THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®
90 Years of Caring for Children—1930–2020

AAP News

www.aapnews.org

Volume 41 • Number 10 • October 2020

AAP: Flu vaccination more important than ever as flu and SARS-CoV-2 co-exist

by **Flor M. Muñoz, M.D., M.Sc., FAAP**

AAP Policy Statement

This season, influenza vaccination — recommended for everyone 6 months and older without medical contraindications — is vital to help protect vulnerable populations and reduce the burden of respiratory illnesses and hospitalizations during the SARS-CoV-2 pandemic, according to a new AAP influenza policy statement.

Reducing the risk among children, who have the highest rates of influenza infection, decreases the burden and transmission of virus to household and community contacts of all ages. It also can help preserve the capacity of the health care infrastructure during the ongoing COVID-19 pandemic.

The policy *Recommendations for Prevention and Control of Influenza in Children, 2020-2021*, from the Committee on Infectious Diseases, is available at https://doi.org/10.1542/peds.2020-024588 and is published in the October issue of *Pediatrics*.

Like the last two years, any licensed, recommended, age-appropriate influenza vaccine available can be administered, and there is no preference for a product or formulation. Both inactivated influenza vaccine (IIV) and live attenuated influenza vaccine (LAIV) are options. Similarly, treatment with any licensed, recommended, age-appropriate influenza antiviral medication can be used.

Antivirals are recommended for children with suspected or confirmed influenza who are hospitalized, have severe or progressive disease, or have underlying conditions that increase their risk of complications. Recent observational studies suggest antivirals can reduce the risk of certain flu complications, including hospitalization and death.

Antiviral treatment also can be considered for any previously healthy, symptomatic outpatient **not** at high risk for influenza who 1) is confirmed or suspected of having flu, or 2) is a child whose siblings or household contacts are younger than 6 months or have a high-risk condition predisposing them to influenza complications, and 3) treatment can be started within 48 hours of illness onset.

See Influenza, page 4

Looking back at the decade's enduring advocacy for children

At a 2015 rally in front of the U.S. Capitol, pediatricians raised their voices and banners urging "Vote like children's futures depend on it" and other messages that still resonate today. The final installment of the AAP 90th anniversary series highlights the challenges and achievements since 2010. **See page 32.**

COVID-19 Coverage

Pediatricians and the Law

COVID-19 fuels questions about patient waivers, standard of care for telemedicine

by **James P. Scibilia, M.D., FAAP**

AAP Fellows often send questions to the Committee on Medical Liability and Risk Management. While the committee is unable to give specific legal advice, it can give some general information that may be helpful. As always, it is important to recognize that laws vary state-to-state, and legal decisions depend on the facts at hand. It is important to consult a qualified attorney for legal issues affecting your practice.

Q&A **I have heard of practices requiring patients to sign waivers from liability for COVID-19 exposure or an infection resulting from a visit. Will these provide legal protection if one of my patients gets ill from an exposure in my office?**

A variety of online forms have circulated that purport to provide broad liability protection to practices when a patient develops COVID-19 infection from exposure during an office visit. These liability waivers may offer a small measure of protection, but they do not cover all potential

See Law, page 5

Keep up with the news from the AAP National Conference

AAP experience VIRTUAL 2020
National Conference & Exhibition

The virtual AAP National Conference & Exhibition is Oct. 2-5. *AAP News* has the highlights from live and on-demand sessions at https://bit.ly/aapnews2020virtual.

In this issue

Health Briefs

by **Melissa Jenco** • *News Content Editor*

11,000 children treated yearly for ATV-related head/neck injuries

♦ Li D, et al. *Clin Pediatr*. https://bit.ly/3bpCoiP.

More than 11,000 children are treated at U.S. emergency departments (EDs) each year for nonfatal head and neck injuries related to all-terrain vehicles (ATVs), a new study showed.

Researchers from Nationwide Children's Hospital analyzed data from the National Electronic Injury Surveillance System on these injuries in children under 18 years. They found that from 1990-2014, about 70% of children with ATV-related head or neck injuries treated in the ED were boys. The median age was 12, despite the AAP's recommendation that ATVs should not be used by children under 16.

These injuries increased about 133% from 1997-2007, which may be due in part to the 1998 expiration of safety measures manufacturers had committed to putting in place, according to the study.

From 2007-2014, head and neck injuries related to ATVs declined 37%, which authors said may have been due to high-profile awareness campaigns, the recession and use of urgent care instead of EDs.

Over the 25-year study period, about 33% of the injuries were considered a concussion/closed head injury. Another 33% were fractures.

Looking at the cause of injuries, 30% of the injured riders were ejected from the ATV, 19% crashed and 16% rolled over.

Just over half of the injuries occurred at home. When children were injured on the street, they were 1.5 times more likely to be admitted to the hospital. Overall, 15% of the children with head and neck injuries were admitted.

ATV riders should be licensed drivers with no passengers and should wear helmets, eye protection and reflective clothing.

The authors, including AAP Council on Injury, Violence and Poison Prevention member Gary A. Smith, M.D., Dr.P.H., FAAP, said many of the injuries are preventable and stressed the importance of taking safety precautions. The Academy's policy on ATVs calls for users to be licensed drivers with no passengers and says riders should wear helmets, eye protection and reflective clothing. ATVs should only be used off-road and during the daytime.

"ATVs are powerful machines designed strictly for off-road use that require mature judgement, coordination, strength, and moment-to-moment decision making," Dr. Smith said in a news release. "Adoption of the safety recommendations outlined by the American Academy of Pediatrics would go a long way in preventing many pediatric ATV-related head and neck injuries."

67% of antibiotic-treated appendicitis cases deemed successful

♦ Minneci PC, et al. *JAMA*. https://bit.ly/2QUELRb.

Roughly 67% of children whose appendicitis was treated with antibiotics did not need surgery within a year, according to a study of 1,068 children ages 7-17 years.

The findings come as about 70,000 children each year undergo an appendectomy, and increasing research indicates nonoperative management of appendicitis is safe and effective.

Researchers studied children with uncomplicated appendicitis at 10 children's hospitals that are part of the Midwest Pediatric Surgery Consortium. About 65% chose laparoscopic surgery, and 35% chose a nonoperative route. The latter consisted of at least 24 hours of intravenous antibiotics and at least one dose of oral antibiotics at the hospital followed by continued oral antibiotics at home for a total of seven days, including those spent in the hospital.

Treatment of about 67% of the children who chose the antibiotics was considered successful, meaning they did not require an appendectomy within a year. In addition, the nonoperative group had an adjusted mean of just under seven disability days compared to almost 11 among the surgery group.

Satisfaction scores were high for both groups, but both the success rate and disability days fell short of expectations. Surgeons had aimed for a nonoperative success rate of at least 70% and expected a difference of at least five disability days. However, authors said patients, families and other clinicians may have a less stringent view of success. In addition, they said decreasing or eliminating the hospital stay for the nonoperative group could improve the benefits.

"Surgeons tend to be passionate about operations, and an appendectomy is a well-tested and trusted procedure," author Katherine J. Deans, M.D., M.H.Sc., FAAP, a member of the AAP Section on Surgery, said in a news release. "However, some patients want to avoid surgery at all costs, and the results of our studies reflect the effectiveness of offering a non-operative management to patients and their families in clinical practice. This allows us to move away from a one-size-fits-all model of appendicitis care and treat each child based on his or her values and preferences."

Few teens are being counseled by doctors on sexual health

♦ Hensel DJ, et al. *J Adolesc Health*. http://bit.ly/3LMdKgP.

Many teens are not being asked about their sexual and reproductive health when they see their doctor.

Researchers reached this conclusion by analyzing data on 826 teens ages 14-17 years from the 2018 National Survey of Sexual Health and Behavior, an online, nationally representative survey.

Teens who had seen a health care provider in the past year were asked whether they had discussed six sexual and reproductive health topics.

Results showed:

- 52% discussed being sexually active,
- 36% discussed no sexual/reproductive health topics,
- 32% were counseled about pregnancy or sexually transmitted infection (STI) prevention,
- 13% discussed sexual identity,
- 8% discussed sexual difficulties,
- 7% were offered an STI test and
- 2% discussed all topics.

Discussions of each topic occurred at the same rate for males and females, but there were differences based on sexual identity, age and race.

Roughly 7% of teens who identified as a sexual minority were asked about their sexual identity compared to 14% of heterosexual teens.

Data also showed older teens were more likely to be asked about being sexually active and preventing pregnancy and STIs than younger teens. Racial/ethnic minority teens were significantly more likely to be asked about almost all of the sexual/reproductive health topics than White teens.

Authors noted the rate of discussions fell far below federal HealthyPeople 2020 goals for pregnancy prevention and STI/HIV screening. They suggested implementing practice-level interventions to standardize sexual and reproductive health screening in all adolescent encounters to prevent adverse outcomes like STIs and unintended pregnancy.

"Because these outcomes are readily preventable — but can contribute to lifelong fertility and economic and physical health challenges if left unchecked — it is imperative that adolescents have ongoing access to sexual and reproductive health care," they wrote.

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Attn: Member and Customer Care
345 Park Blvd. • Itasca, IL 60143

AAP News (ISSN-1073-0397) is published monthly by the American Academy of Pediatrics, 345 Park Blvd., Itasca, IL 60143. Printed in the U.S.A. Periodicals class postage rate is paid at Itasca, IL, and additional mailing offices.

POSTMASTER: Send address changes to American Academy of Pediatrics, Attn: Member and Customer Care, 345 Park Blvd., Itasca, IL 60143.

SUBSCRIPTIONS: Members – price is included in annual AAP membership dues. Nonmembers – $99 per year; $79 online only. Single copy $10. To subscribe, contact (866) 843-2271.

by **Devin Miller** • *Washington Correspondent*

Social media takeover: Members share importance of voting

Pediatricians across the country are finding creative ways to engage their patients and their families around the importance of voting.

As part of its Get Out the Vote campaign, the AAP has partnered with the nonprofit, nonpartisan voter registration effort Vot-ER. This partnership provides tools to help physicians safely encourage their patients to register to vote, using options like a badge backer with a QR code and phone backgrounds.

Several AAP members were featured in a takeover on the Academy's social media accounts, highlighting how they use these tools and educate others about the importance of civic engagement.

From left: Emilia Maria Cadiz, D.O., in Atlanta, Nathaniel K. Jones, M.D., in Washington, D.C., and Margaret Stager, M.D., FAAP, in Cleveland.

VOTE KIDS
THEIR FUTURE DEPENDS ON IT.

Visit http://www.AAP.org/VoteKids to learn more about the AAP's Get Out the Vote campaign and how to get involved.

8 ways you can help get out the vote today

1) Have a plan to cast your ballot on or before Election Day.
2) Know your state's voting requirements and deadlines. Vote.org has more.
3) Share messages about the importance of voting with children's needs in mind using the hashtag #VoteKids.
4) Download the AAP's customizable graphics at https://bit.ly/3lR7Zi5 to tell your followers that you plan to #VoteKids because their futures depend on it.
5) Encourage patients who are old enough to vote to make sure they are registered and have a plan to cast their ballot.
6) Read about key child health issues this election and their health equity connections at https://bit.ly/2EPx4JJ.
7) Look for opportunities to attend virtual town halls and ask candidates where they stand on key child health issues. Find potential questions to ask at https://bit.ly/2EPx4JJ.
8) Consider writing an op-ed in your local newspaper about a child health issue important to your community and why you plan to vote like children's futures depend on it.

These graphics and more are available on AAP.org/VoteKids. There are animated and customizable options to post to social media.

E-cigarette regulation efforts reach key milestone

Early September marked an important milestone in the Academy's efforts to protect children from e-cigarette products through strong federal regulation.

As of Sept. 9, any e-cigarette product that has not submitted an application to the Food and Drug Administration (FDA) is considered illegal and is subject to immediate federal enforcement action to remove the product from the market.

"With the September 9 deadline, the FDA has yet another opportunity to reverse the current epidemic of youth e-cigarette use and stop tobacco companies from addicting a new generation of kids with e-cigarettes, cigars and other tobacco products," the AAP and other health groups said in a press statement. "The FDA must protect kids and public health, not the interests of the tobacco industry."

The FDA will have one year to review applications for products that met the September deadline and determine whether each product is appropriate for the protection of public health. After the one-year period, only products that have been found by the FDA to meet that public health standard can stay on the market.

The Academy's message to the FDA remains clear: E-cigarettes are dangerous to children's health. They are highly addictive and their flavors appeal to youths. The AAP maintains that flavored products cannot meet the public health standard because of their attractiveness to youths. E-cigarettes must be strongly regulated to protect children from nicotine addiction.

Updates for 2020-'21

- **Composition:** All pediatric vaccines are quadrivalent (no trivalents are available for children) and include four viral strain components: influenza A(H1N1)pdm09, A(H3N2), B/Victoria and B/Yamagata. All except the B/Yamagata component are new this season.
- **Vaccine formulations:** Various formulations available for children 6 through 35 months of age have been updated as follows:
  - Afluria Quadrivalent will be the only vaccine for children 6 through 35 months with a dosing volume of 0.25 mL.
  - Fluzone Quadrivalent, licensed in a 0.25-mL and a 0.5-mL dosing volume, likely will be available only in 0.5-mL volume for this age group this season.
  - Fluarix Quadrivalent and FluLaval Quadrivalent have a dosing volume of 0.5-mL for this age group.

Any of these formulations can be used; there is no preference.

- **Dosages, timing:** All influenza immunizations should be completed by the end of October, if possible. Children 6 months through 8 years who are receiving influenza vaccine for the first time, who have received only one dose ever prior to July 1, 2020, or whose vaccination status is unknown, *should be vaccinated as soon as vaccines become available* so they can receive both doses by the end of October (four weeks apart).
- **Contraindications for LAIV:** Children with immunodeficiencies, anatomic or functional asplenia, cochlear implants or active cerebrospinal fluid leaks should not receive LAIV because it is a live attenuated product. For more information on individuals who should not receive LAIV, consult the policy.

RESOURCES

- AAP influenza vaccine implementation guidance, http://bit.ly/2q2vj01
- CDC flu page, https://www.cdc.gov/flu/index.htm
- CDC information on flu supply, https://bit.ly/3hehDrn
- CDC guidance for planning vaccination clinics, https://bit.ly/2ZqliMQ
- Red Book Online influenza resource page, https://bit.ly/33fRa86
- Information for parents from HealthyChildren.org, https://bit.ly/2Fompp4
- Related Parent Plus article on page 37, "See your pediatrician for influenza vaccine during COVID-19 pandemic," https://bit.ly/2Rckwyi

Q&A What do we know about influenza circulating with SARS-CoV-2?

While the impact of the anticipated co-circulation of SARS-CoV-2 with influenza this season is unknown, there were elevated rates of influenza-like illness hospitalization toward the end of the 2019-'20 season when the COVID-19 pandemic began. The possibility of comorbidity makes it critical to receive timely flu vaccination this season.

Q&A Can children with confirmed or suspected COVID-19 receive influenza vaccination?

Children confirmed to have COVID-19 can receive flu vaccine when their acute illness has resolved. Children with nasal congestion that would impede delivery into the nasopharyngeal mucosa should have LAIV deferred until resolution.

Q&A Are special precautions recommended for vaccine administration during COVID-19?

Yes; infection protection measures should be in place for all patient encounters. Those administering vaccines should wear a surgical face mask (not N95 or respiratory mask) and eye protection if the level of community spread is moderate or elevated. Gloves should be worn during LAIV administration and changed with every patient. Gowns are not required.

Q&A What did we learn from the 2019-'20 influenza season?

Last season saw the highest hospitalization rates in children (68.2 per 100,000 population overall). There were 188 laboratory-confirmed flu-related pediatric deaths. Among 168 children with available medical histories, most (57%) had no known underlying medical conditions. Of the 141 children who were 6 months or older when they became ill (meaning eligible for having had flu vaccination), most (74%) were not vaccinated. Children who died ranged from age 2 months to 17 years (median, 6 years), Among 63 of the children who died and had been previously tested, 46% had a bacterial coinfection.

Q&A Is it safe to offer IIV with other vaccines such as 13-valent pneumococcal conjugate vaccine (PCV13)?

Yes, simultaneous administration of IIV with PCV13 and/or other vaccines continues to be recommended for the 2020-'21 influenza season when these vaccines are indicated.

Q&A Can pregnant and/or women who are breastfeeding get the flu vaccine?

IIV is recommended *at any time* during pregnancy (LAIV is contraindicated). This will help provide protection to infants during their first six months of life when they are too young to receive the vaccine themselves. Vaccination during breastfeeding is safe for mothers and infants.

Q&A What about potential allergies to influenza vaccines?

Anaphylactic reactions to any vaccine are considered a contraindication to vaccination. Children with a previous allergic reaction after a dose of influenza vaccine should be evaluated by an allergist to determine whether future receipt of the vaccine is appropriate. Those with egg allergies can receive flu vaccination without any additional precautions beyond those recommended for all vaccines.

Dr. Muñoz, a lead author of the policy statement, is a member of the AAP Committee on Infectious Diseases.

This month in *Pediatrics*

The following is published in the October issue of *Pediatrics*:

Recommendations for Prevention and Control of Influenza in Children, 2020-2021
https://doi/10.1542/peds.2020-024588
— An AAP policy statement from the Committee on Infectious Diseases (see article on page 1)

Coming in November

Clinical reports

- Evaluation and Management of the Infant Exposed to HIV in the United States
- Neonatal Opioid Withdrawal Syndrome
- Routine Neuroimaging of the Preterm Brain

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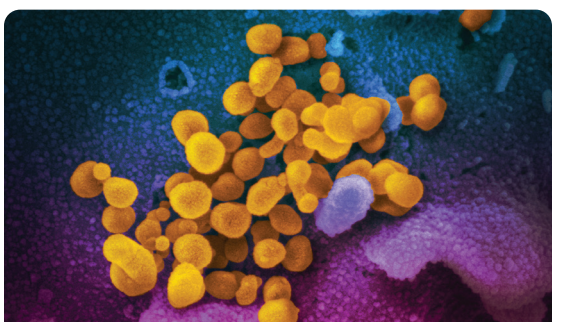


For AAP COVID-19 information and resources, go to www.aap.org.

Intervention reduces unnecessary outpatient antibiotic prescribing for children

from **AAP Research**

Primary care pediatric clinicians prescribed fewer antibiotics for children with acute respiratory tract infections after learning evidence-based strategies to talk with parents about antibiotics, according to results of a recently published study from the AAP Pediatric Research in Office Settings (PROS) network (http://doi.org/10.1542/peds.2020-0038).

Pediatric Research in Office Settings
A program of the American Academy of Pediatrics

Although antibiotic prescribing for pediatric conditions has decreased in the past decade, work remains to reach goals of reducing non-recommended antibiotic prescribing. To address this goal, the PROS study was conducted from 2015 to 2018 among 57 pediatric clinicians at 19 U.S. primary care practices.

Clinicians completed a web-based training program emphasizing communication skills with parents and current guidelines for antibiotic use. They also received feedback about their own antibiotic prescribing.

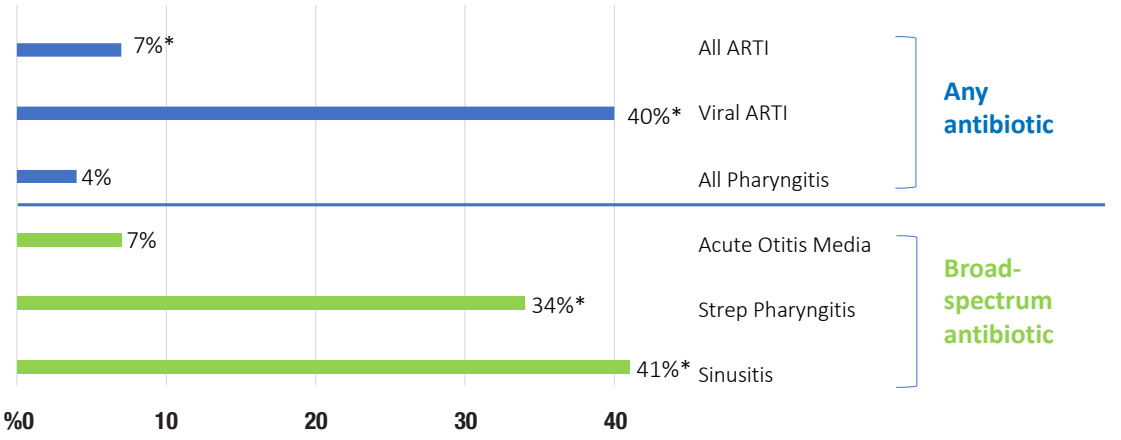
Data from 29,762 children ages 6 months to 10 years from practices' electronic health records were used to compare antibiotic prescribing before and after the training.

After the intervention, pediatric clinicians were 7% less likely to prescribe antibiotics at visits for acute respiratory tract infections overall and 40% less likely to do so at visits for viral acute respiratory infections. In addition, they were 34% less likely to prescribe broad-spectrum antibiotics for streptococcal pharyngitis and 41% less likely to do so for sinusitis (see figure).

No significant differences were found for prescribing at visits for all pharyngitis or for acute otitis media.

The project involved the AAP PROS network collaborating with researchers from Seattle Children's, the University of Washington, Children's Hospital of Philadelphia and NorthShore University HealthSystem in Illinois. The study was supported by the National Institutes of Health under grant R01 HD084547-01 to Rita M. Mangione-Smith, M.D., M.P.H., FAAP (principal investigator). Infrastructure funding to the PROS network is provided by the Health Resources and Services Administration of the U.S. Department of Health and Human Services under grant UA6MC15585.

Decrease in antibiotic prescribing following a clinician training and feedback program



ARTI = acute respiratory tract infection; Strep = streptococcal
* Indicates statistical significance
Data from: Kronman M, et al. *Pediatrics*. http://doi.org/10.1542/peds.2020-0038

RESOURCES

- For more information about PROS, visit https://bit.ly/AAPPROS or contact Laura Shone, Dr.P.H., M.S.W., at LShone@aap.org or 630-626-6710.
- Study materials, including the communication tutorial, antibiotics tutorial, booster videos and webinars, https://www.uwimtr.org/dart/
- Resources for pediatricians on antimicrobial stewardship:
  - Choosing Wisely list from the AAP and Pediatric Infectious Diseases Society, https://bit.ly/3bpf6JX
  - Pediatric Antibiotic Stewardship Program Toolkit, https://www.pids.org/asp-toolkit.html
- Resources for parents:
  - Guidelines for antibiotic use from HealthyChildren.org, https://bit.ly/2DeRdrE
  - Choosing Wisely: Antibiotics for a Sore Throat, Cough, or Runny Nose, https://bit.ly/3julK2V

Law *continued from front page*

liability. Waiver documents will not cover willful or intentional acts or reckless behaviors. Courts generally have sided with plaintiffs in cases involving waivers, and they broadly interpret the definition of reckless or intentional behavior.

To shield providers, the waiver should define the waived liability narrowly and specifically, clearly state the COVID-19 epidemic as the inciting event and include a fixed duration for the waiver. The patient's representative should have an opportunity to review and ask questions about the document, and there should be clear guidelines for how staff should respond when patients refuse to sign. This would be especially important when a parent arrives with a sick child who needs care but refuses to sign; turning this patient away could result in a claim of abandonment.

Q&A I read that my state offers immunity for health care providers from lawsuits during the COVID-19 epidemic. Will this cover any bad outcome in my practice during the crisis?

Many states have enacted some liability protections for physicians during the pandemic, but most have restrictions in coverage. In some cases, the law provides general liability protection, but most states have narrowly focused protections and these often are based on direct care of patients with COVID-19 infection.

Since these are state-specific, it is imperative for clinicians to investigate the laws pertaining to their practice sites. This may be especially important for physicians who work in several states where these legislated protections may vary dramatically.

Some federal laws have been modified during the epidemic to allow care to be provided in new clinical environments necessitated by the pandemic. In particular, the Office of Civil Rights at the Department of Health and Human Services relaxed enforcement of some Health Insurance Portability and Accountability Act rules with regard to telecommunication with patients. However, providers should stay vigilant for rollback of these provisions.

