were similarly attired. Showering (and shaving) became optional.

At the virtual visit, I soon came to realize that the most rewarding part of the visit was to see another person’s smile! Sheltering in place does make one appreciate the little things. More than hand sanitizer and toilet paper, sharing a smile is one of the true blessings of being a pediatrician. It took no less than a global pandemic to make one appreciate the importance of a simple smile.

Back to work
Once back in the office, it was clear that resuming well-child exams would not be easy. No matter whether one wears full PPE for these visits or a face mask and shield, with parents and patients masked as well,
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sations between exam room occupants is difficult. It is near impossible to share a smile and also difficult to do an examination so attired, and I do not remove a patient’s mask to examine the mouth or throat unless it is necessary. Young children unable to wear a mask are sometimes intimidated by the funny looking person doing doctor stuff, who sounds like that nice pediatrician he or she has seen before. Until such time that we can safely unmask—I now try a little harder to make my patients and parents laugh or giggle to make the office visit comforting.

Going forward
While the pandemic curve is flattening, there continues to be widespread COVID-19 cases in my community. Until the crisis is behind us, I suggest that front office staff and office nurses communicate with families via video visits whenever possible. Hopefully we will soon be able to greet families with a smile, a welcoming handshake and a warm hug.

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

ZOMBIE APOCALYPSE VS COVID-19 PANDEMIC

It is difficult to find amusement in the midst of the COVID-19 pandemic, but when one shelters in place for months, one may watch movies like the “Resident Evil” series, or TV shows like “The Walking Dead.”


Its purpose was to educate the public. Here is a quote from the web page that resonates today: “If zombies did start roaming the streets, CDC would conduct an investigation much like any other disease outbreak. CDC would provide technical assistance to cities, states, or international partners dealing with a zombie infection. This assistance might include consultation, lab testing and analysis, patient management and care, tracking of contacts, and infection control (including isolation and quarantine.” I thought it would be appropriate to compare and contrast these two “disasters” for your consideration and amusement:

<table>
<thead>
<tr>
<th></th>
<th>COVID-19 PANDEMIC</th>
<th>ZOMBIE APOCALYPSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Causative Agent</td>
<td>Sars-CoV-2, a novel coronavirus</td>
<td>T-virus (Resident Evil) or Space Spores (Walking Dead)</td>
</tr>
<tr>
<td>R naught</td>
<td>Estimated at 2.5 (at onset estimated to be &gt; 5)</td>
<td>&gt; 1 (Zombie appetite dependent, also dependent on whether apocalypse involves “slow” vs “fast” zombies)</td>
</tr>
<tr>
<td>Origin</td>
<td>Wuhan China</td>
<td>Umbrella Corporation (Resident Evil) or Space Aliens (Walking Dead)</td>
</tr>
<tr>
<td>Degree of spread</td>
<td>Global</td>
<td>Global</td>
</tr>
<tr>
<td>Visibility of Transmitting agent</td>
<td>Invisible</td>
<td>Obvious! (as in “Look at all those zombies, dude!”)</td>
</tr>
<tr>
<td>Transmission</td>
<td>Inhalation of virus via droplet or aerosol</td>
<td>Bite or scratch by infected person i.e. body fluid transmission</td>
</tr>
<tr>
<td>PPE</td>
<td>Cloth masks, Level 2 masks, N95 respirators, face shields, gloves, gowns</td>
<td>Baseball bats, shovels, and most pointy things</td>
</tr>
<tr>
<td>Efficacy of Mask or Face Shield</td>
<td>Effective</td>
<td>Nope! (and BTW very difficult to get zombies to wear these)</td>
</tr>
<tr>
<td>Efficacy of “social distancing”</td>
<td>Can flatten the curve</td>
<td>Effective, only if one runs far enough, fast enough.</td>
</tr>
<tr>
<td>CDC Preparedness</td>
<td>Not so much —“mask” or “no mask,” “testing is available for those who need it,” etc. Seems the CDC did not follow their own advice.</td>
<td>CDC continues to be prepared for the Zombie Apocalypse</td>
</tr>
<tr>
<td>Treatment</td>
<td>Remdesivir looks promising, Hydroxychloroquine not so much.</td>
<td>Traumatic brain injury or anti-virus</td>
</tr>
<tr>
<td>Efficacy of “sheltering in place”</td>
<td>Effective, but boring.</td>
<td>Only if one boards up doors and windows. Best done at a pub. Avoid malls as this will not end well.</td>
</tr>
</tbody>
</table>
Bully bullae in a toddler spreads across the body