Q&A We are providing a lot more care through telemedicine, and my partners are uncomfortable diagnosing and treating patients who are available for exam only via video or telephone. How does the "standard of care" apply to telemedicine?

Standard of care is a critical component in assessing liability in tort actions. The standard of care is not a precise and fixed level of care but is determined by specific characteristics of the patient, circumstances of the care provided, disease process and recently, availability of medical services during the pandemic.

Generally, a standard would be determined as the level of care a prudent health care professional would provide given the same set of circumstances in a specific patient. "Standard" care prior to the pandemic should be modified by the limitations placed on providers and health systems during this national emergency.

If there are concerns about the child's clinical status or a physical examination is required, then the patient should be examined in the office or emergency department. As with many aspects of liability protection, documentation and clear explanation of decision-making during telemedicine encounters are the best protection for providers.

Dr. Scibilia is chair of the AAP Committee on Medical Liability and Risk Management.

Vote for leaders and legislation that put kids first

It often is said that children can't vote so the adults who care about them have to.

As pediatricians, pediatric medical subspecialists and pediatric surgeons, our professional lives have changed dramatically in recent months. We have seen cracks in the health care system — especially health financing — grow into chasms. We have worried over our colleagues and our practices. But most of all, we have worried for our patients.

Public policy is a tool the AAP often uses to affect change. The systemic changes needed to overcome poverty, racism and other social determinants of health require the right policies, laws and leaders.

Voting is one of the main ways we can address health inequities in our communities. So, between now and Nov. 3, please encourage your colleagues, patients/parents and families to vote for leaders and legislation that put kids first.

Here's just some of what's at stake.

- **COVID-19 pandemic.** The effects of COVID-19 on children's physical and mental health are wide-ranging, especially for those living below and near the poverty line. With hunger rising, classrooms closing and parental stress surging, we must vote for policies and candidates that support access to health care and Medicaid coverage and provide nutrition assistance and resources for schools so children can return safely.
- **Racism.** A toxic stressor, racism has been linked to disparities in birth outcomes as well as physical and developmental problems throughout the life course. We must elect leaders at all levels of government who will promote policies that reduce disparities and advance social justice, including improving the quality of education in racially segregated communities, devising alternative strategies to incarceration for managing nonviolent youth behavior as well as employing fair housing practices.
- **Immigrant child health.** Policies like the public charge regulation create barriers to accessing health care, nutrition and housing assistance, and harm the health of immigrants and the communities in which they live. We must elect leaders who support the health and basic rights of immigrant children and families and ensure all who arrive at our border are treated with dignity and respect.
- **Climate change and clean air.** Children are disproportionately affected by the impacts of climate change, including lower air and water quality, extreme heat and weather events, food system insecurity, changing patterns of infectious disease and longer, more severe allergy seasons. Under-resourced groups are the hardest hit. We need to vote to slow the pace of global warming and support clean energy and sustainable transportation and food systems.
- **Gun violence.** Every day, 87 children in the United States are killed or injured by guns. Black and Hispanic children fall victim at much higher rates. We want to cast our ballots for leaders who will protect children, families and communities from gun violence with common-sense steps like strengthening background checks, supporting extreme risk protection orders, encouraging safe firearm storage, banning assault weapons, addressing firearm trafficking and expanding federally funded gun violence prevention research.
- **Health care coverage and access.** After years of progress, the number of children who have health insurance is declining. We must support leaders who support policies that prioritize affordable, comprehensive health coverage for children and families and keep programs like Medicaid and the Children's Health Insurance Program strong.

This past year has been a powerful reminder that our patients' health depends not only on what's happening in our offices and hospitals but also on Capitol Hill and in the halls of government. This is why I vote and use the resources at aap.org/votekids to encourage those around me to learn about the issues and vote as well. A few weeks back, I had the privilege of helping a soon-to-be 18-year-old patient register to vote. I also give everyone in my practice the option of coming in late or leaving early so they can get to the polls.

Voting is not only our responsibility as citizens but our duty as pediatricians. So, please join me in getting out the vote. Our patients' health and future depend on it.

Sara Goza, MD FAAP

Sara "Sally" H. Goza, M.D., FAAP
President, American Academy of Pediatrics

Online from *AAP News* at www.aapnews.org

Recent highlights

- FDA OKs automated insulin device for young children, https://bit.ly/3jYIpWw
- Study: Black children's autism diagnosis typically delayed 3 years, https://bit.ly/35gQsKh

COVID-19 guidance updates

- AAP interim guidance on caring for children with special health care needs during pandemic, https://bit.ly/covid19cyshcn090320
- AAP interim guidance addresses outpatient care of sick children during pandemic, https://bit.ly/acuteillnessguidance082720
- AAP releases interim guidance on safe transportation in vehicles as schools reopen, https://bit.ly/transportationguidance082120

Visit *AAP News* for the latest COVID-19 pandemic updates, https://www.aappublications.org/news/2020/01/28/coronavirus.

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www.aapnews.org

PUBLISHED MONTHLY
American Academy of Pediatrics
345 Park Blvd. • Itasca, IL 60143
(800) 433-9016

AAP News, the official newsmagazine of the American Academy of Pediatrics, is dedicated to informing, educating and inspiring readers on matters related to pediatric health care.

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For children ≤24 months with hemodynamically significant congenital heart disease (HS-CHD)

Don't let RSV undo all that you do

Children ≤24 months with **HS-CHD are at high risk for severe RSV disease.**[1,2]

SYNAGIS showed significant reductions in consequences of severe RSV in children **up to 2 years of age** with HS-CHD[3]:

PRIMARY ENDPOINT

45% relative reduction in hospitalization
(9.7% for placebo vs 5.3% for SYNAGIS; *P*=0.003)

SECONDARY ENDPOINT

56% fewer total days of RSV-related hospitalizations
(per 100 children; 129 days for placebo vs 57.4 days for SYNAGIS; *P*=0.003)

73% fewer total days with increased supplemental oxygen
(per 100 children; 101.5 days for placebo vs 27.9 days for SYNAGIS; *P*=0.014)

FELTES STUDY DESIGN: A randomized, double-blind, placebo-controlled trial of 1287 children with HS-CHD randomly assigned 1:1 to receive 5 monthly intramuscular injections of SYNAGIS 15 mg/kg or placebo.

RSV=respiratory syncytial virus.

Make RSV prevention with **SYNAGIS** an integral part of what you do

INDICATION

SYNAGIS, 50 mg and 100 mg for injection, is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (≤35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

LIMITATIONS OF USE

The safety and efficacy of SYNAGIS have not been established for treatment of RSV disease.

IMPORTANT SAFETY INFORMATION

- SYNAGIS is contraindicated in children who have had a previous significant hypersensitivity reaction to SYNAGIS
- Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to SYNAGIS. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to SYNAGIS. The relationship between these reactions and the development of antibodies to SYNAGIS is unknown. If a significant hypersensitivity reaction occurs with SYNAGIS, its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of SYNAGIS
- As with any intramuscular injection, SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder
- Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays
- Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported

DOSING

The recommended dose of SYNAGIS is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of SYNAGIS should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.

The efficacy of SYNAGIS at doses less than 15 mg/kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

References: 1. Boyce TG, Mellen BG, Mitchel EF Jr, et al. Rates of hospitalization for respiratory syncytial virus infection among children in Medicaid. *J Pediatr.* 2000;137(6):865–870. **2.** Cabalka AK. Physiologic risk factors for respiratory viral infections and immunoprophylaxis for respiratory syncytial virus in young children with congenital heart disease. *Pediatr Infect Dis J.* 2004;23(suppl 1): S41–S45. **3.** Feltes TF, Cabalka AK, Meissner HC, et al; for Cardiac Synagis Study Group. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. *J Pediatr.* 2003;143(4):532–540.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.FDA.gov/medwatch** or call 1-800-FDA-1088.

sobi

Please see Brief Summary of Prescribing Information on adjacent page.

SYNAGIS® PALIVIZUMAB

SYNAGIS®
(palivizumab) injection, for intramuscular use

BRIEF SUMMARY of PRESCRIBING INFORMATION.
For complete prescribing information consult official package insert.

INDICATIONS AND USAGE

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season,
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season,
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season *[see Clinical Studies (14) in full Prescribing Information]*.

Limitations of Use:

The safety and efficacy of Synagis have not been established for treatment of RSV disease *[see Warnings and Precautions (5.4) in full Prescribing Information]*.

DOSAGE AND ADMINISTRATION

Dosing Information

The recommended dose of Synagis is 15 mg per kg of body weight given monthly by intramuscular injection. The first dose of Synagis should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but it may begin earlier or persist later in certain communities.

Synagis serum levels are decreased after cardio-pulmonary bypass *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Children undergoing cardio-pulmonary bypass should receive an additional dose of Synagis as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled.

The efficacy of Synagis at doses less than 15 mg per kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

Administration Instructions

- **DO NOT DILUTE THE PRODUCT.**
- **DO NOT SHAKE OR VIGOROUSLY AGITATE THE VIAL.**
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use any vials exhibiting particulate matter or discoloration.
- Using aseptic techniques, attach a sterile needle to a sterile syringe. Remove the flip top from the Synagis vial and wipe the rubber stopper with a disinfectant (e.g., 70% isopropyl alcohol). Insert the needle into the vial and withdraw into the syringe an appropriate volume of solution. Administer immediately after drawing the dose into the syringe.
- Synagis should be administered in a dose of 15 mg per kg intramuscularly using aseptic technique, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. The dose (volume of injection in mL) per month = patient weight (kg) x 15 mg per kg ÷ 100 mg per mL of Synagis. Injection volumes over 1 mL should be given as a divided dose.
- Synagis is supplied as a single-dose vial and does not contain preservatives. Do not re-enter the vial after withdrawal of drug; discard unused portion. Only administer one dose per vial.
- Use sterile disposable syringes and needles. To prevent the transmission of hepatitis viruses or other infectious agents from one person to another, DO NOT reuse syringes and needles.

CONTRAINDICATIONS

Synagis is contraindicated in children who have had a previous significant hypersensitivity reaction to Synagis *[see Warnings and Precautions (5.1) in full Prescribing Information]*.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to Synagis. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to Synagis. Signs and symptoms may include urticaria, pruritus, angioedema, dyspnea, respiratory failure, cyanosis, hypotonia, hypotension, and unresponsiveness. The relationship between these reactions and the development of antibodies to Synagis is unknown. If a significant hypersensitivity reaction occurs with Synagis, its use should be permanently discontinued. If anaphylaxis or other significant hypersensitivity reaction occurs, administer appropriate medications (e.g., epinephrine) and provide supportive care as required. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of Synagis.

Coagulation Disorders

Synagis is for intramuscular use only. As with any intramuscular injection, Synagis should be given with caution to children with thrombocytopenia or any coagulation disorder.

RSV Diagnostic Test Interference

Palivizumab may interfere with immunological-based RSV diagnostic tests such as some antigen detection-based assays. In addition, palivizumab inhibits virus replication in cell culture, and therefore may also interfere with viral culture assays. Palivizumab does not interfere with reverse transcriptase-polymerase chain reaction based assays. Assay interference could lead to false-negative RSV diagnostic test results. Therefore, diagnostic test results, when obtained, should be used in conjunction with clinical findings to guide medical decisions *[see Microbiology (12.4) in full Prescribing Information]*.

Treatment of RSV Disease

The safety and efficacy of Synagis have not been established for treatment of RSV disease.

Proper Administration

The single-dose vial of Synagis does not contain a preservative. Administration of Synagis should occur immediately after dose withdrawal from the vial. The vial should not be re-entered. Discard any unused portion.

ADVERSE REACTIONS

The most serious adverse reactions occurring with Synagis are anaphylaxis and other acute hypersensitivity reactions *[see Warnings and Precautions (5.1) in full Prescribing Information]*.

Clinical Studies Experience

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 data described below reflect exposure to Synagis (n=1639) compared with placebo (n=1143) in children 3 days to 24.1 months of age at high risk of RSV-related hospitalization in two clinical trials. Trial 1 was conducted during a single RSV season and studied a total of 1502 children less than or equal to 24 months of age with BPD or infants with premature birth (less than or equal to 35 weeks gestation) who were less than or equal to 6 months of age at study entry. Trial 2 was conducted over four consecutive seasons among a total of 1287 children less than or equal to 24 months of age with hemodynamically significant congenital heart disease.

In Trials 1 and 2 combined, fever and rash were each reported more frequently among Synagis than placebo recipients, 27% versus 25%, and 12% versus 10%, respectively. Adverse reactions observed in the 153-patient crossover study comparing the liquid and lyophilized formulations were comparable for the two formulations, and were similar to those observed with Synagis in Trials 1 and 2.

Immunogenicity

In Trial 1, the incidence of anti-palivizumab antibody following the fourth injection was 1.1% in the placebo group and 0.7% in the Synagis group. In children receiving Synagis for a second season, one of the fifty-six children had transient, low titer reactivity. This reactivity was not associated with adverse events or alteration in serum concentrations. Immunogenicity was not assessed in Trial 2.

A trial of high-risk preterm children less than or equal to 24 months of age was conducted to evaluate the immunogenicity of the lyophilized formulation of Synagis (used in Trials 1 and 2 above) and the liquid formulation of Synagis. Three hundred seventy-nine children contributed to the 4 to 6 months post-final dose analysis. The rate of anti-palivizumab antibodies at this time point was low in both formulation groups (anti-palivizumab antibodies were not detected in any subject in the liquid formulation group and were detected in one subject in the lyophilized group (0.5%), with an overall rate of 0.3% for both treatment groups combined).

These data reflect the percentage of children whose test results were considered positive for antibodies to palivizumab in an enzyme-linked immunosorbent assay (ELISA) and are highly dependent on the sensitivity and specificity of the assay.

The ELISA has substantial limitations in detecting anti-palivizumab antibodies in the presence of palivizumab. Immunogenicity samples tested with the ELISA assay likely contained palivizumab at levels that may interfere with the detection of anti-palivizumab antibodies.

An electrochemical luminescence (ECL) based immunogenicity assay, with a higher tolerance for palivizumab presence compared to the ELISA, was used to evaluate the presence of anti-palivizumab antibodies in subject samples from two additional clinical trials. The rates of anti-palivizumab antibody positive results in these trials were 1.1% and 1.5%.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of Synagis. 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.

Blood and Lymphatic System Disorders: severe thrombocytopenia (platelet count less than 50,000 per microliter)

General Disorders and Administration Site Conditions: injection site reactions

Limited information from post-marketing reports suggests that, within a single RSV season, adverse events after a sixth or greater dose of Synagis are similar in character and frequency to those after the initial five doses.

DRUG INTERACTIONS

No formal drug-drug interaction studies were conducted. In Trial 1, the proportions of children in the placebo and Synagis groups who received routine childhood vaccines, influenza vaccine, bronchodilators, or corticosteroids were similar and no incremental increase in adverse reactions was observed among children receiving these agents.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Synagis is not indicated for use in females of reproductive potential.

Lactation

Risk Summary

Synagis is not indicated for use in females of reproductive potential.

Pediatric Use

The safety and effectiveness of Synagis in children older than 24 months of age at the start of dosing have not been established *[see Clinical Studies (14) in full Prescribing Information]*.

OVERDOSAGE

Overdoses with doses up to 85 mg per kg have been reported in clinical studies and post-marketing experience with Synagis, and in some cases, adverse reactions were reported. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment instituted.

PATIENT COUNSELING INFORMATION

Advise the patient's caregiver to read the FDA-approved patient labeling (Patient Information)

Hypersensitivity Reactions

Inform the patient's caregiver of the signs and symptoms of potential hypersensitivity reactions, and advise the caregiver to seek medical attention immediately if the child experiences a severe hypersensitivity reaction to Synagis *[see Contraindications (4) and Warnings and Precautions (5.1) in full Prescribing Information]*.

Administration

Advise the patient's caregiver that Synagis should be administered by a healthcare provider once a month during the RSV season by intramuscular injection and the importance of compliance with the full course of therapy *[see Dosage and Administration (2) in full Prescribing Information]*.

Manufactured by:
MedImmune, LLC, Gaithersburg, MD 20878
Issued: 05/2017 US-17124 12/17

COVID-19 Coverage

Are antiviral drugs available to treat COVID-19 infections?

by H. Cody Meissner, M.D., FAAP

Editor's note: *Ask the Expert is a column that provides pediatricians with information on pressing topics related to COVID-19. Email your questions to ahegland@aap.org.*

Development of an antiviral drug is more challenging than development of an antibiotic agent because antibiotics generally are directed against a metabolic pathway that is unique to bacteria and not shared with eukaryotic cells.

Antibiotics such as penicillin, for example, inhibit specific enzymes (penicillin-binding proteins) that are essential for the synthesis of the bacterial cell wall (peptidoglycan). The rigid peptidoglycan enables bacteria to remain intact in the face of osmotic pressure. Penicillin prevents proper cross-linking of peptidoglycan during the last stages of bacterial cell wall synthesis. Lack of peptidoglycan results in lysis of the bacterium and impaired replication. Since peptidoglycan is not found in human cells, penicillin is selectively toxic for bacteria.

Viruses are obligate intracellular organisms that replicate largely by cannibalizing a host cell's metabolic pathways using the same enzymes present in an uninfected host cell. An antiviral drug that interferes with viral replication is likely to interfere with an essential cell function, resulting in unacceptable toxicity. An example of a successful antiviral drug is oseltamivir, which is active against most influenza viruses because it binds to and inactivates a unique enzyme on a viral protein (neuraminidase). Oseltamivir has little activity against neuraminidase activity found in uninfected human cells, so toxicity for an uninfected cell is limited.

Remdesivir

Remdesivir is an investigational antiviral drug that inactivates a specific viral enzyme (RNA-dependent RNA polymerase) that is unique to certain RNA viruses, including SARS-CoV-2, the coronavirus that causes COVID-19.

Coronaviruses contain an RNA molecule that carries the genetic information of the virus. In order for a coronavirus to replicate and cause disease, the viral polymerase makes multiple copies of the viral RNA, and these copies are incorporated in progeny viral particles. Inhibition of this enzyme causes little toxicity in humans because uninfected human cells have limited (RNA-dependent RNA) polymerase activity.

On May 1, remdesivir received emergency use authorization (EUA) for hospitalized adult or pediatric patients with proven or suspected severe COVID-19 infection. Severe disease is defined as a patient with an oxygen saturation ≤94% while breathing room air or a requirement for supplemental oxygen, mechanical ventilation or extracorporeal membrane oxygenation.

The safety, effectiveness and pharmacokinetics of remdesivir have not been assessed in pediatric patients. Modeling of pharmacokinetic data from healthy adults was used to derive pediatric doses.

Remdesivir should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus. Little information is available regarding the presence of remdesivir in human milk.

An EUA is different from Food and Drug Administration approval for an investigational drug. An EUA is issued following a declaration by the Secretary of Health and Human Services regarding an emergency situation. This happens when available data indicate a drug may be effective in treatment of a disease; no adequate, approved or alternative treatments are available; and the benefits appear to outweigh potential risks. An EUA remains in effect until data from subsequent experience justifies revision or termination.

At present, remdesivir remains an investigational drug that has not been approved or licensed but is the only antiviral agent with demonstrated benefit in patients infected with COVID-19.

Remdesivir has been evaluated in two independent trials for the treatment of COVID-19 pneumonia in adults. Remdesivir is the preferred antiviral option for patients meeting eligibility requirements.

Hydroxychloroquine

On March 28, an EUA was issued for oral chloroquine phosphate and hydroxychloroquine sulfate for treatment of COVID-19 infections in hospitalized adolescents and adults. This EUA was based on reports from China, Italy and France suggesting patients who received these medications with or without azithromycin had more rapid reduction in COVID-19 viral load than patients who did not receive these drugs. A reduction in viral load sometimes is used as a surrogate for antiviral activity.

Recommendations for use of these anti-malarial and rheumatologic drugs were included in guidelines from some countries impacted by COVID-19, including Korea and China. The Infectious Diseases Society of America and the Centers for Disease Control and Prevention did not make a recommendation for or against use of these drugs. When the EUA was issued for chloroquine and hydroxychloroquine use in COVID-19 patients, it appeared these drugs might provide benefit and that the benefit appeared to outweigh the risks of an adverse reaction.

This EUA was revoked on June 15 when results from a randomized clinical trial in hospitalized patients demonstrated that chloroquine and hydroxychloroquine were unlikely to be effective for treatment of COVID-19. Results did not demonstrate reduced mortality, hospital length of stay or need for mechanical ventilation. In vitro data suggested the recommended dosing regimens were unlikely to result in sufficient intracellular concentrations to inhibit the growth of SARS-CoV-2. Cardiac adverse events were reported, particularly prolongation of QT intervals when administered concurrently with azithromycin. Fatal cases of methemoglobinemia occurred. As these data became available, it was determined that the EUA was no longer justified and it was revoked.

Protease inhibitors

HIV protease inhibitors such as lopinavir/ritonavir are not recommended for treatment of COVID-19 infections (except in a clinical trial) because of the absence of data showing benefit in a clinical trial.

Convalescent plasma

Insufficient data are available to recommend convalescent plasma for treatment of COVID-19 infections. It is theorized that plasma from recovered patients may contain antibodies that will suppress viral replication or modify the immune response. Thousands of patients have received convalescent plasma through expanded access treatment trials.

At this time, clear evidence of benefit is not available, and uncommon severe adverse reactions have been reported, including death. Variability in SARS-CoV-2 antibody concentrations in convalescent plasma likely have an impact on the efficacy of plasma products. Currently, standards for screening donor plasma for neutralizing antibody concentrations have not been established.

Potential therapies that are not recommended at this time include baloxavir, nitazoxanide, estrogen products, interferons, ribavirin, niclosamide, famotidine and ivermectin.

A future column will address the status of dexamethasone and other immune modulators, mesenchymal stem cells and immune-based therapy for management of patients with COVID-19 infections.

Dr. Meissner *is professor of pediatrics at Floating Hospital for Children, Tufts Medical Center. He also is an ex officio member of the AAP Committee on Infectious Diseases and associate editor of the AAP* Visual Red Book.

What antiviral therapies are available to treat pediatric patients with influenza

by **Peri Akchurin, D.O.,** and
H. Cody Meissner, M.D., FAAP

The severity of influenza in the 2020-'21 season is difficult to predict in the COVID-19 era. The most important approach to controlling influenza disease is timely and age-appropriate immunization for every person 6 months of age or older. Immunization is particularly important when the health care system is likely to be burdened because of the SARS-CoV-2 pandemic.

Early projections indicate that at least 194 million doses of vaccine will be available this season. A delay in availability of vaccines is not anticipated. Annual influenza vaccination has been recommended since 2010.

All influenza vaccines contain antigens from the same viruses with one exception. About 99% of vaccines for this season will contain antigens from four strains (quadrivalent vaccine), and 1% of vaccines will contain antigens from three strains (trivalent vaccine).

Last influenza season, the overall effectiveness of vaccines in preventing medically attended infection was approximately 39% against any strain of influenza. Even though vaccine effectiveness was less than optimal, immunization was estimated to have prevented more than 4 million illnesses and more than 55,000 hospitalizations among the approximately 50% of the population that were immunized.

For those who remain unvaccinated and experience influenza infection, antiviral drugs will be an important consideration to reduce disease severity and minimize the risk of transmission. Antiviral therapy also may be useful in a vaccinated person who experiences a breakthrough influenza infection.

Influenza antiviral therapy is recommended for patients who are hospitalized, have severe illness or are at increased risk for complications. Multiple clinical trials have shown that early antiviral treatment can shorten the duration of fever and reduce the risk of certain complications such as otitis media and pneumonia.

Which of the following statements are correct?

a) Influenza viruses and SARS-CoV-2 may co-circulate and result in co-infection.
b) Influenza antiviral agents cannot be used for prophylaxis in children.
c) Initiation of antiviral therapy should not be started before testing confirms influenza as the cause of symptoms.
d) Children 6 months through 8 years of age who require two doses of vaccine should receive the first dose as soon as vaccine is available with the second dose given four or more weeks later.
e) Antiviral agents may interfere with the live attenuated intranasal vaccine (LAIV).

Answer: a, d and e

Recommended antiviral drugs for 2020-'21 influenza season

Antiviral drug	Trade name	Treatment (approved age)	Prophylaxis (approved age)	Recommended dose
Oral oseltamivir	Tamiflu	Yes (14 days and older)	Yes (3 months and older)	*
Inhaled zanamivir	Relenza	Yes (7 years and older)	Yes (5 years and older)	*
IV peramivir	Rapivab	Yes (2 years and older)	Not recommended	One 12-mg/kg dose via IV for ages 2-12 years One 600-mg dose via IV ages ≥13 years
Oral baloxavir	Xofluza	Yes (12 years and older)	Not recommended	One 40-mg dose for those weighing 40-80 kg One 80-mg dose for weighing ≥80 kg

*See AAP policy statement *Recommendations for Prevention and Control of Influenza in Children, 2020-2021*

The Food and Drug Administration (FDA) has licensed six antiviral agents for treatment of influenza. In the past, two amantadine class drugs had activity against influenza virus type A (but not type B). Because of high-level resistance (>99%) among presently circulating influenza A viruses (A/H3N2, A/H1N1pnd09), these drugs are not recommended for treatment or prophylaxis.

Three neuraminidase inhibitors are available (see table), including oseltamivir (available as a generic drug or under trade name) and zanamivir. Antiviral treatment is most likely to be beneficial if started within 48 hours of symptom onset. In some patients with severe influenza, treatment after 48 hours still may provide benefit. Decisions about initiating antiviral therapy should not wait for laboratory confirmation. Previous vaccination should not rule out influenza if the presentation is consistent during the influenza season.

Although not an FDA-approved indication, use of oral oseltamivir for influenza treatment in infants younger than 14 days of age and chemoprophylaxis in infants 3 months to 1 year is recommended by the Academy.

Peramivir is the third licensed antiviral neuraminidase inhibitor. This drug is approved for intravenous administration for the treatment of acute, uncomplicated influenza in patients 2 years and older who have been symptomatic for no more than two days.

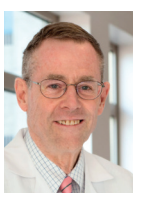
Baloxavir marboxil was approved in October 2018 for management of uncomplicated influenza for people 12 years of age and older and weighing at least 40 kilograms. Baloxavir is administered as a pill in a single dose. The prodrug is hydrolyzed to the active form, baloxavir. Baloxavir inhibits an enzyme unique to influenza virus (polymerase acidic endonuclease), preventing viral replication. Randomized, controlled clinical trials have shown that one dose of baloxavir is equivalent to five days of oseltamivir.

Baloxavir is not approved for post-exposure prophylaxis in the United States. However, a recent study from Japan showed that post-exposure prophylaxis with baloxavir reduced the risk of influenza transmission among household contacts by more than 75% compared to placebo (Ikematsu H, et al. *N Engl J Med.* 2020;383:309-320).

Antiviral agents administered within two weeks after vaccination with LAIV may reduce vaccine effectiveness. LAIV should not be given to people who have taken oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous five days or baloxavir within the previous 17 days, according to the Centers for Disease Control and Prevention.

Although the FDA has approved a number of drugs for the prevention and treatment of influenza, they are not a substitute for yearly vaccination.


Dr. Akchurin


Dr. Meissner

***Dr. Akchurin** is a resident member of the AAP Sections on Pediatric Trainees and Osteopathic Pediatricians. She is in her third year of triple board (pediatrics/adult psychiatry/child psychiatry) residency at Tufts Medical Center. **Dr. Meissner** is professor of pediatrics at Floating Hospital for Children, Tufts Medical Center. He also is an ex officio member of the AAP Committee on Infectious Diseases and associate editor of the AAP* Visual Red Book.

FACTS AND MYTHS ADHD DECODED

To learn more, visit www.TEAM-ADHD.com/awareness, or scan here.

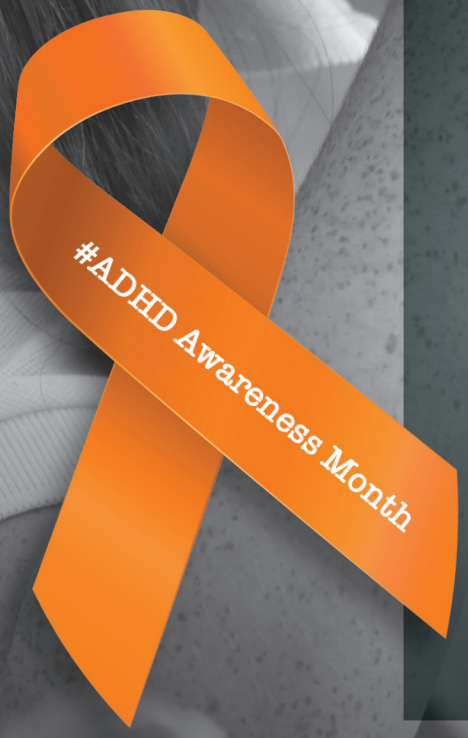
MYTH: ADHD IS A SIMPLE SCHOOL-DAY DISORDER

FACT: UP TO 75% OF CHILDREN AND ADOLESCENTS HAVE AT LEAST 1 OVERLAPPING COMORBIDITY[1]

In pediatric patients with ADHD, the following conditions are commonly reported[2,3]:

CO-OCCURRING IN UP TO 50% OF CASES[2,3]

- Depression
- Anxiety disorders
- Oppositional defiant disorder
- Pervasive developmental disorders/ autism spectrum disorder



You can help. Dive deeper into complex ADHD.

As a trusted resource for your patients and their caregivers, please encourage them to visit **MoreToADHD.com.** Here, they can learn more about the treatment complexities often associated with ADHD.

Actor Portrayal.

REFERENCES: 1. Banaschewski T, Becker K, Dopfner M, Holtmann M, Rosler M, Romanos M. Attention deficit/hyperactivity disorder. *Dtsch Arztebl Int*. 2017;114(9):149-159. **2.** Clemow DB, Bushe C, Mancini M, Ossipov MH, Upadhyaya H. A review of the efficacy of atomoxetine in the treatment of attention-deficit hyperactivity disorder in children and adult patients with common comorbidities. *Neuropsychiatr Dis Treat*. 2017;13:357-371. **3.** Turgay A, Ansari R. Major depression with ADHD in children and adults. *Psychiatry (Edgmont)*. 2006;3(4):2-32.

TEAM ADHD™
TREATING, EDUCATING AND MANAGING ADHD

Supernus® Pharmaceuticals

Surveillance, research needed to identify optimal treatments for MIS-C

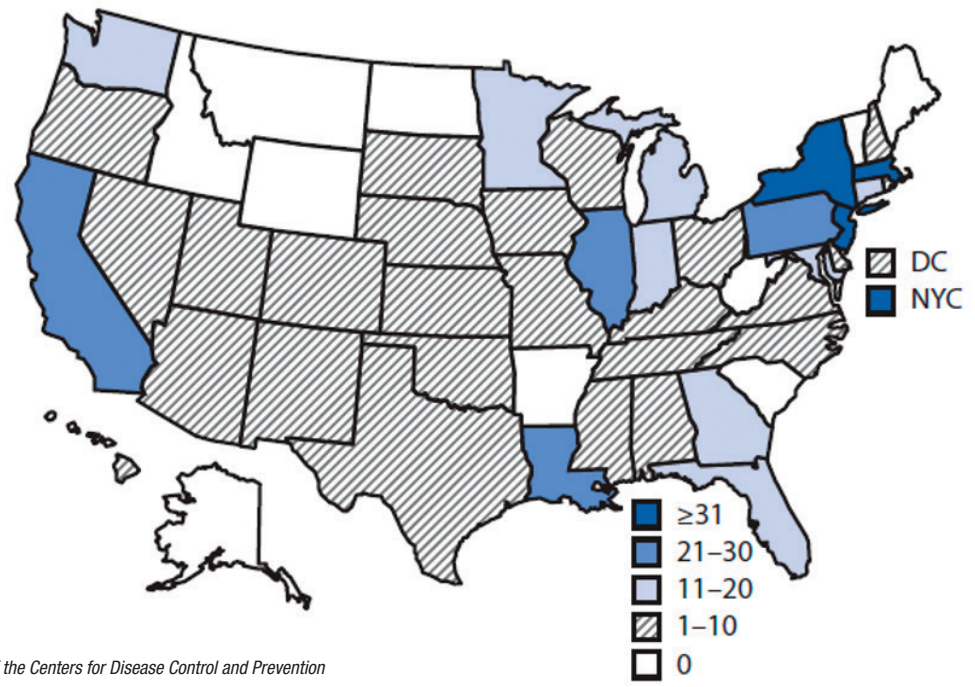
by **Satoshi Kamidani, M.D., FAAP**, and
Larry K. Pickering, M.D., FIDSA, FPIDS, FAAP

• Godfred-Cato S, et al. "COVID-19-Associated Multisystem Inflammatory Syndrome in Children - United States, March-July 2020." *MMWR Morb Mortal Wkly Rep.* 2020;69:1074-1080.

A cluster of eight previously healthy children with hyperinflammatory shock and clinical features similar to atypical Kawasaki disease or toxic shock syndrome was first reported from the United Kingdom in April. The cases occurred in children who were positive for SARS-CoV-2 on polymerase chain reaction (PCR) test, had a positive SARS-CoV-2 serology test or had an epidemiologic link to a COVID-19 case.

Following case reports in Europe, the New York State Department of Health identified 102 patients with a similar clinical presentation. On May 14, the Centers for Disease Control and Prevention (CDC) issued a Health Alert Network advisory notice to providers formally naming this condition multisystem inflammatory syndrome in children (MIS-C) associated with COVID-19, which included a case definition with the intention of being more inclusive.

Geographic distribution of 570 reported cases of multisystem inflammatory syndrome in children — United States, March–July 2020



Courtesy of the Centers for Disease Control and Prevention

Abbreviations: DC = District of Columbia; NYC = New York City.

Characteristics of MIS-C

As of July 29, a total of 570 MIS-C patients who met the case definition had been reported to CDC (see figure). The median patient age was 8 years (range: 2 weeks–20 years), and 55.4% were male, 40.5% were Hispanic or Latino, 33.1% were non-Hispanic Black and 13.2% non-Hispanic White. Whereas 66% of MIS-C patients did not have underlying medical conditions, obesity was the most common underlying medical condition (25.6%) followed by chronic lung disease (8.4%).

Four or more organ systems were involved in 490 (86%) patients. Most patients had gastrointestinal (90.9%), cardiovascular (86.5%) or dermatologic or mucocutaneous (70.9%) involvement. Severe complications were common, including cardiac dysfunction (40.6%), shock (35.4%), myocarditis (22.8%), coronary artery dilatation or aneurysm (18.6%) and acute kidney injury (18.4%). Overall, 364 patients (63.9%) were treated in an intensive care unit, and 10 patients (1.8%) died.

This study divided the MIS-C cases into three groups by underlying similarities using latent class analysis with specific indicator variables, a statistical modeling technique that is well-suited to describe different manifestations of a novel clinical syndrome. A total of 203 (35.6%) patients (Class 1) had a clinical course consistent with previously published MIS-C reports characterized predominantly by shock, cardiac dysfunction, gastrointestinal symptoms and markedly elevated inflammatory markers. Almost all Class 1 patients (98%) had positive SARS-CoV-2 serology test results with or without positive PCR test results.

Respiratory manifestations, including pneumonia or acute respiratory distress syndrome, that appeared to overlap with acute COVID-19 were more common in 169 (29.6%) patients (Class 2). This group had the highest rates of PCR positivity: 84%.

The remaining 198 (34.7%) patients (Class 3) were younger than other groups (the median age was 6 years) and more commonly met the criteria for complete Kawasaki disease (6.6%).

Importantly, Class 1 patients had the highest prevalence (21.1%) of coronary artery abnormalities compared with Class 2 (15.8%) and Class 3 (18.2%).

One of the study's limitations is that the CDC's broad case definition might have led to the unintentional inclusion of children whose illnesses overlapped with acute COVID-19 and Kawasaki disease.

Among all 570 patients, 527 (92.5%) were treated. The treatments included intravenous immunoglobulin (80.5%), steroids (62.8%), antiplatelet agents (58.6%), anticoagulation agents (44.2%) and vasoactive agents (41.9%). To date, there are no established guidelines on the management of MIS-C, and randomized controlled trials are urgently needed. AAP interim guidance on the treatment approach for MIS-C is available at https://bit.ly/3lveqY2.

What percentage of MIS-C patients reported to the CDC from March to July 2020 developed coronary artery abnormalities?

A. 1%
B. 6%
C. 12%
D. 18%
E. 24%

Answer: D

Pathogenesis of MIS-C and vaccine safety concern

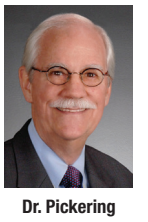
Although the pathogenesis of MIS-C remains unknown, it is hypothesized that MIS-C results from immune-mediated injury triggered by SARS-CoV-2 infection based on evidence of hyperinflammation and the delayed onset in relation to SARS-CoV-2 infection coincident with antibodies development. While elucidating the exact mechanism of this new syndrome is critical, the hypothesis of immune-mediated pathogenesis of MIS-C associated with natural SARS-CoV-2 infection, potentially involving a delayed aberrant cellular or humoral adaptive immune response, raises concern for MIS-C as a possible serious adverse event in children who receive COVID-19 vaccines. Therefore, once COVID-19 vaccines become available for children, it is crucial to evaluate MIS-C as a possible COVID-19 vaccine safety outcome through the U.S. vaccine safety monitoring systems.

Further surveillance and research are critical

Suspected MIS-C cases should be reported to local or state health departments. While a specific ICD-10-CM code for MIS-C has not yet been developed, the AAP has released coding guidance on MIS-C based on COVID-19 status at https://downloads.aap.org/AAP/PDF/COVID 2020.pdf. Appropriate coding for MIS-C is crucial to identify cases of MIS-C through electronic medical record systems for future studies and surveillance.

Since Dr. Tomisaku Kawasaki first described Kawasaki disease in the 1960s, we now encounter a novel mysterious syndrome in the era of the COVID-19 pandemic. Continued surveillance and research are needed to understand this syndrome further and provide insights into optimal treatments for MIS-C.

Dr. Kamidani



Dr. Pickering

***Dr. Kamidani** is a pediatric infectious diseases fellow at Emory University School of Medicine. **Dr. Pickering** is adjunct professor of pediatrics at Emory University School of Medicine.*

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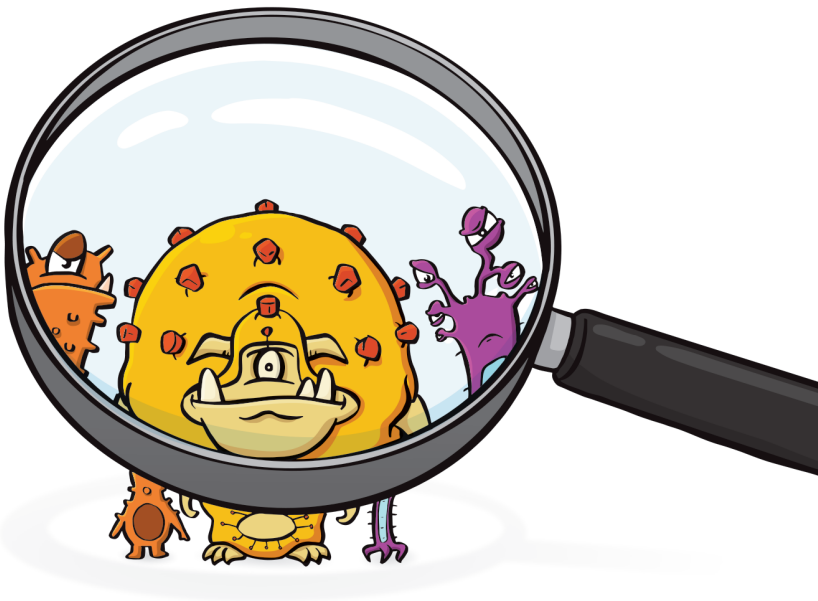

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BFR0001-0005-01

Subspecialists rise to challenge during COVID-19 pandemic

Editor's note: *This is the second of two articles in which members of AAP sections reflect on the challenges their specialty has faced during the COVID-19 pandemic and how it has changed the way they practice. Read the first article at https://bit.ly/3bMFtta.*

Rheumatology: Social distancing and community building


Dr. Hong

Pediatric rheumatology has experienced unprecedented collaboration during the pandemic as the widespread use of online platforms has opened the door to virtual meetings across institutions, specialties and international borders. This has affected not only patient care related to COVID-19 but all patient care.

In April, news from Italy and the United Kingdom (U.K.) indicated the appearance of a hyper-inflammatory syndrome in children associated with COVID-19. I joined the Pediatric Intensive Care-COVID-19 International Collaborative via Zoom. This group of over 500 pediatric specialists, including intensivists, rheumatologists and cardiologists, across the world is collecting data about COVID-19 treatment and outcomes. By early May, we were able to learn about the presentations and treatments used for what is now referred to as multisystem inflammatory syndrome in children (MIS-C). This was several weeks prior to the first publications from the U.K.

In June, the Childhood Arthritis and Rheumatology Research Alliance, which includes most of the pediatric rheumatologists in the U.S. and Canada, had its first ever online Zoom meeting open to all members to discuss MIS-C. These international collaborations and sharing of data were essential for information that helped me participate in the formation of the AAP interim guidance on MIS-C (https://bit.ly/3lveqY2).

Prior to the COVID-19 pandemic, I had never used Webex, Zoom or practiced telehealth. On my first day using video-health, I had a new patient who presented with bone marrow failure and a newly discovered heterozygous adenosine deaminase 2 (ADA2) mutation. Patients with ADA2 deficiency are at risk of stroke if not treated appropriately. Within weeks, I met via Zoom with his referring hematologist from another institution and an expert on ADA2 deficiency from the National Institutes of Health to discuss his case and his care.

The COVID-19 pandemic has propelled pediatric rheumatologists to leverage technology to enhance the speed at which we share data and form international collaborations and has opened avenues of patient-to-physician and physician-to-physician communication in ways that were not common in the pre-pandemic era. We are faster, more open and grateful to be part of a community.

*— **Sandy D. Hong, M.D., FAAP,** chair of the AAP Section on Rheumatology Executive Committee*

Critical care: Finding joy in caring for adults

In March, pediatric intensivists and ethicists, along with other colleagues, began discussing scarce resource allocation in the context of a pandemic. The concepts


Dr. Mack

we'd studied and tabletop exercises we'd performed in epidemiology and ethics courses were becoming more tangible. We imagined scenarios where ventilators or perhaps dialysis machines were in short supply.

Soon thereafter, we would learn that the surge of adults infected with COVID-19 would result in shortages of adult intensive care unit beds, respiratory therapists, nurses, physicians and many other members of the multidisciplinary care team. Pediatric intensive care units (PICUs) around the globe, along with the new Shawn Jenkins Children's Hospital in Charleston, S.C., saw a need in the adult hospital and capacity in the children's hospital.

Dual trained intensivists published their recommendations on anticipated educational, supply and equipment needs (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7331597/). Locally, we created criteria for adult transfer or admission, but our criteria yielded very few patients, so we opened up to match the need. We spoke with other PICUs around the world about lessons learned. The learning curve was tremendous, as was the joy and fulfillment that came from caring for these incredible adult humans with careers, families and tremendous lived experiences.

We also gained an appreciation for our own health, as it was no longer easy to distance ourselves from the virus' wrath.

Our adult colleagues have been gracious and patient, and our teams have appreciated the child in each of us. The humanity in these experiences is sealed in the hearts of our pediatric critical care teams forever.

*— **Elizabeth Mack, M.D., M.S., FAAP,** chair of the AAP Section on Critical Care*

Infectious diseases: Multidisciplinary teams blossom


Dr. Bishara

Infectious diseases do not honor man-made divisions between specialties and subspecialties, and SARS-CoV-2 is no different. This virus has been the most deceiving and disrespectful opponent we have ever known. We could not possibly expect to defeat this enemy by remaining as separate individuals within our respective specialties.

With one mind focused on the same goal, barriers initially built and upheld for years out of mass insecurity to maintain the vertical hierarchy within medicine came crumbling down. Sharp lines drawn between subspecialties faded away.

Multidisciplinary teams of both trainees and experts naturally blossomed. Roles and their corresponding limitations were identified, allowing for the development of diagnostic and therapeutic algorithms. In discovering the necessity of each part in our collective functioning, we uncovered the value in ourselves. The driving energy was no longer self-preservation to confirm an identity distinct from others, but rather preservation of the whole to confirm an identity intricately united as one.

With this novel pandemic, we watched our pediatric infectious diseases (ID), infection control, epidemiology and lab teams join forces. We developed algorithms, implemented multidisciplinary COVID-19 huddles and arranged web conferences with other area hospitals to share knowledge and make treatment protocols in real time, in response to what was being seen clinically. We witnessed a cool, collected demeanor and readiness to rise to an unprecedented challenge that carried us through when SARS-CoV2 reached our shores.


Dr. Daniel

There is still much to be learned about COVID-19. As pediatric ID fellows in the nation's capital, under the guidance of incredible mentors and alongside impressive colleagues, we plan to rise to the challenge.

Adversity has the potential to destroy or to allow us to rise to overcome the problem. While challenging, it has been an honor to play even the smallest role in this force that has evolved to defend and protect one another from our most unwelcome enemy.

*— **Amy Bishara, D.O., and Jency Daniel, M.D.** pediatric infectious diseases fellows and members of the AAP Section on Infectious Diseases*

Developmental and behavioral pediatrics: Returning to our roots


Dr. Schonwald

Developmental-behavioral pediatricians (DBPs) thought, "We have to see our patients in person!" Then overnight, we went remote. We adapted and found we're well-suited to operate in the setting of a pandemic. We've shifted much of our practice to supporting families facing uncertainty.

Managing ambiguity is the superpower of DBPs. We're accustomed to developmental changes, varied symptoms across settings and evolving diagnostic categories.

To diagnose autism, we assess facial expression during play and conversation. Since we can't play with very young children mask-free, we now rely more on history and observation. None of the remote or "no-touch" diagnostic testing options are yet validated, but the bar isn't lowered; the priority is to do no harm. Delaying a diagnosis when treatment is most effective would confer harm.

For children and teens with attention-deficit/hyperactivity disorder, we now focus on at-home behaviors. Many parents observe how hard learning is or how short their child's attention span is. We use digital measures to diagnose learning and cognitive disorders, typically tools already validated for remote use (https://iopc.squarespace.com/teleneuropsychology-research). Recommendations now include supporting students during remote education.

We've shifted how we think about mental health disorders. During social isolation, anxiety, depression and sleep disruption may be medication side effects, co-morbid disorders and/or results of pandemic-related upheavals. Children are at increased risk for abuse;

family stress is high. We've returned to our professional roots, thinking about each child's strengths, weaknesses and function within an eco-bio-developmental context. The psychosocial stressors of their ecology have become a focus: How can we support a child and family in this moment in history?

Telehealth is a new window into family life. We see more family dynamics and watch children function in the most comfortable setting. As a field, we must develop new ways to diagnose/monitor accurately, without the regularity of school and office materials, but (payment allowing) I suspect telehealth will be a long-lasting part of DBP care.

*— **Alison D. Schonwald, M.D., FAAP**, member of the AAP Section on Developmental and Behavioral Pediatrics*

Endocrinology: Telemedicine a success, but access to medications a concern


Dr. Bruggeman

Pediatric endocrinologists have adopted innovative techniques to care for our patients in the midst of COVID-19, including the widespread use of telemedicine.

As a cognitive specialty, many of our visits are well-suited to the telemedicine model. Pediatric endocrinologists already provide a substantial amount of care remotely, from continuous glucose monitoring interpretation in between diabetes visits to adjusting levothyroxine doses over the phone based on interim lab results.