AUSTIN BURNS, BS, MS3; BERNARD A COHEN, MD

You are asked to evaluate a healthy 19-month-old boy with a history of recurrent blisters on his arms and legs for over a year that have now spread to his face. The blisters scab over quickly, ulcerate, and heal with post-inflammatory pigmentary changes.

CBDC is characterized by the linear deposition of IgA along the basement membrane zone (BMZ). This leads to neutrophilic infiltrate and subepidermal bullae, often with increased prevalence of eosinophils. LABD cannot be definitively diagnosed by light microscopy and should be confirmed with immunofluorescent studies which show linear staining for IgA at the basement membrane zone.

Conditions associated with LABD include autoimmune diseases, malignancy, and infections, with insufficient data to determine the statistical significance of these relationships. One known association is drug-induced LABD, especially with vancomycin. This condition differs from idiopathic LABD in both distribution and disease course.

Differential diagnosis

The differential diagnosis for CBDC/LABD is extensive; the two most common conditions that mimic LABD are dermatitis herpetiformis and bullous pemphigoid, which may present with bullae or vesicles in similar distributions. Direct immunofluorescence is the gold standard for differentiating between these conditions in the absence of other clinical distinguishers. The linear deposition of IgA along the BMZ is pathognomonic for CBDC and LABD; dermatitis herpetiformis

CONTINUED ON PAGE 35
is characterized by granular IgA deposition in the dermal papillary tips or along the basement membrane and bullous pemphigoid is characterized by linear IgG deposition along the epidermal BMZ. Besides direct immunofluorescence, circulating anti-BMZ IgA antibodies may be found in 60-70% of LABD patients, not found in dermatitis herpetiformis or bullous pemphigoid.

**Management**

While CBDC is generally self-limited, it may lead to morbidity and requires systemic treatment. The standard of care for treatment is dapsone for controlling blistering without adverse reactions in most cases. Dapsone is initiated at low doses (<0.5mg/kg) and increased until symptoms are controlled. Adverse effects include hemolysis, especially in patients with glucose-6-phosphate dehydrogenase deficiency. Second-line therapies include erythromycin, dicloxacillin, oxacillin, colchicine, and systemic corticosteroids.

**Patient outcome**

CBDC was diagnosed clinically. Following bloodwork, this patient started on dapsone 12.5 mg, then 18.75 mg, with improvement of the lesions. A skin biopsy and direct immunofluorescence confirmed the diagnosis.

Mr Burns is a third-year medical student at Johns Hopkins School of Medicine, Baltimore, Maryland.

**FIGURE 2** Ruptured blisters with central ulcerations and older lesions with post-inflammatory hyper- and hypopigmentation.

**COMMENTS?** E-mail them to levine@mh lifesciences.com

For references, go to ContemporaryPediatrics.com/dermcase-0820
NEW

Aquaphor Baby Healing Ointment

Provides immediate protection by creating a barrier from wetness, acidity, and chafing

Uniquely formulated with 41% Petrolatum plus 4 key ingredients to protect and soothe baby’s skin

*Data on File.

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Recommend Aquaphor® Baby as the complete solution for babies’ diaper area needs

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Aquaphor Baby Diaper Rash Paste

96% of babies had an improvement in diaper rash and irritation within 24 hours*

Formulated with 40% Zinc Oxide, thick, easy-to-apply, paste that is free of parabens, talc, fragrances, and preservatives

HAPPY BOTTOMS MAKE HAPPY PATIENTS