Our division at the University of Florida adapted remarkably to the pandemic by increasing our telemedicine visits 100-fold; we actually had more overall visits with our patients through a combined in-person and telemedicine model than at the same point in 2019. A combined model has allowed us to provide comprehensive, safe care for our patients. We will need to work to ensure that support and funding for access to this valuable resource continues to be available. Research assessing the use of at-home HbA1c kits and other innovations will make telemedicine even more effective within our specialty.

While telemedicine has sustained access to office care, pediatric endocrinologists continue to worry about the impact of COVID-19 on patients' access to health insurance and vital medications. Prior to the pandemic, families of children with diabetes already spent three times as much on health care than those without diabetes due to the exorbitant cost of insulin and diabetes supplies. Now, millions more Americans are without health insurance, and the list price of analogue insulins continues to be hundreds of dollars per prescription. A recent study by the T1D Exchange showed that nearly one-third of patients with type 1 diabetes experienced diabetic ketoacidosis after infection with COVID-19 (Ebekozien OA, et al. *Diabetes Care.* 2020;43:e83-e85, https://doi.org/10.2337/dc20-1088). Without intervention, additional adverse outcomes could result from lack of access to health insurance, medications and supplies.

*— **Brittany Bruggeman, M.D., FAAP**, fellowship trainee member of the AAP Section on Endocrinology Executive Committee*

Hospital medicine: Changes in care coordination may be everlasting


Dr. Magyar

Pediatric hospital medicine (PHM) has faced some interesting challenges due to the pandemic, one of which is how best to coordinate care of the hospitalized patient while working under the uncertainty of COVID-19 testing and diagnosis.

We have seen several patients with multisystem inflammatory syndrome in children (MIS-C) whose treatment requires the assistance of several subspecialty colleagues. While ideal for all involved to round on these patients, this approach also needs to be balanced with concerns about preventing viral spread and minimizing exposure.

Subsequently, hospitalists have helped lead daily rounds on our MIS-C patients where pertinent specialists utilize teleconsults for a group discussion over a secure line. This modality empowers the care team to share patient updates, including lab results and physical exam findings, while the team collaboratively discusses next steps in treatment. This has improved workflow as it provides answers from consultants relatively early in the day while maintaining a unified approach to patient care — something that can be difficult when multiple providers are involved and seeing the same patient at varying times. In addition, when we conduct family-centered rounding, we have a more definitive plan of care, which parents appreciate.

Another step in care coordination has been ensuring our patients continue to have good follow-up after discharge. Due to the pandemic, families remain cautious about travel outside their home, which may impact seeing their primary care provider. By utilizing our hospital's telehealth structure, we can follow up on outstanding clinical issues and smooth discharge planning. This practice change has benefited many patients and their families, not just the ones with COVID-19.

Overall, PHM has adapted many of its traditional practices due to the pandemic, some of which may be everlasting.

*— **Matt Magyar, M.D., FAAP**, candidate member of the AAP Section on Hospital Medicine*

Neurology: Pioneering new aspects to care


Dr. Lotze

As a child neurologist at Texas Children's Hospital, telemedicine is a silver lining of this pandemic for me and my patients.

Online visits have reduced parents' and patients' time away from work and school, provided greater access for families living far from a child neurologist and eliminated transportation difficulties for children with complex medical needs.

This revitalization of "house calls" allows us to better understand how neurological conditions affect patients in their home environment. In addition, most online telemedicine platforms let neurologists share their screen, allowing them to display and discuss an MRI or other lab results as well as guide parents to online resources. Follow-up visits for patients doing well are shorter, allowing us to have more clinic visits or spend time on other academic pursuits. Telemedicine eventually could allow a child neurologist to be "in the office" with the pediatrician and patient having urgent neurological issues for real-time consultation.

As we navigate this new reality, challenges remain. I worry about disadvantaged populations with limited access to the necessary technology, and this will require vigilance and advocacy. In addition, nothing can truly replace the in-person neurological examination, although with a little ingenuity, key components of the exam can be observed. Teaching families how to do parts of the neurological exam, such as briskly tapping the patellar tendon, not only provides part of the exam but also can be a useful way for the patient and parents to better understand how the nervous system works.

While it can be easy to bemoan the tremendous limitations the pandemic has placed on our lives, this is an exciting time for child neurologists to pioneer new aspects of care for the benefit of our patients.

*— **Timothy Edward Lotze, M.D., FAAP** member of the AAP Section on Neurology Executive Committee*

Urgent care: Committed to minimizing risk, testing, caring for acute conditions

Pediatric urgent care (PUC) has stood as a vital and adaptable frontline vehicle to diagnose, treat and contain the spread of COVID-19. The first case of community spread of COVID-19 in the United States was identified in February at a pediatric urgent care. As the pandemic continues, PUC remains committed to the acute care of children for injuries, illnesses and testing.

Some PUCs with multiple locations designated specific sites for patients with respiratory symptoms and others for nonrespiratory complaints. Some PUCs shifted their hours to complement primary care availability and to limit exposure risk for patients with chronic diseases where physical spaces were shared with subspecialty clinics. Many PUCs implemented or increased use of telemedicine to provide a virtual alternative for acute care.

COVID-19 testing became an immediate and important mission for PUCs to document and contain spread of disease. Some PUC systems transformed locations into testing centers, often featuring drive-up services or outdoor tents. PUC-initiated testing centers allowed staff to conserve personal protective equipment and reference labs to consolidate supply chains. Some PUCs partnered with pediatric practices so the PUC could be an extension of care by providing antigen, polymerase chain reaction or antibody testing, allowing primary care practices to stay "clean" and focus on well care. Some PUCs performed more than 100 tests daily. PUCs capable of laboratory testing screened febrile children for signs of multisystem inflammatory syndrome in children by measuring serum inflammatory markers.

Many PUCs reported increases in injury management and patient acuity. One multistate PUC group reported that compared to previous years, the relative use of X-ray increased by 50% while the percent of patients requiring laceration repair more than quadrupled (from 1.6% to 9.4%). Similarly, the relative number of patients transferred to the emergency department doubled (from 1% to 2.2%).

— AAP Provisional Section on Urgent Care

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10 • 20 • 30 • 40 • 50 • 60 • 70 mg capsules
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INDICATION AND LIMITATION OF USE

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[1-3]

For appropriate patients with ADHD

Start with Vyvanse[1]

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Hypothetical patient portrayal. Individual results may vary.

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.

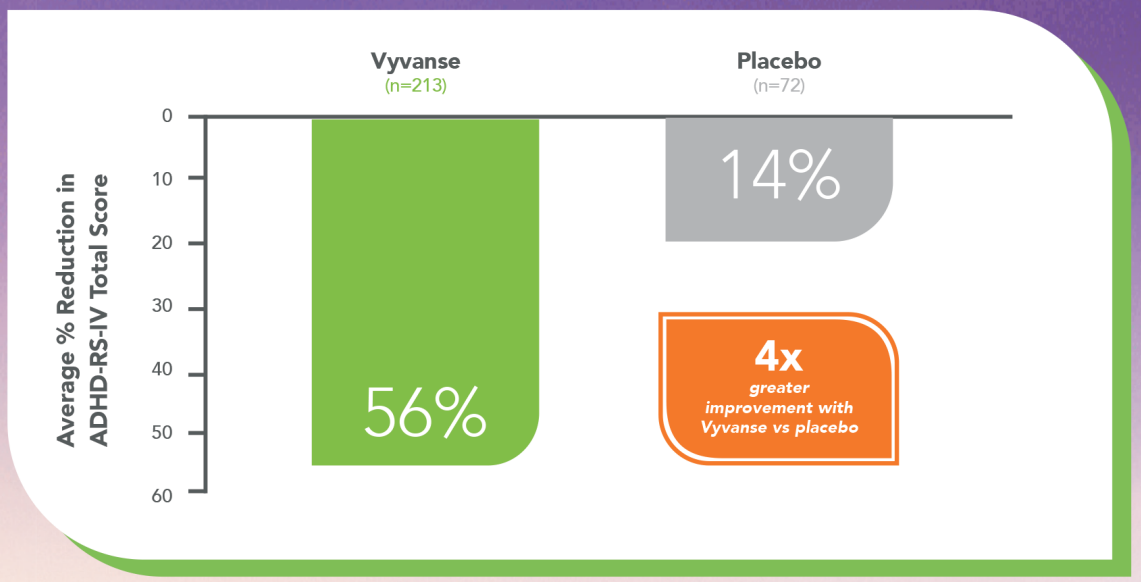
Study 301 Review Clinical Study

In a clinical study of children aged 6-12 years with ADHD, Vyvanse (lisdexamfetamine dimesylate) demonstrated a

Significant reduction in ADHD-RS-IV* total score[1-3]

PRIMARY ENDPOINT: Change from baseline to endpoint in ADHD-RS-IV total score†[1,2]

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.

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

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

- **Warnings and Precautions (continued)**
  - CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients (monitor weight and height). Treatment may need to be interrupted in children not growing or gaining weight as expected.
  - CNS stimulants, including Vyvanse, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; very rare sequelae include digital ulceration and/or soft tissue breakdown. Observe patients during treatment for new numbness, pain, skin color change, or sensitivity to temperature in fingers and toes. Further evaluation may be required, including referral.
  - Increased risk of serotonin syndrome when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans) and CYP2D6 inhibitors, but also during overdosage situations. Discontinue Vyvanse if it occurs and initiate supportive treatment.
- **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.

References: 1. Vyvanse [package insert]. Lexington, MA: Shire US Inc. **2.** Biederman J, Krishnan S, Zhang Y, McGough JJ, Findling RL. Efficacy and tolerability of lisdexamfetamine dimesylate (NRP-104) in children with attention deficit/hyperactivity disorder: a phase III, multicenter, randomized, double-blind, forced-dose, parallel-group study. *Clin Ther*. 2007;29(3):450-463. **3.** Data on file; LDX006; Shire.

US-LIS-0305v1.0 06/20

VYVANSE® (lisdexamfetamine dimesylate)
Capsules 10, 20, 30, 40, 50, 60, 70 mg
Chewable tablets 10, 20, 30, 40, 50, 60 mg CII Rx Only

BRIEF SUMMARY: Consult the Full Prescribing Information for complete product 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

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.

WARNINGS AND PRECAUTIONS

Potential for Abuse and Dependence *(See Above)*

Serious Cardiovascular Reactions

Sudden death, stroke and myocardial infarction have been reported in adults with CNS stimulant treatment at recommended doses. Sudden death has been reported in children and adolescents with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during VYVANSE treatment.

Blood Pressure and Heart Rate Increases

CNS stimulants cause an increase in blood pressure (mean increase about 2-4 mm Hg) and heart rate (mean increase about 3-6 bpm). Monitor all patients for potential tachycardia and hypertension.

Psychiatric Adverse Reactions

Exacerbation of Pre-existing Psychosis

CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder.

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a mixed/manic episode in patients with bipolar disorder. Prior to initiating treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, and depression).

New Psychotic or Manic Symptoms

CNS stimulants, at recommended doses, may cause psychotic or manic symptoms, e.g. hallucinations, delusional thinking, or mania in children and adolescents without a prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing VYVANSE. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in 0.1% of CNS stimulant-treated patients compared to 0% in placebo-treated patients.

Suppression of Growth

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants, including VYVANSE. In a 4-week, placebo-controlled trial of VYVANSE in patients ages 6 to 12 years old with ADHD, there was a dose-related decrease in weight in the VYVANSE groups compared to weight gain in the placebo group. Additionally, in studies of another stimulant, there was slowing of the increase in height.

Peripheral Vasculopathy, including Raynaud's Phenomenon

Stimulants, including VYVANSE, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in postmarketing reports at different times and at therapeutic doses in all age groups throughout the course of treatment. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Serotonin Syndrome

Serotonin syndrome, a potentially life-threatening reaction, may occur when amphetamines are used in combination with other drugs that affect the serotonergic neurotransmitter systems such as monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort. Amphetamines and amphetamine derivatives are known to be metabolized, to some degree, by cytochrome P450 2D6 (CYP2D6) and display minor inhibition of CYP2D6 metabolism. The potential for a pharmacokinetic interaction exists with the co-administration of CYP2D6 inhibitors which may increase the risk with increased exposure to the active metabolite of VYVANSE (dextroamphetamine). In these situations, consider an alternative non-serotonergic drug or an alternative drug that does not inhibit CYP2D6. 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 serotonergic agents immediately if symptoms of serotonin syndrome occur, and initiate supportive symptomatic treatment. Concomitant use of VYVANSE with other serotonergic 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% (1/72) 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% (1/77) of placebo-treated patients. Most frequent adverse reactions leading to discontinuation were irritability (3/233; 1%), decreased appetite (2/233; 1%), and insomnia (2/233; 1%).

In the controlled adult trial, 6% (21/358) of VYVANSE-treated patients discontinued due to adverse reactions compared to 2% (1/62) of placebo-treated patients. 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%), 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

Clinically 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

Serotonergic 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 seratonergic drugs), quinidine, ritonavir.

Alkalinizing Agents

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

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

Examples: Urinary alkalinizing 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, methenamine salts).

Tricyclic Antidepressants

Clinical Impact: May enhance the activity of tricyclic or sympathomimetic agents causing striking 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, lansoprazole, clobazam), and CYP3A4 (e.g. midazolam, pimozide, simvastatin) is necessary when VYVANSE is co-administered.

USE IN SPECIFIC POPULATIONS

Pregnancy

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 d, l-) is present in human milk, at relative infant doses of 2% to 13.8% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.9 and 7.5. 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 dosages 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 vasculopathy, 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 m^2), the maximum dose should not exceed 50 mg/day. The maximum recommended dose in ESRD (GFR <15 mL/min/1.73 m^2) 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 overdosage. Individual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses.

Manifestations of amphetamine overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia, and rhabdomyolysis. 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

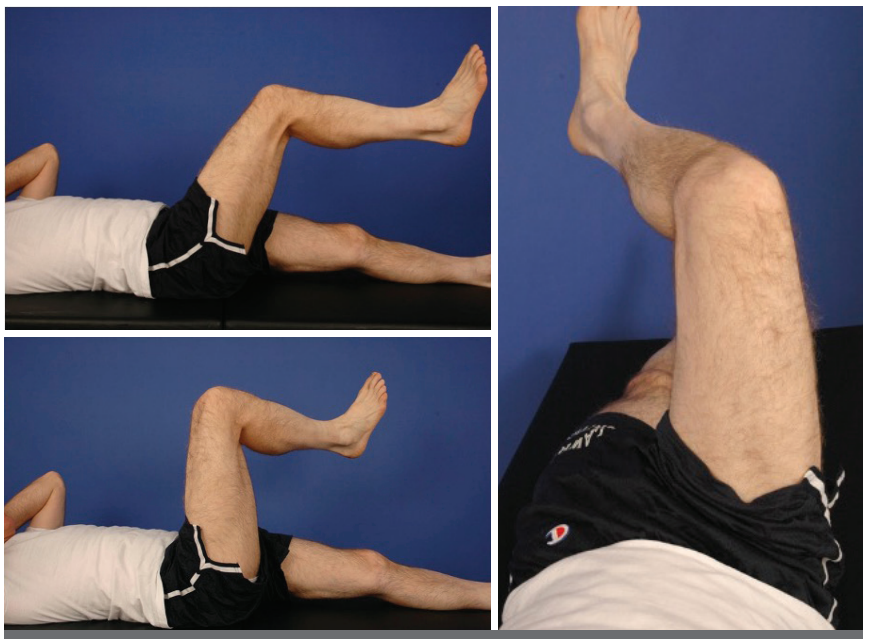
For more information call 1-800-828-2088

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-0320v1.0 06/20

Simple physical exam maneuvers can help identify hip impingement

by **Rachel Goldstein, M.D.**, and **Michael B. Millis, M.D.**



Michael B. Millis, M.D., demonstrates how to screen for anterior hip impingement by checking the amount of passive internal rotation with the hip flexed 90 degrees. The photo at right shows a positive screening test, where the flexed hip cannot be rotated even to neutral. Orthopedic evaluation is indicated in this situation.

Adolescent hip pain can be caused by a variety conditions, some requiring urgent identification and treatment. With limited resources and insufficient time, pediatricians are expected to rapidly identify these conditions to prevent life-altering repercussions.

Hips are complex and have a wide range of "normal." The expectation is that the hip needs to be both stable and mobile, creating a host of potential issues. Hip osteoarthritis (OA) is common. Approximately 80% of cases are directly related to childhood or adolescent onset hip conditions, and almost half of those are "impingement"-related conditions.

Femoroacetabular impingement (FAI) is a dynamic abnormal contact between the proximal femur and the acetabulum. This can cause damage to the acetabular rim and adjacent adolescent cartilage leading to OA. FAI is a common cause of hip pain but is commonly missed. Symptoms may be vague, and pain may not be present until significant cartilage damage is present. To decrease the progression to OA, earlier diagnosis and referral for joint-preserving procedures are necessary.

FAI is a key feature of certain pediatric and adolescent hip disorders. The most common and morbid is slipped capital femoral epiphysis (SCFE). SCFE is a condition of pre-adolescent and adolescent hips, in which femoral head slips posteriorly through the growth plate on the femoral neck. Simultaneously, the neck and upper femur slip forward and rotate out. SCFE can displace precipitously, but there is rarely severe displacement without weeks to months of symptoms. Because initial symptoms are vague and pain often is minimal, delayed diagnosis commonly results in major deformity, with morbidity preventable by earlier diagnosis.

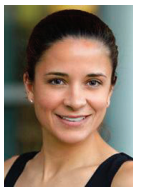
Legg-Calve-Perthes (LCP) disease, an idiopathic osteonecrosis of the femoral head that typically presents in school-aged children, also presents with an impingement type picture. Children initially have hip/groin pain or a painless limp. As the femoral head deforms, it can become more ovoid, leading to limited motion that can become permanent and lead to OA.

Assessment of range of motion is a quick and easy way to screen for FAI in children and adolescents. History often reveals groin pain worse in flexion. To examine the hip, the patient should be placed supine on the examination table. Check passive hip flexion first with the hip maintained in neutral rotation. From this position, internal and external rotation can be checked. A normal hip should have at least 90 degrees of flexion and some internal rotation beyond neutral without discomfort. By maintaining the hip flexed and internally rotated, it can then be adducted. If this maneuver elicits pain, the patient has a positive anterior impingement sign.

If these physical examination maneuvers are abnormal, the patient is at risk for having or developing FAI. If a hip is stuck in external rotation, the potential risk of anatomically based FAI is high. More than 97% of patients diagnosed with SCFE have limited internal rotation of their hip on physical examination, and 80% have limited hip flexion. Similarly, children with LCP typically have limited internal rotation and flexion.

In patients with concerning physical exam findings, a supine anteroposterior and frog radiograph of the pelvis are indicated with referral to an orthopedist for further evaluation.

FAI rarely is diagnosed in time for optimal treatment result. And some impingement-type conditions, including SCFE and LCP, can cause lifelong disability if not recognized and referred urgently. With a quick, simple set of physical examination maneuvers, pediatricians can decrease the risk of missing hip impingement and associated conditions.



Dr. Goldstein

Dr. Millis

Drs. Goldstein and Millis are members of the AAP Section on Orthopaedics.

New medication a major breakthrough for cystic fibrosis patients

by **Deborah K. Froh, M.D., FAAP**, and **Amy B. Dettori, M.D.**

In a major breakthrough, a new drug therapy that addresses the basic cellular defect in cystic fibrosis (CF) has become available, representing a triumph of 30 years of bench-to-bedside progress.

Historically, treatment options for people with CF have been mainly supportive and targeted toward end organ effects in the lungs, sinuses, digestive tract and elsewhere. Characteristic pulmonary and gastrointestinal problems such as thick mucus, chronic lung infections, failure to thrive and pancreatic insufficiency require intense management beginning in infancy.

Most CF cases now are diagnosed by newborn screening, with prompt referral to an accredited care center to initiate education, follow-up and treatment. Pediatricians likely are familiar with the early concerns centered on growth and nutrition, as well as the gradual onset and progression of lung manifestations during childhood.

Daily respiratory treatments are time-consuming and cumbersome, often incorporating multiple modalities such as airway clearance (e.g., chest physiotherapy or chest wall oscillating vest), nebulized mucolytics such as hypertonic saline and dornase alfa, and inhaled antibiotics. However, such regimens alone do not resolve disease symptoms adequately or eliminate the risk of exacerbations. Therefore, correcting the basic CF defect has long been a goal of therapeutic development.

In October 2019, the U.S. Food and Drug Administration approved a new drug therapy addressing the cellular defect of CF, based on dramatic results from two key clinical trials (Heijerman HGM, et al. *Lancet.* 2019;394:1940-1948; Middleton PG, et al. *N Engl J Med*. 2019;381:1809-1819). Elexacaftor-tezacaftor-ivacaftor is an oral combination "modulator" drug that specifically targets the predominant CF mutation, F508del, which is present in one or both gene copies in nearly 90% of people with CF. Almost half of the U.S. CF population is homozygous for F508del, and another 40% is heterozygous with one F508del mutation plus a different mutation in the CF gene.

The newly approved medication combines two "corrector" molecules (elexacaftor and tezacaftor) that address protein misfolding plus a "potentiator" (ivacaftor) that improves chloride channel opening. For people homozygous for F508del, data published in the *Lancet* showed a mean 10% increase in lung function (reflected by forced expiratory volume in 1 second [FEV1]) over four weeks when compared to the best previously available combination modulator, tezacaftor-ivacaftor.

For patients with just one copy of F508del, who had no previously approved modulator, there was a mean increase of 13.8% in FEV1 over four weeks, according to the study published in the *New England Journal of Medicine*.

In addition to these striking findings on lung function, the trials showed a marked reduction in respiratory

See Cystic fibrosis, page 21

Benefits of spinal anesthesia for pediatric urologic procedures continue to evolve

by **Gina Lockwood, M.D., M.S., FAAP**

It is not unusual for parents to become tearful when discussing their child having to "go under" anesthesia, the prospect of which often provokes more apprehension than surgery itself.

Over the last decade, there has been renewed interest in spinal anesthesia (SA) as an alternative to general anesthesia (GA) in some patient populations. Pediatric urologic procedures, given their frequent elective nature, pelvic location and short duration, are uniquely amenable to SA. Collaboration between urologists and anesthesiologists is underway to make SA a safe option for children at an increasing number of centers.

Pediatricians refer to surgical specialists for many conditions and are in an ideal position to support and educate parents. Thus, knowledge of current anesthesia strategies is essential.

Performing spinal anesthesia

Spinal anesthesia for surgery in children was first described in 1899, but its use has waxed and waned over the years. Local anesthetic, with or without additional agents, is injected into the cerebrospinal fluid via awake lumbar puncture, resulting in sensorimotor blockade below the mid-thorax. A peripheral IV is placed, usually in one of the insensate lower extremities. Many children will fall asleep without additional medications, likely due to loss of sensation over the anesthetized area. Oral sucrose can be given for additional soothing, with pharmacologic sedation as needed.

If conditions are suboptimal, usually secondary to inability to place the spinal needle or excessive patient movement, GA can be administered. The rate of conversion from SA to GA is estimated to be around 15%.

Inadequate block is by far the most common adverse event. More serious complications such as bradycardia, cerebrospinal fluid leak and high spinal block are rare.

A multidisciplinary approach is required among all operating room personnel to ensure a successful anesthetic, as the management of an awake child in the operating room can be challenging. SA is particularly appropriate for patients younger than 6-12 months of age and for surgery lasting less than one to two hours. With sufficient expertise, SA can be used in older children and for longer procedures.

Courtesy of Stephen Robert Hays, M.D., M.S., FAAP

Many children undergoing procedures with spinal anesthesia, like this 6-month-old male, fall asleep without additional medications, likely due to loss of sensation over the anesthetized area.

Benefits of spinal anesthesia

Renewed interest in SA in recent years can be attributed at least partially to strategies seeking to avoid potentially neurotoxic general anesthetics in young children. Animal studies have reproducibly shown multiple adverse neurocognitive effects of GA in developmentally immature subjects, with particular vulnerability in the early neonatal period.

Results of several recent prospective studies on the effects of a single, brief GA in healthy children are reassuring. However, the neurocognitive consequences of repeated or prolonged GA in young patients remain unknown, and the optimal time to perform elective surgeries under GA in children remains controversial.

In addition to avoidance of potential neurotoxicity, current research shows additional benefits to SA. It can be used as the sole anesthetic in many cases, obviating the need for airway management, sedatives and opioids. Advantages in the early neonatal period are particularly compelling, as age is inversely correlated with cardiorespiratory risk of GA. In a recent series, SA patients were less likely than GA patients to receive narcotics and supplemental medications, including corticosteroids, intraoperatively. No complications of SA were noted (Ebert KM, et al. *J Pediatr Urol.* 2019;15:49.e1-49.e5).

For parents, SA not only alleviates the anxiety associated with intubation and sedation, but also promotes more rapid reunion with their child, often bypassing stage 1 recovery. If the child never goes to sleep, there is no delay waking up. SA also has implications for cost, potentially shortening operating room, recovery and turnover times with associated cost savings.

SA an option for many urological procedures

Urologists and anesthesiologists at an increasing number of centers are offering SA for procedures, including circumcision, circumcision revision, hidden penis repair, chordee repair, distal hypospadias repair, orchiopexy and hydrocele repair. SA also is an option for early neonatal procedures, including ureterocele puncture, posterior urethral valve ablation, cutaneous vesicostomy, inguinal hernia repair and testicular torsion exploration.

Importantly, use of SA can make the decision of whether to operate at a young age more straightforward, as some providers advocate that urologic procedures be deferred at an early age because of the increased cardiopulmonary risks of GA.

Emmett Whitaker, M.D., a pediatric anesthesiologist at the University of Vermont, states that often it takes watching only a few cases to convince interested parties of the merits of SA and that "parents' eyes light up when you tell them their child may not need a breathing tube."

With continued research and collaboration, spinal anesthesia may become a more widely used alternative to "going under" for children undergoing not only urologic but numerous other types of procedures.

***Dr. Lockwood** is a member of the AAP Section on Urology.*

Cystic fibrosis *continued from page 20*

symptom scores and in the rate of pulmonary exacerbations requiring intravenous antibiotics or hospitalizations, which became approximately one-fourth as likely. Extrapulmonary effects also were found, such as increased body mass index and a dramatic reduction in sweat chloride concentrations to levels near or below the CF diagnosis threshold of 60 mmol/L.

To help put the pulmonary findings in perspective, the natural rate of FEV1 decline in CF has been about 1%-2% predicted per year with previous supportive therapies. Based on the large and sustained boost in FEV1 seen within weeks of starting elexacaftor-tezacaftor-ivacaftor, there appears to be potential to reverse years of lung function decline and possibly reduce the rate of loss.

Furthermore, the oral route of administration means that effects are systemic, which could favorably impact not only nutrition but also other complications such as CF-related diabetes or liver disease.

With the development of this highly effective modulator, and its applicability to up to 90% of patients, the morbidity and mortality commonly associated with CF is likely to change significantly.

The drug is approved for patients ages 12 and older, but trials are exploring expansion to younger patients, as early initiation could maximize long-term benefits. Children who are not eligible for this drug (about 10% have no F508del) or are younger than the approved age for the new triple combination therapy still may struggle with nutrition and respiratory illness. However, pediatricians should anticipate a more optimistic outlook, including improved quality of life and potentially enhanced survival for their CF patients. There is even the prospect that daily care regimens could be simplified.

While not a true cure, this therapy is a major breakthrough in the treatment of CF and gives new hope to affected children and their families.

Dr. Froh

Dr. Dettori

***Dr. Froh** is a member of the AAP Section on Pediatric Pulmonology and Sleep Medicine. **Dr. Dettori** is a pediatric pulmonology fellowship trainee and section member.*

Treatment of pilonidal disease based on symptom acuity, extent of disease

by **Loren Berman, M.D., FAAP**, and
Steven Lee, M.D., M.B.A., FAAP

Pilonidal disease is a common and often chronic disease of the skin/soft tissue in the sacrococcygeal region. It occurs in roughly 26 per 100,000 individuals in the U.S., and is more frequent in males than females (2:1 to 4:1).

Pilonidal disease typically starts in adolescence and is most prevalent in older teenagers and young adults. The mean age of presentation is 19 years for women and 21 years for men.

Pilonidal disease is an acquired problem and has multiple contributing factors. Predisposing anatomic factors include hirsutism, obesity and a deep gluteal cleft. Lifestyle factors include sedentary habits and prolonged sitting.

Hair is the inciting factor underlying pilonidal disease. Although the exact mechanism is unclear, hair and debris become trapped below the skin. A foreign body reaction against the subcutaneous hair and debris occurs, leading to inflammation, infection and/or chronic granulation tissue. Inflammation and granulation tissue often develop into draining, epithelialized sinuses or pits. In the setting of infection with inadequate drainage, an abscess will develop.

About half of patients with pilonidal disease will present with an acute infection with significant pain. The other half will present with chronic, intermittent symptoms of bloody drainage or foul-smelling discharge.

Treating abscesses and chronic disease

Treatment is based on symptom acuity and extent of the disease.

Incision and drainage is indicated for pilonidal abscess. This procedure often can be done under local anesthetic with or without sedation. In cases of larger or more extensive abscess, general anesthesia may be required. Once the infection is eradicated, patients are re-evaluated for chronic or recurrent disease.

Various operative techniques can be used to treat chronical pilonidal disease, but there is no consensus on which is preferable. Wide local excision with or without skin closure has been the mainstay of treatment but is associated with significant pain, morbidity and a high recurrence rate. Thus, many have advocated for rotational or advancement flaps. Flap techniques, however, are more complex and often require drain placement and postoperative hospitalization.

Recently, the trend has been to preserve as much normal tissue as possible.

One technique of unroofing and marsupialization consists of simply unroofing the sinuses to clean out the hair, debris and granulation tissue and leave the wound open. This technique has low morbidity and low risk of recurrence, but time to full healing is lengthy.

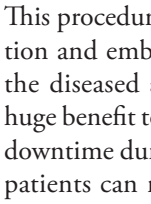
A more recent technique called the Gips procedure has shown promising early results in children. This procedure is less invasive than flap reconstruction and embraces the principle of removing only the diseased area and preserving normal skin. A huge benefit to patients is that there is practically no downtime during the recovery. Even active, athletic patients can resume normal activity within a few days. With flap reconstruction, significant activity restriction is important because there is a danger of wound breakdown if the patient does so much as sit directly on the wound.

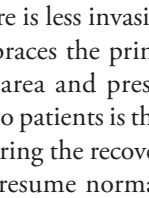
During the Gips procedure, a circular skin biopsy instrument is used to remove each pit that connects the skin to the pilonidal cyst. The surgeon curettes out the debris and hair through these small circular incisions and leaves the surrounding skin intact. The area is irrigated copiously with saline and sodium peroxide, and the circular incisions are left open to heal by secondary intention. Some surgeons do the procedure in the office, but most commonly it is performed in the operating room under sedation or general anesthesia.

After a Gips procedure, patients are counseled that they can expect drainage from the open areas for days to weeks. Gradually, the circular areas heal from the inside out. Occasionally, the procedure needs to be repeated, but this generally is well-tolerated since the recovery is easy.

One of the guiding principles of pilonidal disease management is to avoid wide local excision if possible due to issues with wound healing and recurrence. The Gips procedure offers an alternative with far less morbidity and promising results. Although not all patients with pilonidal disease will require an operation, experienced surgeons should be involved with the management of patients with pilonidal disease.

Regardless of whether a surgical procedure is performed, hygiene (regular, thorough cleansing of the gluteal cleft) and hair removal are essential to prevent flare-ups.


Dr. Berman


Dr. Lee

Drs. Berman and Lee are members of the AAP Section on Surgery.

Pediatric information added to labeling for 80 drugs, vaccines, blood products

from the **Food and Drug Administration's Office of Pediatric Therapeutics, the Center for Drug Evaluation and Research, Division of Pediatric & Maternal Health** and the **Center for Biologics Evaluation and Research**

The Food and Drug Administration (FDA) continues efforts to increase the availability of pediatric information in therapeutic product labeling. From January 2019 through April 2020, new pediatric information was added to the labeling of 74 drugs, one allergenic product, two vaccines and three blood products, covering a broad range of therapeutic areas (see table).

For some products, the new pediatric information represents the first approval in pediatric patients with the indicated condition, including:

- chronic hepatitis C virus (HCV) infection, including genotypes 1, 4, 5 and 6 (Epclusa [sofosbuvir/velpatasvir] and Harvoni [ledipasvir/sofosbuvir]);
- fibromyalgia (Cymbalta [duloxetine]);
- stable symptomatic heart failure due to dilated cardiomyopathy (Corlanor [ivabradine]);
- symptomatic heart failure with systemic left ventricular systolic dysfunction (Entresto [sacubitril/valsartan]) and
- systemic lupus erythematosus (Benlysta [belimumab]).

The FDA approved new pediatric-friendly dosage forms for several products, including oral pellets for treatment of pediatric patients 3 years and older with chronic HCV infection (Harvoni [ledipasvir/sofosbuvir] and Sovaldi [sofosbuvir]); an oral solution for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients 6 months and older (Corlanor Oral Solution [ivabradine]); and a nasal powder for treatment of severe hypoglycemia in pediatric patients 4 years and older with diabetes (Baqsimi [glucagon]).

New pediatric labeling for caffeine citrate (Cafcit Injection), clindamycin (Cleocin Phosphate) and doxycycline (Actilate, Actilate Cap, Doryx, Doryx MPC, Vibramycin, Vibra-Tabs) resulted from studies conducted by the Pediatric Trials Network under the Best Pharmaceuticals for Children Act (BPCA). In collaboration with the National Institute of Child Health and Human Development, BPCA provides a mechanism to study drugs that no longer are under patent to obtain pediatric dosing, safety or efficacy data.

Revised labeling for caffeine citrate now allows for a broader gestational age range and longer duration for treatment of apnea of prematurity. Revised labeling for clindamycin and doxycycline now includes weight-based dosing recommendations for oral and intravenous dosage forms.

Pediatric studies did *not* demonstrate efficacy for seven drugs: Abraxane (paclitaxel) for recurrent or refractory pediatric solid tumors, Opana (oxymorphone hydrochloride) for postoperative pain, Mydayis (mixed salts of a single-entity amphetamine) for attention-deficit/hyperactivity disorder (ADHD) in pediatric patients 12 years and younger, Aptensio XR (methylphenidate hydrochloride) for ADHD in pediatric patients 6 years and younger, Sutent (sunitinib malate) for refractory solid tumors, Chantix (varenicline) as an aid to smoking cessation treatment and Viibryd (vilazodone hydrochloride) for major depressive disorder.

RESOURCE

Information on pediatric labeling changes since 1998 can be found at http://bit.ly/2pPzga0.

Examples of products with new pediatric labeling changes

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Drugs		
Avycaz (ceftazidime/avibactam)	Complicated urinary tract infection and complicated intra-abdominal infection in pediatric patients 3 months and older	March 2019
Baqsimi Nasal Powder (glucagon)	Severe hypoglycemia in pediatric patients with diabetes 4 years and older	July 2019
Benlysta (belimumab)*	Active, auto-antibody positive systemic lupus erythematosus in pediatric patients 5 years and older	April 2019
Cafcit (caffeine citrate) Injection	Apnea of prematurity Previously indicated for short-term use in infants 28 to less than 32 weeks gestational age (GA) New labeling information: • Lower and upper GA limits were removed to include a broader range of premature infants • The term "short-term" was removed, allowing for a longer treatment duration	March 2020
Corlanor Oral Solution (ivabradine)*	Stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients 6 months and older	April 2019
Cymbalta (duloxetine)*	Fibromyalgia in pediatric patients 13 years and older	April 2020
Descovy (emtricitabine/tenofovir alafenamide)	HIV-1 pre-exposure prophylaxis in at-risk adolescents weighing at least 35 kilograms (kg)	October 2019
Entresto (sacubitril/valsartan)*	Symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients 1 year and older	October 2019
Epclusa (sofosbuvir/velpatasvir)*	Chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 infection in pediatric patients 6 years and older weighing at least 17 kg	March 2020
Fiasp (insulin aspart)	Diabetes mellitus in pediatric patients	December 2019
Harvoni (ledipasvir/sofosbuvir)*	Chronic hepatitis C virus genotype 1, 4, 5 or 6 infection in pediatric patients 3 years and older	November 2019
Sorilux (calcipotriene) Topical	Plaque psoriasis of the scalp and body in pediatric patients 4 years and older	November 2019
Teflaro (ceftaroline fosamil) Injection	Acute bacterial skin and skin structure infections in pediatric patients at least 34 weeks gestational age and 12 days postnatal age to less than 2 years	September 2019
Zovirax (acyclovir) Injection	Neonatal herpes simplex virus infection Updated dosing regimen: • 20 mg/kg every 8 hours for 21 days for post-menstrual age (PMA) ≥34 weeks • 20 mg/kg every 12 hours for 21 days for PMA <34 weeks	January 2019
Allergenic product		
Palforzia (Peanut [Arachis hypogaea] Allergen Powder-dnfp)	Mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in pediatric patients 4 years and older with a confirmed diagnosis of peanut allergy	January 2020
Vaccine		
Dengvaxia(Dengue Tetravalent Vaccine, Live)	Prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in pediatric patients 9 years and older	May 2019

* First approval in pediatric patients with the indicated condition

BEXSERO
Meningococcal Group B Vaccine

GOING HALFWAY

The person depicted here is a model used for illustrative purposes only.

It takes 2 doses to complete the BEXSERO vaccination series[1]

According to 2018 CDC survey data, **only 17.2% of 17-year-olds had received at least 1 dose of a meningococcal serogroup B (MenB) vaccine.**[2] That means you could have patients who started the series and haven't come back for their second dose. And since there's no telling if a patient will return to your office to finish the series on their own, it's important that you remind them.

CDC=Centers for Disease Control and Prevention.

Indication for BEXSERO

BEXSERO is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. BEXSERO is approved for use in individuals aged 10 through 25 years.

Approval of BEXSERO is based on demonstration of immune response, as measured by serum bactericidal activity against three serogroup B strains representative of prevalent strains in the United States. The effectiveness of BEXSERO against diverse serogroup B strains has not been confirmed.

Important Safety Information for BEXSERO

- BEXSERO is contraindicated in cases of hypersensitivity, including severe allergic reaction, to any component of the vaccine, or after a previous dose of BEXSERO
- Appropriate observation and medical treatment should always be readily available in case of an anaphylactic reaction following the administration of the vaccine
- The tip caps of the prefilled syringes contain natural rubber latex, which may cause allergic reactions
- Syncope (fainting) can occur in association with administration of BEXSERO. Ensure procedures are in place to avoid injury from falling associated with syncope
- The most common solicited adverse reactions observed in clinical trials were pain at the injection site (≥83%), myalgia (≥48%), erythema (≥45%), fatigue (≥35%), headache (≥33%), induration (≥28%), nausea (≥18%), and arthralgia (≥13%)

DOESN'T CUT IT

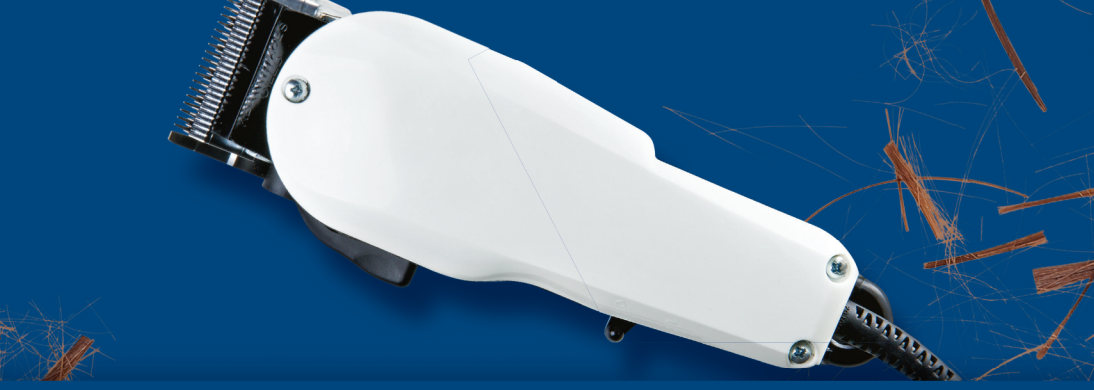
Consider scheduling the second dose during the holiday break

Remember: BEXSERO offers the fastest MenB vaccination series—allowing you to complete vaccination with 2 doses in as fast as 1 month.[1,3]

Vaccination may not protect all recipients.

Learn more about creating a MenB vaccination protocol in your practice

Visit **ScheduleTheSeries.com**



Important Safety Information for BEXSERO (cont'd)

- Vaccination with BEXSERO may not provide protection against all meningococcal serogroup B strains
- Some individuals with altered immunocompetence may have reduced immune responses to BEXSERO
- Individuals with certain complement deficiencies and individuals receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *Neisseria meningitidis* serogroup B even if they develop antibodies following vaccination with BEXSERO
- Vaccination with BEXSERO may not result in protection in all vaccine recipients

Please see Brief Summary of Prescribing Information for BEXSERO following this ad.

References: 1. Prescribing Information for BEXSERO. **2.** Centers for Disease Control and Prevention. National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years—United States, 2018. *MMWR*. 2019;68(33):718-723. **3.** Prescribing Information for Trumenba.

BRIEF SUMMARY

BEXSERO (Meningococcal Group B Vaccine)
suspension, for intramuscular injection

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

BEXSERO is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. BEXSERO is approved for use in individuals aged 10 through 25 years.

Approval of BEXSERO is based on demonstration of immune response, as measured by serum bactericidal activity against three serogroup B strains representative of prevalent strains in the United States. The effectiveness of BEXSERO against diverse serogroup B strains has not been confirmed.

4 CONTRAINDICATIONS

Hypersensitivity, including severe allergic reaction, to any component of the vaccine, or after a previous dose of BEXSERO *[see Description (11) of full prescribing information]*.

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Reactions

Appropriate observation and medical treatment should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

5.2 Syncope

Syncope (fainting) can occur in association with administration of BEXSERO. Ensure procedures are in place to avoid injury from falling associated with syncope.

5.3 Latex

The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions.

5.4 Limitation of Vaccine Effectiveness

BEXSERO may not protect all vaccine recipients. BEXSERO may not provide protection against all meningococcal serogroup B strains *[see Clinical Pharmacology (12.1) of full prescribing information]*.

5.5 Altered Immunocompetence

Some Individuals with altered immunocompetence may have reduced immune responses to BEXSERO.

Complement Deficiency

Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *N. meningitidis* serogroup B even if they develop antibodies following vaccination with BEXSERO *[see Clinical Pharmacology (12.1) of full prescribing information]*.

6 ADVERSE REACTIONS

The most common solicited adverse reactions observed in clinical trials were pain at the injection site (≥83%), myalgia (≥48%), erythema (≥45%), fatigue (≥35%), headache (≥33%), induration (≥28%), nausea (≥18%), and arthralgia (≥13%).

6.1 Clinical Trials Experience

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

In 4 clinical trials, 3,058 individuals aged 10 through 25 years received at least one dose of BEXSERO, 1,436 participants received only BEXSERO, 2,089 received only placebo or a control vaccine, and 1,622 participants received a mixed regimen (placebo or control vaccine and BEXSERO).

In a randomized controlled study[1] conducted in U.S. and Poland, 120 participants aged 10 through 25 years received at least 1 dose of BEXSERO, including 112 participants who received 2 doses of BEXSERO 2 months apart; 97 participants received saline placebo followed by MENVEO [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine]. Across groups, median age was 13 years, males comprised 49%, and 60% were white, 34% were Hispanic, 4% were black, <1% were Asian, and 2% were other.

In a second randomized controlled study[2] conducted in Chile, all subjects (N=1,622) aged 11 through 17 years received at least 1 dose of BEXSERO. This study included a subset of 810 subjects who received 2 doses of BEXSERO 1 or 2 months apart. A control group of 128 subjects received at least 1 dose of placebo containing aluminum hydroxide. A subgroup of 128 subjects received 2 doses of BEXSERO 6 months apart. In this study, median age was 14 years, males comprised 44%, and 99% were Hispanic.

In a third randomized controlled study[3] conducted in the United Kingdom (U.K.), 974 university students aged 18 through 24 years received at least 1 dose of BEXSERO, including 932 subjects who received 2 doses of BEXSERO 1 month apart. Comparator groups received 1 dose of MENVEO followed by 1 dose of placebo containing aluminum hydroxide (n=956) or 2 doses of IXIARO (Japanese Encephalitis Vaccine, Inactivated, Adsorbed) (n=947). Across groups, median age was 20 years, males comprised 46%, and 88% were white, 5% were Asian, 2% were black, <1% were Hispanic, and 4% were other.

In an uncontrolled study[4] conducted in Canada and Australia, 342 participants aged 11 through 17 years received at least 1 dose of BEXSERO, including 338 participants who received 2 doses of BEXSERO 1 month apart. The median age was 13 years, males comprised 55%, and 80% were white, 10% were Asian, 4% were Native American/Alaskan, and 4% were other.

Local and systemic reactogenicity data were solicited from all participants in the studies conducted in Chile, U.S./Poland, Canada/Australia, and in a subset of participants in the U.K. study. Reports of unsolicited adverse events occurring within the first 7 days after each vaccination were collected in all studies. In the U.S./Poland study, reports of unsolicited adverse events were collected up to 1 month after the second vaccination.

Reports of all serious adverse events, medically attended adverse events, and adverse events leading to premature withdrawal were collected throughout the study period for the studies conducted in Chile (12 months), U.K. (12 months), U.S./Poland (8 months), and Canada/Australia (2 months).

Solicited Adverse Reactions

The reported rates of local and systemic reactions among participants aged 10 through 25 years following each dose of BEXSERO administered 2 months apart or control in the U.S./Polish study[1] are presented in Table 1.

Table 1: Percentage of U.S. and Polish Participants Aged 10 through 25 Years Reporting Solicited Local and Systemic Adverse Reactions within 7 Days after BEXSERO or Control, by Dose

		Dose 1		Dose 2[b]	
		BEXSERO	Placebo (Saline)	BEXSERO	MENVEO
Solicited Reaction[a]		**n = 110-114**	**n = 94-96**	**n = 107-109**	**n = 90-92**
Local Adverse Reactions					
Pain	Any	90	27	83	43
	Mild	27	20	18	26
	Moderate	44	5	37	9
	Severe	20	2	29	8
Erythema	Any	50	13	45	26
	1-25 mm	41	11	36	13
	>25-50 mm	6	1	5	6
	>50-100 mm	3	0	5	4
	>100 mm	0	0	0	2
Induration	Any	32	10	28	23
	1-25 mm	24	9	22	16
	>25-50 mm	7	0	4	0
	>50-100 mm	1	1	2	4
	>100 mm	0	0	0	2
Systemic Adverse Reactions					
Fatigue	Any	37	22	35	20
	Mild	19	17	18	11
	Moderate	14	5	10	7
	Severe	4	0	6	2
Nausea	Any	19	4	18	4
	Mild	12	3	10	3
	Moderate	4	1	5	1
	Severe	4	0	4	0
Myalgia	Any	49	26	48	25
	Mild	21	20	16	14
	Moderate	16	5	19	7
	Severe	12	1	13	4
Arthralgia	Any	13	4	16	4
	Mild	9	3	8	2
	Moderate	3	1	6	2
	Severe	2	0	2	0
Headache	Any	33	20	34	23
	Mild	19	15	21	8
	Moderate	9	4	6	12
	Severe	4	1	6	3
Fever	≥38°C	1	1	5	0
	38.0-38.9°C	1	1	4	0
	39.0-39.9°C	0	0	1	0
	≥40°C	0	0	0	0

Clinicaltrials.gov Identifier NCT01272180.

[a] Erythema and induration: Any (≥1 mm). Pain and systemic reactions: Mild (transient with no limitation in normal daily activity); Moderate (some limitation in normal daily activity); Severe (unable to perform normal daily activity).

[b] Administered 2 months after Dose 1.

(continued on next page)

Solicited adverse reaction rates were similar among participants aged 11 through 24 years who received BEXSERO in the other 3 clinical studies,[2,3,4] except for severe myalgia which was reported by 3% to 7% of subjects. Severe pain was reported by 8% of university students in the U.K.[3]

Non-serious Adverse Reactions

In the 3 controlled studies[1,2,3] (BEXSERO n=2,221, control n=2,204), non-serious unsolicited adverse events that occurred within 7 days of any dose were reported by 439 (20%) participants receiving BEXSERO and 197 (9%) control recipients. Unsolicited adverse reactions that were reported among at least 2% of participants and were more frequently reported in participants receiving BEXSERO than in control recipients were injection site pain, headache, and injection site induration unresolved within 7 days, and nasopharyngitis.

Serious Adverse Events

Overall, in clinical studies, among 3,058 participants aged 10 through 25 years who received at least 1 dose of BEXSERO, 66 (2.1%) participants reported serious adverse events at any time during the study. In the 3 controlled studies[1,2,3] (BEXSERO n=2,716, control n=2,078), serious adverse events within 30 days after any dose were reported in 23 (0.8%) participants receiving BEXSERO and 10 (0.5%) control recipients.

6.2 Additional Pre-licensure Safety Experience

In response to outbreaks of serogroup B meningococcal disease at 2 universities in the U.S., BEXSERO was administered as a 2-dose series at least 1 month apart. Information on serious adverse events was collected for a period of 30 days after each dose from 15,351 individuals aged 16 through 65 years who received at least 1 dose. Overall 50 individuals (0.3%) reported serious adverse events, including one reaction considered related to vaccination, a case of anaphylaxis within 30 minutes following vaccination.

6.3 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of BEXSERO. 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 the vaccine.

General Disorders and Administration Site Conditions

Injection site reactions (including extensive swelling of the vaccinated limb, blisters at or around the injection site, and injection site nodule which may persist for more than 1 month).

Immune System Disorders

Allergic reactions (including anaphylactic reactions), rash, eye swelling.

Nervous System Disorders

Syncope, vasovagal responses to injection.

7 DRUG INTERACTIONS

Sufficient data are not available to establish the safety and immunogenicity of concomitant administration of BEXSERO with recommended adolescent vaccines.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a 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% to 4% and 15% to 20%, respectively.

There are no adequate and well-controlled studies of BEXSERO in pregnant women in the U.S. Available human data on BEXSERO administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

A developmental toxicity study was performed in female rabbits administered BEXSERO prior to mating and during gestation. The dose was 0.5 mL at each occasion (a single human dose is 0.5 mL). This study revealed no adverse effects on fetal or pre-weaning development due to BEXSERO (*see Data*).

Data

Animal Data: In a developmental toxicity study, female rabbits were administered BEXSERO by intramuscular injection on Days 29, 15, and 1 prior to mating and on Gestation Days 7 and 20. The total dose was 0.5 mL at each occasion (a single human dose is 0.5 mL). No adverse effects on pre-weaning development up to Postnatal Day 29 were observed. There were no fetal malformations or variations observed.

8.2 Lactation

Risk Summary

It is not known whether the vaccine components of BEXSERO are excreted in human milk. Available data are not sufficient to assess the effects of BEXSERO on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for BEXSERO and any potential adverse effects on the breastfed child from BEXSERO or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness of BEXSERO have not been established in children younger than 10 years.

8.5 Geriatric Use

Safety and effectiveness of BEXSERO have not been established in adults older than 65 years.

15 REFERENCES

1. NCT01272180 (V102_03).
2. NCT00661713 (V72P10).
3. NCT01214850 (V72_29).
4. NCT01423084 (V72_41).

17 PATIENT COUNSELING INFORMATION

Give the patient, parent, or guardian the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Inform patients, parents, or guardians about:

- The importance of completing the immunization series.
- Reporting any adverse reactions to their healthcare provider.

Manufactured by **GSK Vaccines, Srl**
Bellaria-Rosia 53018, Sovicille (SI), Italy
U.S. License No. 1617

Distributed by **GlaxoSmithKline**
Research Triangle Park, NC 27709

BXS:5BRS

Revised: 10/2019

BEXJRNA200008 July 2020
Produced in USA.

2020 AAP Award Winners

Editor's note: *The award winners' AAP committee, section and council affiliations are listed except when they are a member of the same group issuing the award.*

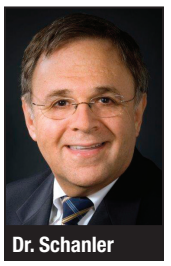
AAP Education Award


Dr. Schubert

Council on Communications and Media, Committee on Pediatric Education, Committee on Continuing Medical Education
Charles J. Schubert, M.D., FAAP

He is division director of Urban, Underserved and Global Health in the Department of Family and Community Medicine at University of Cincinnati College of Medicine, and professor of pediatrics at Cincinnati Children's Hospital. Dr. Schubert is a member of the Section on Emergency Medicine and Section on Global Health.

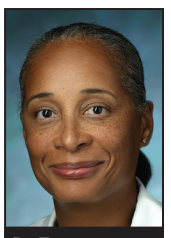
AAP Samuel J. Fomon Nutrition Award


Dr. Schanler

Committee on Nutrition
Supported by the Infant Nutrition Council of America
Richard J. Schanler, M.D., FABM, FAAP

He is director of neonatal-perinatal medicine at Cohen Children's Medical Center and Northwell Health in Long Island, N.Y., and professor of pediatrics at Zucker School of Medicine at Hofstra/Northwell. Dr. Schanler is a founding member of the Section on Breastfeeding and former chair of its executive committee. He is senior editor of the AAP/ACOG *Breastfeeding Handbook for Physicians*. He is a member of the Section on Neonatal-Perinatal Medicine.

Adele Dellenbaugh Hofmann Award


Dr. Trent

Section on Adolescent Health
Maria E. Trent, M.D., M.P.H., FSAHM, FAAP

She is chief of the Division of Adolescent/Young Adult Medicine at Johns Hopkins Children's Center; director of the adolescent medicine fellowship program; and professor of pediatrics, public health and nursing at Johns Hopkins University. Dr. Trent also is Bloomberg Professor of American Health at Johns Hopkins Bloomberg School of Public Health. Immediate past chair of the AAP Section on Adolescent Health Executive Committee, she is the liaison from the Society for Adolescent Health and Medicine to the Committee on Adolescence.

Advocacy Award


Dr. Maholtz

Section on Critical Care
Danielle Maholtz, D.O., FAAP

She is a clinical fellow in the Division of Critical Care Medicine at Cincinnati Children's Hospital.


Dr. Reddy

Anireddy Reddy, M.D., FAAP

She is a pediatric critical care fellow at Children's Hospital of Philadelphia. Dr. Reddy is a member of the Section on Pediatric Trainees.

Arnold J. Capute Award


Dr. Norwood

Council on Children with Disabilities
Kenneth W. Norwood Jr., M.D., FAAP

He is professor of pediatrics at the University of Virginia Children's Hospital in Charlottesville. Dr. Norwood is a member of the Section on Developmental and Behavioral Pediatrics and Section on Uniformed Services.

Avroy Fanaroff Neonatal Education Award


Dr. Benitz

Section on Neonatal-Perinatal Medicine
Sponsored by Mead Johnson Nutrition
William E. Benitz, M.D., FAAP

He is the Philip Sunshine Professor in Neonatology Emeritus at Stanford University School of Medicine.

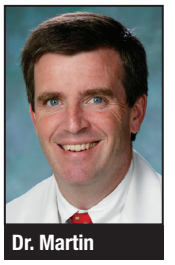
Award for Outstanding Service to Maltreated Children


Dr.Crawford-Jakubiak

Council on Child Abuse and Neglect
James E. Crawford-Jakubiak, M.D., FAAP

He is medical director of the Center for Child Protection at the UCSF Benioff Children's Hospital, Oakland and professor of pediatrics at the UCSF School of Medicine. Dr. Crawford-Jakubiak is a member of the Section on LGBT Health and Wellness.

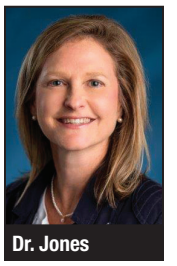
Award for Pediatric Innovation


Dr. Martin

Section on Advances in Therapeutics and Technology
Gerard R. Martin, M.D.

He is a cardiologist and medical director of global services at Children's National Hospital.

Bret Ratner Pediatric Allergy and Immunology Research Award


Dr. Jones

Section on Allergy and Immunology
Sponsored by Abbott Nutrition
Stacie M. Jones, M.D., FAAP

She is professor of pediatrics and chief of allergy and immunology at University of Arkansas for Medical Sciences and Arkansas Children's Hospital.

Byron Oberst Award


Dr. Galvin

Council on Clinical Information Technology
Hannah K. Galvin, M.D., FAAP

She is chief medical information officer for Cambridge Health Alliance.

Calvin (C.J.) Sia Community Pediatrics Medical Home Leadership and Advocacy Award


Dr. Nageswaran

Council on Community Pediatrics
Supported by the Cal Sia Endowment
Savithri Nageswaran, M.D., M.B.B.S., M.P.H., FAAP

She is professor of pediatrics at Wake Forest University Health Sciences. Dr. Nageswaran is a member of the Council on Children with Disabilities, Section on Home Care and Section on Hospice and Palliative Medicine.

C. Anderson Aldrich Award for Lifetime Achievement in Developmental-Behavioral Pediatrics


Dr. Duby

Section on Developmental and Behavioral Pediatrics
John C. Duby, M.D., FAAP

He is professor and chair of the Department of Pediatrics at Wright State University Boonshoft School of Medicine, and vice president of academic affairs, community and behavioral health at Dayton Children's Hospital. Dr. Duby is a member of the Council on Children with Disabilities, Council on Community Pediatrics and Council on Early Childhood.

2020 AAP Award Winners

Charles "Buzzy" Vanchiere Award


Dr. Lessin

Section on Administration and Practice Management
Herschel R. Lessin, M.D., FAAP

He practices at The Children's Medical Group in Poughkeepsie, N.Y. Dr. Lessin is the section liaison to the Payer Advocacy Advisory Committee and a member of the Section on Dermatology. He has been on more than a dozen medical missions.

Child Health Advocate Award


Dr. Levine

Committee on State Government Affairs
Rachel L. Levine, M.D., FAAP

She is secretary of health for the Commonwealth of Pennsylvania. Dr. Levine is recognized for "outstanding work to improve the lives of children and families in Pennsylvania." She is a member of the Section on Adolescent Health.

Clifford G. Grulee Award


Dr. Raulerson

AAP Executive Committee/ AAP Board of Directors
Marsha D. Raulerson, M.D., M.Ed., FAAP

She is a pediatrician in Brewton, Ala. Former chair of the AAP Committee on Federal Government Affairs and past president of the AAP Alabama Chapter, Dr. Raulerson has founded or led programs to improve child health locally and nationally. Dr. Raulerson is a member of the Section on Senior Members and Section on Tobacco Control.

Dave Berry Award


Dr. Bayly

Section on Uniformed Services
Lt. Cmdr. Terrence Bayly, M.D., FAAP

He is director of the graduate medical education department and staff pediatrician at the U.S. Naval Hospital in Naples, Italy.

Dale Richmond/Justin Coleman Award


Dr. Schonfeld

Section on Developmental and Behavioral Pediatrics
Supported by the Richmond/ Coleman Endowment
David J. Schonfeld, M.D., FAAP

He established and directs the National Center for School Crisis and Bereavement at Children's Hospital Los Angeles (see Martin C. Ushkow Award) and is professor of clinical pediatrics at Keck School of Medicine. Dr. Schonfeld, a developmental-behavioral pediatrician, is a member of the Council on Children and Disasters Executive Committee, Council on Children with Disabilities and Council on School Health.

David W. Smith Award for Excellence in Genetics and Birth Defects Education


Dr. Jones

Council on Genetics
Marilyn C. Jones, M.D., FAAP

She is Distinguished Professor of Clinical Pediatrics and the Benard L. Maas Chair in Inherited Metabolic Disease at the University of California, San Diego School of Medicine in La Jolla. Dr. Jones is a former member of the council's executive committee.

Distinguished Career Award


Dr. Conway

Section on Critical Care
Edward E. Conway Jr., M.D., M.S., FCCM, FAAP

He is chief of pediatric critical care medicine and vice chair of the Lewis M. Fraad Department of Pediatrics at Jacobi Medical Center in Bronx, N.Y. Dr. Conway is a member of the Section on Emergency Medicine, Council on Child Abuse and Neglect, and Council on Injury, Violence and Poison Prevention.

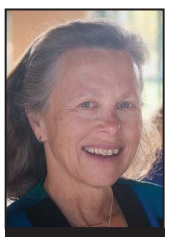
Distinguished Service Award


Dr. Raney

Section on Orthopaedics
Supported by Shriners Hospitals for Children
Ellen M. Raney, M.D., FAAP

She is affiliate professor in the Department of Orthopaedics and Rehabilitation at Oregon Health and Science University in Portland and a pediatric orthopedic surgeon at Shriners Hospital for Children – Portland. Dr. Raney is a member of the Council on Children with Disabilities.

Donald W. Schiff, M.D., FAAP, Child Advocacy Award


Dr. Gladstone

Section on Senior Members
Gwendolyn (Wendy) R. Gladstone, M.D., FAAP

She is a retired child abuse pediatrician who maintains an administrative volunteer position with the Child Advocacy and Protection Program at Children's Hospital at Dartmouth. Dr. Gladstone serves on New Hampshire state committees addressing child health and wellness issues and is active in the AAP New Hampshire Chapter.

Dr. Susan S. Aronson Early Education and Child Care Advocacy Award


Shuman

Council on Early Childhood
Steve Shuman

He is senior training and technical assistance associate in the Education Development Center at the National Center on Early Childhood Health and Wellness in Waltham, Mass.

Ellen Perrin Award for Excellence in LGBTQ+ Health and Wellness


Pawelski

Section on LGBT Health and Wellness
Jim Pawelski, M.S.

He leads LGBTQ+ health initiatives at the American Medical Association. Prior to this role, Pawelski was director of state advocacy at the AAP, where he led efforts to support chapters in state and local advocacy work, with expertise in issues related to LGBTQ+ children, families and physicians.

Emerging Leader Award


Dr. Hadland

Section on Adolescent Health
Scott E. Hadland, M.D., M.P.H., M.S., FAAP

He is an assistant professor of pediatrics at Boston Medical Center and Boston University School of Medicine.

F. Edwards Rushton CATCH Award


Dr. Plumb

District CATCH Facilitators
Supported by Rushton Endowment
Jennifer Plumb, M.D., M.P.H., FAAP

She is a pediatric emergency medicine physician, associate professor of pediatrics at the University of Utah and medical director of Utah Naloxone. Dr. Plumb's 2015 Community Access to Child Health planning grant was "Overdose Death Prevention: Naloxone Rescue Kits." She is a member of the Section on Emergency Medicine.

Henry L. Barnett Award


Dr. Norwood

Section on Nephrology
Victoria Norwood, M.D., FAAP

She is the Robert J. Roberts Professor of Pediatrics and vice chair of academic affairs in the Department of Pediatrics at University of Virginia (UVA) Health System. In addition, Dr. Norwood is chief of pediatric nephrology at UVA, where she directs clinical research activities and heads the fellowship training program.

2020 AAP Award Winners

Hillman-Olness Award for Lifetime Service and Lasting Contributions to Global Child Health


Dr. Kazembe

Section on Global Health

Peter N. Kazembe, MB.Ch.B. FRCP(C), Hon. FRCP (UK), 1954-2020

He was vice chair of the board of directors and retired executive director of Baylor College of Medicine Children's Foundation Malawi. Dr. Kazembe has been called the grandfather of pediatrics in Malawi for his work in pediatric HIV/AIDS and other areas. Professor of pediatrics at Baylor College of Medicine, he also was an adjunct faculty member at University of North Carolina.

Holroyd-Sherry Award


Dr. Moreno

Council on Communications and Media

Megan A. Moreno, M.D., M.S.Ed., M.P.H., FAAP

She is professor of pediatrics at the University of Wisconsin-Madison; vice chair of digital health for the Department of Pediatrics; and division chief for General Pediatrics and Adolescent Medicine. Dr. Moreno is principal investigator of the Social Media and Adolescent Health Research Team. She is a member of the Section on Adolescent Health.

Jim Seidel Distinguished Service Award


Dr. Bachur

Section on Emergency Medicine

Richard G. Bachur, M.D., FAAP

He is chief of the Division of Emergency Medicine at Boston Children's Hospital and the Michael W. Shannon Professor of Pediatrics and Emergency Medicine at Harvard Medical School.

Job Lewis Smith Award


Dr. Jones

Council on Community Pediatrics

Veronnie Faye Jones, M.D., Ph.D., M.S.P.H., FAAP

She is professor and associate vice president for health affairs/diversity initiatives at the University of Louisville. Dr. Jones is a member of the Council on Foster Care, Adoption and Kinship Care.

Ken Graff Young Investigator Research Award


Dr. McLaren

Section on Emergency Medicine

Supported by
the Graff Endowment

Son H. McLaren, M.D., M.S., FAAP

She is assistant professor of pediatrics and emergency medicine at Columbia University Medical Center, New York-Presbyterian, Morgan Stanley Children's Hospital in New York. Dr. McLaren received the award for "High-Throughput Sequencing Platform for the Diagnosis of Bacteremia in Children with Cancer."

Leonard Apt Lectureship Award


Dr. Donahue

Section on Ophthalmology

Sean P. Donahue, M.D., Ph.D., FAAP

He is the Coleman Professor and vice chair for clinical affairs at Vanderbilt University Medical Center in Nashville.

Local Hero Award


Dr. Shah

Council on Community Pediatrics

Shetal I. Shah, M.D., FAAP

He is a neonatologist and professor at New York Medical College. Dr. Shah is a member of the Section on Neonatal-Perinatal Medicine and Section on Tobacco Control. He is president of AAP New York Chapter 2.

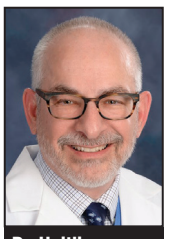
Martin C. Ushkow Community Service Award

Council on School Health

National Center for School Crisis and Bereavement

The center at Children's Hospital Los Angeles supports students through crisis and loss. Established in 1990 and directed by David J. Schonfeld, M.D., FAAP, it has assisted hundreds of schools and communities in the U.S. and abroad coping in the aftermath of tragedy.

Murray Davidson Award


Dr. Heitlinger

Section on Gastroenterology, Hepatology and Nutrition

Supported by
Abbott Laboratories

Leo A. Heitlinger, M.D., FAAP

He is a pediatric gastroenterologist at St. Luke's Hospital in Bethlehem, Pa., and a clinical professor of pediatrics at the Lewis Katz School of Medicine at Temple University. Dr Heitlinger is a board member of the AAP Pennsylvania Chapter.

Neonatal Landmark Award


Dr. Wiswell

Section on Neonatal-Perinatal Medicine

Sponsored by
Mead Johnson Nutrition

Thomas E. Wiswell, M.D., FAAP

He is a neonatologist at Kaiser Permanente Moanalua Medical Center in Honolulu. Dr. Wiswell is a member of the Section on Senior Members.

Neonatal Pioneer Award


Dr. Sola

Section on Neonatal-Perinatal Medicine

Augusto Sola, M.D.

He is an internationally known neonatologist and educator who also is director of the Ibero-American Society of Neonatology, a nonprofit public charity that promotes neonatal health.

Oral Health Service Award (national)


Dr. Fisher-Owens

Section on Oral Health

Susan A. Fisher-Owens, M.D., M.P.H., FAAP

She is a clinical professor of pediatrics at the University of California, San Francisco (UCSF) School of Medicine and clinical professor of preventive and restorative dental sciences at UCSF School of Dentistry. Dr. Fisher-Owens also is the informatics director for Pediatrics, Primary Care and Public Health Integration and clinical informaticist for the Public Hospital Redesign and Incentives in Medi-Cal and Quality Incentive Program in California. She is a former member of the Section on Oral Health Executive Committee.

Oral Health Service Award (state)


Dr. Holve

Section on Oral Health

Stephen A. Holve, M.D., FAAP

He is chief of pediatrics at Tuba City (Ariz.) Regional Health Care Corp. and clinical instructor in pediatrics at Johns Hopkins University School of Medicine. Dr. Holve served as the chief clinical consultant in pediatrics for the Indian Health Service for 16 years. He is a member of the Indian Health Special Interest Group and Council on Community Pediatrics.

2020 AAP Award Winners

Outstanding Achievement Award

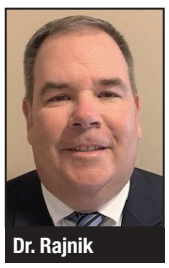

Dr. Ramos-Bonoan

Section on Epidemiology, Public Health, and Evidence and Council on Community Pediatrics

Carmen Ramos-Bonoan, M.D., FAAP

She has held a variety of public health leadership positions in New York City, including medical director of child health clinics in the city health department that provided primary pediatric care to underserved communities. Dr. Ramos-Bonoan also served as assistant commissioner of the health department's Office of Child and Adolescent Health; co-chaired a public health residency program; and held leadership roles in Reach Out and Read. She is a member of the Section on Tobacco Control, Section on Global Health and Section on International Medical Graduates.

Outstanding Service Award


Dr. Rajnik

Section on Uniformed Services

Col. (ret.) Michael Rajnik, M.D., FAAP

He is chief of the Division of Infectious Diseases and associate professor of pediatric infectious diseases in the Department of Pediatrics at Uniformed Services University of the Health Sciences. Dr. Rajnik is a member of the Section on Infectious Diseases.

Pediatric Hospital Medicine Abstract Research Award


Dr. Bonsmith

Section on Hospital Medicine

Sponsored by Abbott Nutrition
Kathleen Bonsmith, M.D., M.I.P.H., M.S., FAAP

She is a fellow at Seattle Children's Hospital. Her research was titled "Markers of social disadvantage and hospital quality of care for pediatric respiratory illness."

Richard B. Heyman Award


Dr. Upadhya

Section on Adolescent Health

Krishna K. Upadhya, M.D., M.P.H., FAAP

She is the senior medical adviser at Planned Parenthood Federation of America. Dr. Upadhya is a member of the Committee on Adolescence.

Robert M. Smith Award


Dr. Deshpande

Section on Anesthesiology and Pain Medicine

Jayant K. Deshpande, M.D., M.P.H., FAAP

He is chief of quality, safety and clinical analytics at Nemours Children's Hospital and professor of pediatrics at University of Central Florida in Orlando. Dr. Deshpande is a member of the Section on Critical Care.

Section on Infectious Diseases Award for Lifetime Contributions in Infectious Diseases Education


Dr. Baker

Section on Infectious Diseases

Carol J. Baker, M.D., FAAP

She is an adjunct professor of pediatrics at the University of Texas Health Science Center, McGovern Medical School. Dr. Baker was associate editor of the AAP *Red Book* (1998-2012) and member of the AAP Committee on Infectious Diseases (1999-2005).

Senator Daniel Inouye & Calvin C.J. Sia Advocacy Award


Dr. Attridge

Section on Emergency Medicine

Megan Attridge, M.D., FAAP

She is a pediatric emergency medicine fellow at the Ann & Robert H. Lurie Children's Hospital in Chicago. Dr. Attridge is a member of the Section on Early Career Physicians; Section on Minority Health, Equity and Inclusion; and Section on Pediatric Trainees.


Dr. Stewart

Amanda Stewart, M.D., M.P.H., FAAP

She is assistant in medicine in the Division of Emergency Medicine and lead physician for clinician advocacy in the Office of Government Relations at Boston Children's Hospital, and instructor of pediatrics at Harvard Medical School. Dr. Stewart is a member of the Council on Immigrant Child and Family Health; Section on Early Career Physicians; Section on Minority Health, Equity and Inclusion; and Section on Simulation and Innovative Learning Methods.

Steve Miller Award for Excellence in Education & Mentorship


Dr. Avner

Section on Emergency Medicine

Jeffrey R. Avner, M.D., FAAP

He is the chair of pediatrics at Maimonides Children's Hospital in Brooklyn. Dr. Avner also is professor of clinical pediatrics at SUNY Downstate Medical School. He is a member of the Section on Advances in Therapeutics and Technology.

Technological Innovations in Pediatric Emergency Medicine Award

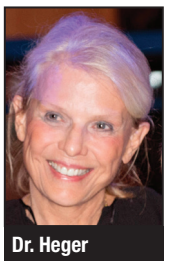

Dr. Liu

Section on Emergency Medicine

Sponsored by EBSCO Health/ DynaMed Plus
Deborah R. Liu, M.D., FAAP

She is director of process improvement and associate director of the Division of Emergency and Transport Medicine at the Children's Hospital Los Angeles. Dr. Liu also is an associate professor of clinical pediatrics at University of Southern California Keck School of Medicine.

Thomas F. Tonniges, M.D., FAAP, Lifetime Achievement Award for Advocacy on Behalf of Vulnerable Children


Dr. Heger

Council on Foster Care, Adoption and Kinship Care

Astrid Heppenstall Heger, M.D., FAAP

She is professor of clinical pediatrics and founder and CEO of the Violence Intervention Program at Keck School of Medicine of University of Southern California. Dr. Heppenstall Heger is a member of the Council on Child Abuse and Neglect.

Virginia Apgar Award


Dr. Vohr

Section on Neonatal-Perinatal Medicine

Sponsored by Abbott Nutrition
Betty R. Vohr, M.D., FAAP

She is professor of pediatrics at Alpert Medical School of Brown University and medical director of the Follow-up Clinic Program in the Department of Pediatrics, Women & Infants Hospital of Rhode Island. Dr. Vohr is a member of the Section on Developmental and Behavioral Pediatrics, Section on Breastfeeding and Section on Senior Members.

William G. Bartholome Award for Ethical Excellence


Mitchell

Section on Bioethics

Christine Mitchell, R.N., M.S.N., M.T.S., FAAN

She is executive director of the Center for Bioethics at Harvard Medical School.

Laying the groundwork for the future, AAP tackles challenges of 2010-'20

by **Alyson Sulaski Wyckoff** • *Associate Editor*

Editor's note: *This is the final installment in a series highlighting the AAP's 90th anniversary. For previous articles, visit http://bit.ly/AAP90thAnniversary.*

In the last decade leading up to its 100th anniversary, the AAP faced new and old challenges as it marked milestones.

The Affordable Care Act (ACA), a central priority, significantly boosted health coverage for children, although its future remained in peril. Bright Futures guidelines were the benchmark for preventive care in the ACA. The Children's Health Insurance Program was reauthorized in 2015, after lapsing for months; funding expired again in 2017 but was extended in 2018 through 2023. Medicaid expansion in some states also helped bring more health services to underserved children.

A new Headquarters of the Future in Itasca, Ill., took shape, and AAP staff moved into the facility (https://bit.ly/3hQL9or), which was designed to enable growth, foster innovation and better serve the Academy for years to come. Helping to shepherd development of the new home for pediatrics was then-CEO/Executive Vice President Karen Remley, M.D., M.B.A., M.P.H., FAAP.

Crises spur AAP efforts

A host of events tested the country: terrorist attacks, school shootings, the COVID-19 pandemic and measles outbreaks, separation and detention of immigrant children, racial strife and a divided nation. Hurricanes, floods and wildfires flared in certain regions.

As it has since its 1930 founding, the AAP responded with advocacy and resources.

Policy statements and reports addressed toxic stress, gun violence, e-cigarettes/vaping, opioids, media use, abusive head trauma, drowning and inequities. Guidance was issued regularly on aspects of COVID-19.

The AAP launched or improved the following: a child health data registry, revamped Neonatal Resuscitation Program, a FamilY Partnerships Network, member access to the latest news and research via Gateway, digital transformation, interactive Periodicity Schedule, AAP Mentorship program, *HealthyChildren.org en Español*, virtual meetings, pediatrician wellness efforts, the Institute for Healthy Childhood Weight and new AAP books, educational programs and other products and services.

The Academy received a grant to operate the Head Start National Center on Health, which provides training and technical assistance to help some of the nation's neediest children.

Advocacy and legislative efforts

When the National Institutes of Health finally took steps to require inclusion of children in research via the 21st Century Cures Act, it marked the culmination of decades of AAP advocacy. Among other successes, the AAP led efforts to improve payment to pediatricians, counsel about firearms, promote gun violence prevention research, implement policies to cut e-cigarette use, improve funding to strengthen the pediatric workforce, and gain emergency funding to support practices during the pandemic. It successfully pushed for a recall of deadly infant inclined sleepers.

Photo courtesy of Dipesh Navsaria, M.D., M.P.H., M.S.L.I.S., FAAP

Designed as a Headquarters of the Future, the spacious new AAP building opened in 2018 in Itasca, Ill.

The AAP spoke out against family separation and detention of immigrant children at the border.

In 2018-'19, AAP leaders, including President Colleen A. Kraft, M.D., M.B.A., FAAP, spoke out extensively and made several visits to see detained children and families at the border. A 2017 policy statement drew attention to the care needed for children in immigrant families.

Dr. Kraft also testified before Congress, as did current President Sara "Sally" H. Goza, M.D., FAAP.

"We just have to keep focusing on what we know is right for children," noted Dr. Goza at the time. "(The AAP) is for the health and well-being of all children. We can't turn our back on this."

The AAP continues to draw attention to the needs of vulnerable children and families.

"In the 90-year history of the AAP, advancing child health has often meant fighting for social justice," said AAP CEO/Executive Vice President Mark Del Monte, J.D., who in 2019 became the first nonphysician to hold the position.

In addition to national efforts, AAP chapters took stands against harmful policies impacting their states, such as vaccine exemptions, lack of children's access to Medicaid services and discrimination against transgender children and adolescents.

Policy themes

Many policy statements and reports carried overlapping guidance on how to better identify and help children overcome disparities related to poverty, separation, food insecurity, housing instability, exposure to toxins, violence and toxic stress.

Former AAP President Benard P. Dreyer, M.D., FAAP (2016), has long made poverty a priority of his work.

"Almost half of pediatric patients are poor or in financial distress, and pediatricians should support the Academy's mission statement for *all* children," he reminded attendees of the 2016 AAP National Conference & Exhibition.

In that year, the AAP Blueprint for Children recommended what the next U.S. presidential administration needed to do to improve the lives of children and make it a national priority (http://bit.ly/2dyjxT2).

"Every child and adolescent needs access to the conditions that foster healthy and safe development," the document stated.

An AAP Five-Year Strategic Plan (https://bit.ly/3jAtZf3) was issued in 2017 under Fernando Stein, M.D., FAAP, the first Latin American AAP president. Goal #1 reflects the core strengths of the Academy: advancing child health through policy, education and advocacy.

An equity agenda was established in 2019 under Kyle E. Yasuda, M.D., FAAP, the first Asian American AAP president, to promote diversity and inclusion in the organization and throughout child health. Later, task forces and other groups were established, an anti-racism policy was released and the AAP apologized for discriminating against the first two Black members, Drs. Roland Scott and Alonzo deGrate Smith. At the 2020 Annual Leadership Forum, leaders unanimously voted to hold a referendum to allow members to vote on including a broad-based anti-discrimination statement in AAP bylaws.

What is striking and inspiring is the constancy of the mission, Del Monte often says, as the AAP continues to advance child health through scientific and medical advances.

That commitment, AAP leaders insist, is fully aligned with what the founders envisioned 90 years ago.

Other AAP accomplishments

The AAP also achieved the following:

- Saw membership grow from 62,109 in 2010 to 69,677 in 2019, as new categories were added.
- Approved activities for Maintenance of Certification parts 2 and 4.
- Launched *Hospital Pediatrics* and the Pediatrics On Call podcast.
- Celebrated *Red Book's* 75th anniversary.
- Released a new edition of *Bright Futures*.
- Partnered with then-first lady Michelle Obama's Let's Move initiative.
- Released a customizable emergency plan for managing allergy and anaphylaxis.
- Hosted a summit on gun injury prevention.
- Added three new elected positions to the board of directors.
- Advocated for completion of the 2020 Census.
- Saw the first pediatrician elected to Congress (Kimberly Schrier, M.D., FAAP).
- Encouraged a Get Out the Vote campaign to prioritize children's interests in the 2020 election.

Visit the AAP Gartner Pediatric History Center at https://bit.ly/pediatrichistorycenter.

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Grants foster partnerships between primary care, DB pediatricians

from **Healthy Resilient Children, Youth and Families**

The AAP Section on Developmental and Behavioral Pediatrics (SODBP) provided grants to six chapters to encourage collaboration between pediatric primary care providers (PCPs) and developmental-behavioral pediatricians and address issues such as developmental screening, autism and early brain development.


Dr. Levine

"This grant program sought to improve local understanding of the role of developmental-behavioral pediatricians, workforce challenges on the state and local level, and relevant developmental-behavioral pediatric topics," said Jack M. Levine, M.D., FAAP, a member of the section's executive committee. "The grants also sought to improve collaboration between local chapters and SODBP."

The application period for a new round of grant proposals is open until Oct. 16 (see sidebar).


Dr. Tellerman

The Maryland Chapter, organized by Kenneth H. Tellerman, M.D., FAAP, used its grant to support the GROW YOUR KIDS: TREE (talk, read, engage, encourage) program (https://www.mdaap.org/tree/). The chapter's Emotional Health Committee developed the program to promote positive interactions between parents and children from birth to 2 years living in poverty. The grant was used to support the first large-scale implementation of the program with pediatric residents at Sinai Hospital in the children's outpatient continuity of care clinic.

The grant also supported three pediatric residents with an interest in developmental-behavioral pediatrics to present their experiences with the TREE program at the 2019 Society for Developmental-Behavioral Pediatrics National Meeting.

Deadline approaching to apply for grant program

The Section on Developmental and Behavioral Pediatrics funds up to seven one-year chapter grants of up to $2,000 each and a limited number of projects up to $3,000 to improve collaboration between primary care pediatricians and developmental-behavioral pediatricians.

Potential areas of focus include developmental impacts of disasters and crises, effects of racism on child development, early intervention, school readiness, mental health, developmental screening, primary care education, autism identification and treatment, foster care, social determinants of health, mental health of immigrants and refugees, transition and systems of care.

Applicants are encouraged to include early career physicians and/or medical students and residents in their projects.

To apply for a grant, visit www.aap.org/sodbp. Applications are due Oct. 16.

For more information, contact Carolyn McCarty at cmccarty@aap.org or 630-626-6540.

Aven J. Poynter, B.Sc., M.D., FRCPC, led the British Columbia Chapter project, which focused on developing collaboration among provincial pediatricians, developmental pediatricians and neuropsychiatrists at British Columbia Children's Hospital. The chapter organized interactive video conferences throughout the province on autism, behavioral manifestations of mental health issues and treatment, including psychopharmacologic medications and counseling.

"The sessions were well-received, and future sessions and continuing collaboration are being planned at the request of chapter members," Dr. Poynter said.


Dr. Iyengar

Sandhyaa S. Iyengar, M.D., FAAP, led the Pennsylvania Chapter project to support implementation of universal standardized developmental and autism spectrum disorder screenings in primary care pediatrics. The chapter surveyed pediatricians across the state to learn about their screening practices and their perspectives on benefits and barriers. The chapter also created a toolkit for primary care pediatricians.

The Mississippi Chapter used grant funds to support nationally recognized speakers and experts on childhood brain development at its spring meeting "Mississippi Thrive! Child Health and Development Summit" and to reduce registration costs. Speakers addressed early brain development, universal prekindergarten and using technology to support families' understanding of child development.

The meeting is part of ongoing chapter activities to encourage pediatricians to incorporate developmental-behavioral activities into their practices and to advocate for legislation that can positively impact child development.

Theodora J. Nelson, M.D., FAAP, developed nine webinars for California Chapter 3 on development and behavior in the general pediatrician's office, autism spectrum disorder, encopresis and enuresis, behavioral issues in young children, learning disabilities, tic disorders and anxiety. The topics were chosen based on a survey of chapter members. Most of the webinars are available on the chapter website (https://aapca3.org/developmental-and-behavioral-webinars/).

The webinars are part of a larger program called HealthEPupil (https://healthepupil.org/) developed by Stephen H. Carson, M.D., FAAP, to increase PCP comfort in addressing developmental and behavioral issues. The chapter plans to continue the webinar series, which was well-attended and positively reviewed.

Developmental-behavioral pediatrician Trevena B. Moore, M.D., FAAP, organized a Kansas Chapter project in which she was co-located in two resident primary care continuity clinics twice a month. She met with two to four residents and led didactic sessions on attention-deficit/hyperactivity disorder, sleep, developmental and autism surveillance and screening, toileting, emotional/behavioral screening tools and anxiety. She also provided formal and informal patient consultations and well-visit observations. Resident and attending pediatricians reported positive experiences with the co-location experience, and there are plans to continue developmental-behavioral pediatrician presence in the primary care setting.


Dr. Moore

Dr. Moore also presented a virtual continuing medical education lecture at the chapter's Progress in Pediatrics meeting.

American Academy of Pediatrics

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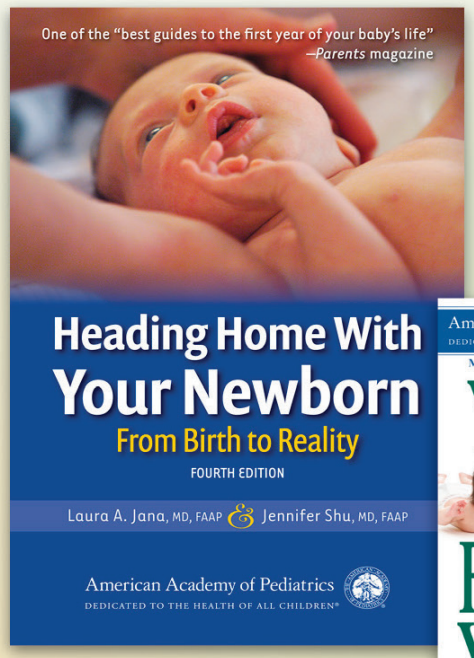

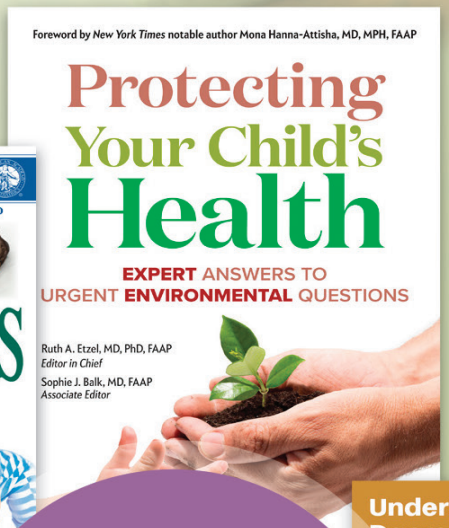

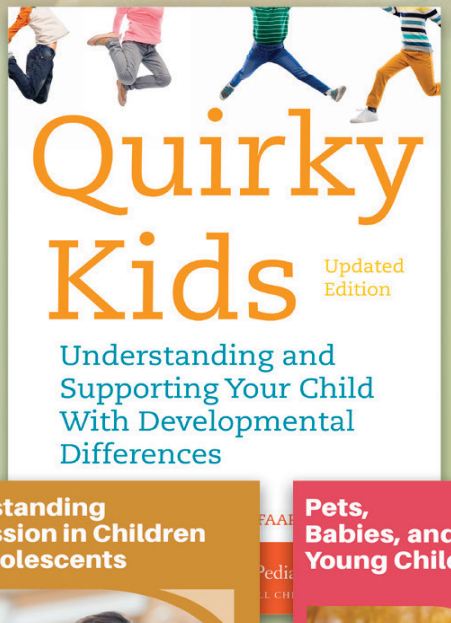

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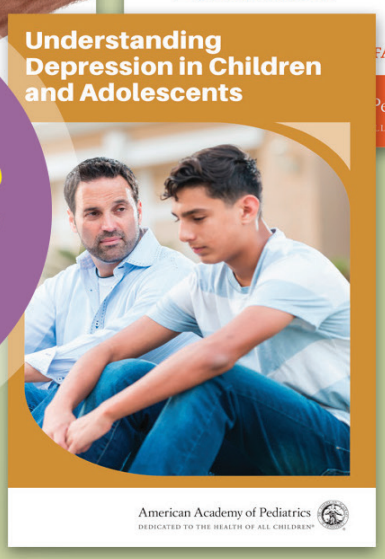

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Visit shop.aap.org/for-parents/ or call 888/227-1770.

Online influenza resources for your practice

Looking for answers as you navigate influenza season during the COVID-19 pandemic?

The AAP has resources in a variety of formats to support pediatricians, pediatric medical subspecialists and pediatric surgical specialists working to make sure their patients receive influenza vaccine and keep patients, families and practice teams safe.

On the AAP website, find links to virtual townhall webinars featuring panelists sharing practice tips as well as everything you need to know to set up drive-through flu clinics.

An FAQ section addresses key points from the AAP influenza policy, important practice points on the Vaccines for Children program and details about testing for influenza, respiratory syncytial virus and COVID-19. Visit https://bit.ly/prepforfluaap2020.

Make wise choices in pediatric pulmonology, sleep medicine

Pediatricians and families should consider new guidance from Choosing Wisely before using medical therapies and practices to treat asthma and sleep disorders in children. The guidance is published at https://bit.ly/choosingwisely083120.

The AAP Section on Pediatric Pulmonology and Sleep Medicine produced the following evidence-based list of Five Things Physicians and Patients Should Question:

- Do not add new drugs, go to higher doses or otherwise step up asthma therapy before assessing adherence and appropriateness of device and technique with current asthma medications.
- Do not use long-acting beta-agonist/steroid combination drugs as initial therapy for intermittent or mild persistent asthma.
- Avoid administering nebulized medications by "blow by." A t-piece with mouthpiece or face mask should be used instead.
- Do not perform or interpret pediatric sleep studies using adult standards, even if performed in a laboratory that predominantly studies adults.
- Do not routinely use airway clearance therapy in conditions such as asthma, bronchiolitis and pneumonia.

Choosing Wisely is an initiative of the ABIM Foundation that promotes conversations between clinicians and patients in choosing care that is supported by evidence, does not duplicate other tests or procedures already received, is free from harm and is truly necessary. More than 500 recommendations aimed at improving quality and reducing waste in health care have been developed by more than 80 participating medical specialty societies.

Find rationale and references behind this AAP list and others on the Choosing Wisely Lists of Recommendations webpage, https://bit.ly/32jDisS.

Free education series

PediaLink has a free education series on Duchenne muscular dystrophy (DMD) that includes five webinars about emerging therapies related to the care and management of DMD.

The series covers common issues affecting children with DMD and the role of pediatricians, other physicians, nonphysician clinicians and allied health professionals in providing coordinated care for individuals living with DMD.

Participants can earn AMA PRA Category 1 credit and Maintenance of Certification Part 2 credit. Visit www.aap.org/DMD.

COVID-19 handouts

Pediatric Patient Education has a collection of one-page printable handouts that answer common questions and concerns from parents and caregivers about COVID-19. All handouts come in English and Spanish. Topics include:

- Cloth Face Coverings for Children During COVID-19,
- COVID-19: Infant Formula Advice,
- Getting Children Outside While Social Distancing for COVID-19,
- Co-Parenting Through COVID-19: Putting Your Children First and
- Teens and COVID-19: Challenges and Opportunities During the Outbreak.

Pediatric Patient Education™
Expert advice from the American Academy of Pediatrics

Pediatric Patient Education includes more than 800 pediatric health care handouts, with more than 300 in Spanish, on topics for well-child visits from birth through young adulthood. Find out more at http://patiented.solutions.aap.org.

Call for president-elect candidates

The AAP National Nominating Committee is calling for members interested in being considered as a candidate for AAP president-elect to submit a biographical summary by 11:59 p.m. CST Oct. 9. Apply at https://www.surveymonkey.com/r/6WM9S67. Email questions to nationalelections@aap.org.

Transition to adult health care

Got Transition, the federally funded national resource center on health care transition, recently launched Six Core Elements of Health Care Transition 3.0. Clinicians can use the tools to help youths and young adults implement the health care transition process. The collection includes measurement tools and customizable sample tools in English and Spanish.

The Got Transition website also offers new toolkits, online quizzes, FAQs and more. Visit https://www.gottransition.org/.

Health Alerts

The U.S. Consumer Product Safety Commission (CPSC) has announced the recall of the following products. Consumers should stop using recalled products unless otherwise instructed. Consumers can submit reports of harm to CPSC's searchable online product safety database at www.SaferProducts.gov. A searchable food and medical product recall database is available at www.fda.gov/Safety/Recalls/default.htm.

Plush duck

Units: About 635,500
Hazard: The buttons on the lab coat worn by the plush duck contain lead, which is toxic if ingested by young children.
Description: Recalled are plush ducks dressed in a white coat to look like a doctor. The plush ducks were given out as a promotion from Aflac.
Sold to: Aflac employees and licensed agents from January 2005 through July 2020 for $3 to $5 and handed out to customers.
Remedy: Throw away the recalled plush duck.
Contact: Call 800-642-3522 or visit https://bit.ly/3h17b6o.

Water blaster toys

Units: About 52,900
Hazard: The decorative sticker on the water tank of the water blaster toys contains lead, which is toxic if ingested by young children.
Description: Recalled are Nerf Super Soaker XP20 (E6286), a green and orange hand-held water blaster, and XP 30 (E6289), an orange and blue hand-held water blaster.
Sold at: Target from March to July for $8 to $13.
Remedy: Contact Hasbro Inc. for a refund.
Contact: Call 888-664-3323, email SuperSoakerRecall@Hasbro.com or visit https://consumercare.hasbro.com/en-us/recall-information.

Moravian star lights

Units: About 50,000
Hazard: The lights are not wired properly, and the overcurrent can cause fire and electrical shock.
Description: The Moravian star lights, including those with incandescent and LED bulbs, have a white, multipointed star design and hang from a ceiling. Moravian stars were sold in 12-inch and 21-inch sizes.
Sold at: MoravianStarCompany.com and Amazon.com from November 2016 through December 2019 for about $20.
Remedy: Stop using the light and contact Hercules for a repair kit.
Contact: Call 800-626-8807, ext. 4340, email recall@herculesoem.com or visit https://www.herculesoem.com/hercules-oem-recall.html.

Lawn dart sets

Units: About 19,400 darts
Hazard: Lawn darts are banned in the United States due to serious risks of skull punctures and other injuries.
Description: Recalled are lawn dart sets sold for two, four and five players that contain four, eight and 10 darts, as well as individual spare darts. The darts have polypropylene fins designed to be held at the tail. The main part is brass, and the end is stainless steel. They were sold in red, blue, yellow, purple, pink, orange, ivory and green. Crown Darts is printed on the product.
Sold: Online at www.crowndarts.com from May 2004 through June 2020 for $15 to $139.
Remedy: Destroy the dart sets and throw them away.
Contact: Call the Consumer Product Safety Commission hotline at 800-638-2772.

To share this information, go to https://www.aappublications.org/news/2020/10/01/healthalerts100120

AAP News Parent Plus

See your pediatrician for influenza vaccine during COVID-19 pandemic

Make sure your child gets an influenza vaccine, ideally by the end of October. This is especially important during the COVID-19 pandemic.

The American Academy of Pediatrics (AAP) says all children 6 months and older should get a flu shot each year.

Influenza and COVID-19 will be spreading this fall and winter. They have similar symptoms, so it can be hard to tell them apart (see chart).

Both can cause no symptoms or an illness with mild to severe symptoms. Influenza symptoms show up about one to four days (two days on average) after being exposed to a sick person. COVID-19 symptoms appear about two to 14 days (five days on average) after being exposed to a sick person.

Is it COVID-19 or influenza?

Common symptoms of BOTH influenza and COVID-19

Fever/chills
Cough
Shortness of breath, difficulty breathing
Extreme tiredness
Muscle or body aches
Headache
Stuffy, runny nose
Vomiting and diarrhea

Symptom more common in COVID-19

Loss of taste or smell

Source: Centers for Disease Control and Prevention, https://bit.ly/3jvlbHe

It appears more likely that otherwise healthy children get serious illness from the flu than from COVID-19, especially if they did not get a flu shot.

The best place to get a flu shot is your pediatrician's office. During the visit, your child can get vaccinations required for school and other care that was delayed due to the pandemic.

There is a flu shot and a nasal spray vaccine. The flu shot can be given to otherwise healthy children and children with underlying medical conditions, starting at 6 months of age. The nasal spray vaccine can be given to healthy children who are at least 2 years old.

The AAP recommends:

- Children 6 months through 8 years of age getting the vaccine for the first time need two doses, at least four weeks apart.
- Children ages 9 and older get only one dose.
- Children who have recovered from COVID-19 can get influenza vaccine after symptoms go away, if they have not already been vaccinated.
- Children with a stuffy nose should wait until their nose is not blocked before getting the nasal spray vaccine.
- Children with egg allergy of any severity can get a flu shot without additional precautions beyond those recommended for any vaccine.
- Children who had allergic reactions to prior influenza vaccines should not be vaccinated until they see an allergist.

— Trisha Korioth

healthychildren.org
Powered by pediatricians. Trusted by parents.
from the American Academy of Pediatrics

Numerous CPT coding changes coming in 2021

from the **AAP Division of Health Care Finance**

Much of the focus on Current Procedural Terminology (CPT) updates that take effect on Jan. 1 has been on office or other outpatient evaluation and management (E/M) services (e.g., 99203, 99213). Yet, other changes have been made to the code set that are important for pediatrics. Following are some of those changes.

□ New CPT code
▲ Revised CPT code
Resequenced CPT code
✚ Designated add-on CPT code
► ◄ New guidelines

Evaluation and management

Care management services

New guidance was added regarding care plans.

►A comprehensive plan of care for health problems is based on a physical, mental, cognitive, social, functional, and environmental evaluation. It is intended to provide a simple and concise overview of the patient, and be a useful resource for patients, caregivers, health care professionals and others, as necessary.◄

►A typical plan of care is not limited to, but may include:

- □ Problem list
- □ Expected outcome and prognosis
- □ Measurable treatment goals
- □ Cognitive assessment
- □ Functional assessment
- □ Symptom management
- □ Planned interventions
- □ Medical management
- □ Environmental evaluation
- □ Caregiver assessment
- □ Interaction and coordination with outside resources and other health care professionals and others, as necessary
- □ Summary of advance directives◄

►The above elements are intended to be a guide for creating a meaningful plan of care rather than a strict set of requirements, so should be addressed only as appropriate for the individual.◄

►The plan of care should include specific and achievable goals for each condition and be relevant to the patient's well-being and lifestyle. When possible, the treatment goals should also be measurable and time bound. The plan should be updated periodically based on status or goal changes. The entire care plan should be reviewed at least annually.◄

►An electronic and/or printed plan of care must be documented and shared with the patient and/or caregiver.◄

Chronic care management services

Code 99490 is reported when, during the calendar month, at least 20 minutes of clinical staff time is spent in care management activities. Code 99439 is reported in conjunction with 99490 for each additional 20 minutes of clinical staff time spent in care management activities during the calendar month up to a maximum of 60 minutes total time (i.e., 99439 may be reported only twice per calendar month).

#▲99490 Chronic care management services, with the following required elements:

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

#✚□□99439 each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code **99490**)

Surgery

Cardiovascular

New shunting procedure codes were added. Note that codes 92992 and 92993 were deleted.

►Codes 33741, 33745 are used to report creation of effective intracardiac blood flow in the setting of congenital heart defects. Code 33741 (transcatheter atrial septostomy) involves the percutaneous creation of improved atrial blood flow (eg, balloon/blade method), typically in infants ≤4 kg with congenital heart disease. Code 33745 is typically used for intracardiac shunt creation by stent placement to establish improved intracardiac blood flow (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles). Code 33746 is used to describe each additional intracardiac shunt creation by stent placement at a separate location during the same session as the primary intervention (33745).◄

□□33741 Transcatheter atrial septostomy (TAS) for congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (eg, Rashkind, Sang-Park, balloon, cutting balloon, blade)

□□33745 Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt

✚□□33746 each additional intracardiac shunt location (Use 33746 in conjunction with 33745)

Medicine

Audiologic function tests

Three new codes were added under auditory evoked potentials, and codes 92585 and 92586 were deleted.

Code 92650 is a screening service.

Code 92651 was added to report post-screening follow-up for auditory evoked potential for hearing determination.

Code 92652 was added for threshold estimation at multiple frequencies.

#□92650 Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis

#□□92651 for hearing status determination, broadband stimuli, with interpretation and report

#□□92652 for threshold estimation at multiple frequencies, with interpretation and report

A new code was added for exercise test for bronchospasm without the requirement of an electrocardiographic recording.

▲94617 Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; with electrocardiographic recording(s)

□□94619 without electrocardiographic recording(s)

Category III

Code 0615T has been added because there was no specific Category III code for eye movement analysis without spatial calibration. Eye movement analysis without spatial calibration is performed to diagnose conditions such as concussion by detecting deficits in a patient's ability to fixate and gaze upon a specific object. The rationale for specifying that the exam is performed without spatial calibration in the code descriptor is that spatial calibration assesses how well a patient can follow commands with eye movements, and these data may obscure deficits in gaze and fixation.

□0615T Eye movement analysis without spatial calibration, with interpretation and report

Refer to the 2021 CPT resources for full guidelines on reporting new or revised codes and services.

RESOURCES

- *AAP News* article "What changes will be made to office, other outpatient E/M codes in 2021?" https://bit.ly/3hQm2lz
- *Coding for Pediatrics 2021*, 26th Edition, https://shop.aap.org/coding-for-pediatrics-2021-paperback/
- *Pediatric Office-Based Evaluation and Management Coding*: 2021 Revision, https://bit.ly/3bm6iUS
- Pediatric Evaluation and Management: Coding Quick Reference Card 2021, https://bit.ly/3jMt37D
- AAP Pediatric Coding Newsletter (free sample available), https://coding.solutions.aap.org/

New CPT code covers prep time, supplies, PPE needed during pandemic

Effective Sept. 8, new Current Procedural Terminology code **99072** may be reported for:

Additional supplies, materials, and preparation time required and provided by the physician or other qualified health care professional and/or clinical staff over and above those usually included in an office visit or other service(s), when performed during a nationally declared public health emergency due to respiratory transmitted infectious disease.

Code 99072 is to be reported only once per in-person patient encounter per provider identification number, regardless of the number of services rendered at that encounter.

Code 99072 is designed to capture the following practice expense factors:

- Time over what is included in the primary service of clinical staff time to conduct a pre-visit phone call to screen the patient (symptom check), provide instructions on social distancing during the visit, check patients for symptoms upon arrival, apply and remove personal protective equipment, and additional cleaning of the examination/procedure/imaging rooms, equipment and supplies
- Three surgical masks
- Additional cleaning supplies (e.g., hand sanitizers, disinfectant wipes)

Pediatricians' need for specific EHR functionality finally recognized

by **Susan J. Kressly, M.D., FAAP**, and **Emily C. Webber, M.D., FAAP**

As pediatricians, we know that many electronic health record (EHR) functionalities that were made with the adult population in mind fall short of supporting safe and effective care for infants, children and adolescents. For more than a decade, AAP leaders have been championing efforts to improve pediatric health information technology (IT).


Dr. Lehmann

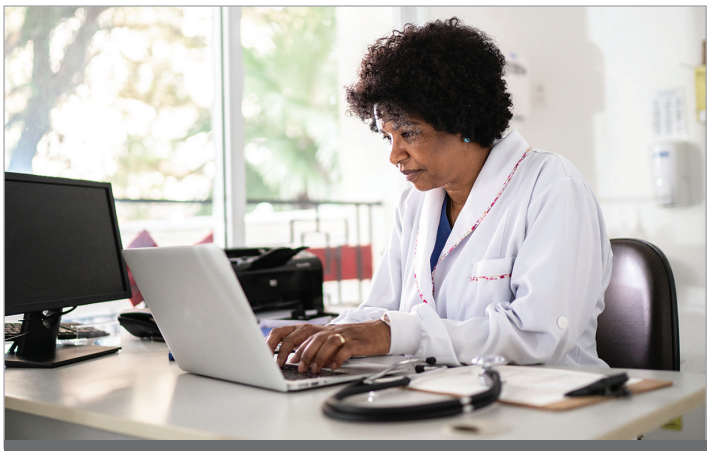

Dr. Weinberg

A 21st Century Cures Act final rule that took effect on June 30 includes key recommendations for the voluntary certification of health IT to support the health care of children. This work builds on previous federal and stakeholder activities, including the Children's Electronic Health Record Format supported by the Agency for Healthcare Research and Quality and the Centers for Medicare & Medicaid Services.

"Children represent a quarter of all patients and deserve EHRs that can support their unique needs. Certification of EHRs will make care safer, more reliable and more effective as pediatricians no longer will have to do necessary work outside the EHR," said Christoph U. Lehmann, M.D., FAAP, founding medical director of the AAP Child Health Informatics Center.

To be clear, there is no separate pediatric EHR certification path. In development is a voluntary certification that EHR developers can choose to go through to demonstrate their commitment to pediatricians as part of general EHR certification. Several pediatricians, including Stuart T. Weinberg, M.D., FAAP, are involved in these efforts.

"It has been gratifying to work with a certification body to outline exactly what functionalities should be tested as we work towards a goal of making electronic medical records more supportive of pediatric practices with improved usability and decreased cognitive load that leads to mental fatigue," said Dr. Weinberg, a member of the AAP Council on Clinical Information Technology.


Voluntary certification aims to make EHRs more effective for pediatric practices.

In order for every pediatrician to have access to these improvements, they first must be part of the solution. Following are recommendations for what pediatricians can do to advance pediatric functionality in their EHRs.

- Familiarize yourself with the developer resource from the Office of the National Coordinator for Health Information Technology at https://bit.ly/2Z1e41w.
- Identify leaders in your practice organization and make the case for why having pediatric certification should be the standard for providing safe and effective care to children.
- Identify your contact between your practice leadership and your EHR vendor (often an account manager) and be part of a connected conversation.
- Contribute to conversations with your EHR vendor by participating in user groups and physician advisory groups.
- Join the AAP Council on Clinical Information Technology, http://bit.ly/AAPCOCIT.

As we work together to address disparities in care delivery, move to value-based payment and use data to improve care via the AAP Child Health Improvement through Longitudinal Data registry, having appropriate EHR tools to care for children is key to success. Pediatricians are invited to be part of this important work.


Dr. Kressly


Dr. Webber

Dr. Kressly is chair of the AAP Payer Advocacy Advisory Committee and a member of the Child Health Informatics Center Project Advisory Committee. Dr. Webber is chair of AAP Council on Clinical Information Technology Executive Committee.

RESOURCE

Information on choosing and using an EHR, http://bit.ly/2qoXTcK

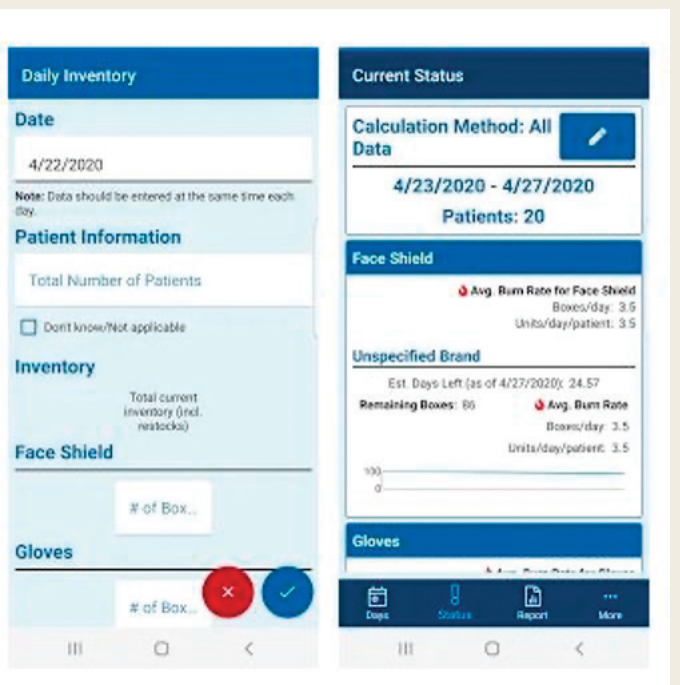
Tech Tip

App allows health care systems to track PPE inventory

from the **AAP Division of Quality**

The National Institute for Occupational Safety and Health (NIOSH) within the Centers for Disease Control and Prevention has developed a mobile app that allows health care systems and others to track their supply of personal protective equipment (PPE).

Hospitals and office-based practices can use the NIOSH PPE Tracker App to calculate their PPE consumption rate and to predict how long a supply of PPE will last.



Key features of the app include:

- ability to track different types of PPE (e.g., gowns, gloves, surgical masks, etc.),
- ability to add restock as PPE is replenished,
- ability to calculate use rate by type of PPE and
- ability to download data and share reports via email.

The NIOSH PPE Tracker app is available for free on the App Store and Google Play.

If you would like to share a firsthand experience using technology, such as software, program, app, widget, etc., to improve patient care or practice management, email submissions of 250 words or less to Lisa Krams at lkrams@aap.org.

10th anniversary

Helping Babies Breathe pauses to reflect, look toward challenges

Editor's note: *For its 10th anniversary, Helping Babies Breathe has published a supplement with the October issue of* Pediatrics *and an online oral history. Read on for highlights.*


Dr. Niermeyer


The Helping Babies Breathe training program includes educational materials and therapeutic tools, including a realistic newborn simulator, suction bulb, bag-mask and resuscitator that can be cleaned and reused (produced by Laerdal Global Health).

At a health post in Rukungiri, Uganda, Susan Niermeyer, M.D., M.P.H., FAAP, was teaching a Helping Babies Breathe (HBB) course to midwives in a room adjacent to the delivery room. One midwife who slipped away to deliver a patient came running back to report that she had tried stimulation, but the baby was not breathing. Before that day, the facility did not have a newborn mask. Dr. Niermeyer stopped training and wiped the mask. She handed it to the midwife, who got the baby and bag situated and began to ventilate. Within 45 seconds, the baby started to cry. "And that whole room was really transformed. A baby's outcome had been changed because of the training, immediately," she said.

The story is one of several shared in an oral history on the past decade. Beena Kamath-Rayne, M.D., FAAP, vice president, AAP Global Newborn and Child Health, interviewed the four original HBB editors: William J. Keenan, M.D., FAAP, George A. Little, M.D., FAAP, Dr. Niermeyer and Nalini Singhal, M.D., FAAP. The oral history is published at https://bit.ly/HBB10thAnniversary.

Before HBB was born 10 years ago, the idea of a global curriculum and model program for neonatal resuscitation in the developing world was viewed as an insurmountable task.

HBB has now been implemented in more than 80 countries with over 850,000 providers trained. It has taken a global alliance to get where HBB is today.

That alliance was formed in June 2010 in Washington, D.C. USAID invited the AAP, Save the Children/Saving Newborn Lives, the Eunice Kennedy Shriver National Institute of Child Health and Human Development and Laerdal Global Health. Soon after, Latter-day Saint Charities, Johnson & Johnson, Catholic Medical Missions board, Earth Institute/Columbia University, Project CURE and the International Pediatric Association joined what is now known as the Global Development Alliance.

In the oral history, HBB editors look back on the decade-long evolution and explain how and why the need for HBB became evident. They noted that there was no suitable place for the information needed by low- and middle-income countries within the Neonatal Resuscitation Program (NRP). The countries faced challenges in decreasing neonatal mortality and struggled with solutions to reach newborns and mothers in remote areas. It required a separate approach.

HBB and NRP both are based on the International Liaison Committee on Resuscitation guidelines. But they are designed for different care environments, especially with respect to resources.

HBB focuses on The Golden Minute, with the goal of having an experienced provider help babies breathe and take care of them, no matter where in the world babies are born.

Data have been collected over 10 years so the program can continue to improve. A supplement with the October issue of *Pediatrics* looks at major strides made. The supplement examines data, tracks progress and gathers insight of stakeholders (https://pediatrics.aappublications.org/content/146/Supplement_2).

Numerous publications have documented HBB's success in decreasing early neonatal mortality and stillbirth rates, noted Dr. Kamath-Rayne. From it, other programs were born under a broader umbrella, Helping Babies Survive, as well as links to the Helping Mothers Survive program.


Dr. Kamath-Rayne

"A deeper understanding of the ongoing work that happens after training, ongoing practice and quality improvement, has been achieved. Deep collaborations with sister pediatric associations, global implementing partners and governments have been forged," Dr. Kamath-Rayne added.

HBB materials are available online at no cost as part of the Helping Babies Survive suite of evidence-based, hands-on programs developed to reduce neonatal mortality in resource-limited environments. The materials can be accessed even in areas with intermittent internet access. Hard copies can be purchased or printed. The action plan now hangs on the walls of countless labor and delivery units, and thousands of training flipcharts have been disseminated worldwide.

Most recently, HBB's value has been recognized by the World Health Organization, which has adapted HBB into its soon-to-be-released essential newborn care program.

Throughout the supplement and oral history, authors allude to the anniversary as a time to frame challenges that lie ahead in ending preventable maternal and newborn deaths. Most of all, they note, it is a reminder of the continued goal that every baby, no matter where he or she is born, has the same chance to survive and thrive.

RESOURCE

Helping Babies Survive: Helping Babies Breathe, 2nd Edition, http://hbs.aap.org

Father of medical home: Dr. Sia remembered as 'quintessential advocate'


Dr. Sia

Calvin C.J. Sia, M.D., FAAP, father of the medical home concept of care and Emergency Medical Services for Children Program, died Aug. 19 in Honolulu at age 93.

It was Dr. Sia who said, "Every child and youth deserves a medical home."

The medical home concept is well-known and embraced by all pediatricians, but not everyone is aware of its beginnings, said Fan Tait, M.D., FAAP, AAP chief medical officer/senior vice president.

"He was one of the greats in pediatrics," Dr. Tait said. "If not for Dr. Sia and his leadership, we would not have family-centered care within the medical home. He helped develop the medical home concept in collaboration with Family Voices, the Maternal and Child Health Bureau and the AAP."

In 1958, Dr. Sia opened a pediatric practice in Honolulu. As a community pediatrician, Dr. Sia valued the insight of colleagues at schools, social services and other groups.

Just as he did with the medical home concept, he often set out to solve challenges within his community, then brought those solutions to the state, national and sometimes global level. His advocacy spanned the scope of pediatrics, including children with disabilities, emergency services for children, child abuse prevention and early periodic screening, diagnosis and treatment standards.

"You couldn't end up sitting next to him in any kind of event that he didn't just win you over and convince you about the medical home," said AAP Past President Judith S. Palfrey, M.D., FAAP (2009-'10). Dr. Palfrey worked with Dr. Sia on community pediatrics initiatives, including on the advisory committee for the Annie E. Dyson Foundation's initiative for pediatric residency training in community pediatrics.

Early in his career, Dr. Sia developed a home visiting program to prevent child abuse and neglect among children with special health care needs. After introducing the Hawaii Healthy Start Home Visitors Program, he brought the model to the nation as Healthy Families America.

While he was president of the Hawaii Medical Association (1976-'77), Dr. Sia worked on expanding the quality of emergency care provided to children with injuries, where responders were not equipped for children. He urged the AAP to support a system of emergency medical care for children. The resulting Emergency Medical Services for Children (EMS) Act was enacted in 1984.

"You kind of dig into anything that's really, really good in pediatrics and Cal was somewhere working on it and often leading it," Dr. Palfrey said. "He just never stopped being the quintessential advocate."

Passionate and persistent in his leadership and mentorship, Dr. Sia was "a willing resource" who always put other people first, Dr. Tait said.

This trait served the AAP well when Dr. Sia helped bring the AAP and American Medical Association (AMA) together to advance child health issues.

"He was a tremendous champion for children who cared about all kids. The breadth of his work reflects that. Some people have ideas. He took them and got them implemented," said California state Sen. Richard J. Pan, M.D., M.P.H., FAAP, a past AAP delegate to the AMA House and past member of the AMA Section Council on Pediatrics, both chaired by Dr. Sia.

In 2007, the AAP, American Academy of Family Physicians, American College of Physicians and the American Osteopathic Association adopted the Joint Principles of the Patient-Centered Medical Home, setting a standard definition of the medical home.

Dr. Sia chaired the National Center for Medical Home Implementation Project Advisory Committee.

Throughout his career, he received numerous honors, including the Barbara Starfield Primary Care Leadership Award from the Patient-Centered Primary Care Collaborative (2015), Clifford G. Grulee Award (2001), Job Lewis Smith Award in Community Pediatrics (2001), AMA Benjamin Rush Award (1998), the first Emergency Medical Service for Children National Heroes Lifetime Achievement Award (1998) and the AMA/AAP Abraham Jacobi Award (1992). In 2005, the AAP Council on Community Pediatrics established the Calvin C.J. Sia Community Pediatrics Medical Home Leadership and Advocacy Award.

He was a member of the AAP Sections on Community Pediatrics, International Child Health and Emergency Medicine.

Dr. Sia was born in China, and at age 12 moved with his family to Hawaii. The son of a physician father and musician mother, his maternal grandparents were the first Chinese physicians in Hawaii. He earned his M.D. from Case Western Reserve University School of Medicine in 1955, was a lieutenant in the U.S. Army Medical Corps at William Beaumont Army Hospital and completed his pediatric residency at Kauikeolani Children's Hospital in Honolulu.

Dr. Sia's wife, Katherine Wai Kwan Li, died Oct. 19, 2019. Dr. and Mrs. Sia are survived by three sons, including Michael Hung Tai Sia, M.D., FAAP, of Honolulu, their wives, six grandchildren and one great-grandchild.

— *Trishia Korioth*

Richard E. Alpert, M.D., FAAP, of Lansdale, Pa., died July 17 at age 87.

Robert D. Burnett, M.D., FAAP, of Cupertino, Calif., died July 15 at age 95. He was a past president of the California Medical Association.

William B. Carey, M.D., FAAP, of Swarthmore, Pa., died July 26, of congestive heart failure at age 93. He received the 1991 AAP C. Anderson Aldrich Award and the 1992 AAP Practitioner Research Award.

Irwin Danziger, M.D., FAAP, of Beaufort, S.C., died Aug. 9 at age 91.

Elmer R. Grossman, M.D., FAAP, of Berkeley, Calif., died Aug. 15 at age 91.

❖ **George W. Moll Jr., M.D., Ph.D., FAAP**, of Brandon, Miss., died Aug. 13 of complications from COVID-19 at age 72.

Richard L. Plumb, M.D., FAAP, of Houston, died May 9 at age 88.

Dora A. Stinson, M.D., FAAP, of Halifax, Nova Scotia, Canada, died July 25 at age 80.

Richard Umansky, M.D., FAAP, of Oakland, Calif., died July 17 at age 91.

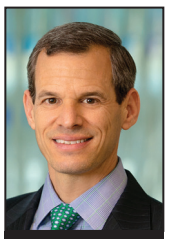
❖ COVID-19 or COVID-19-related death

Remembering those who died from COVID-19

The AAP is acknowledging pediatricians who have died of complications related to COVID-19. To ensure that a colleague, friend or family member who has died of COVID-19 is included in *AAP News*' In Memoriam, email Trisha Korioth at tkorioth@aap.org.

To make a gift in memory of a colleague, visit donate.aap.org or email the AAP Development Office at development@aap.org.

Fellows in the News


Dr. Morse

Rustin B. Morse, M.D., M.M.M., FAAP, of Columbus, Ohio, was named chief medical officer at Nationwide Children's Hospital.

Dr. Morse is a pediatric emergency medicine physician and a faculty member at The Ohio State University College of Medicine. He serves on the national Clinical Steering Committee for Solutions for Patient Safety, as well as the quality and safety committee of the Children's Hospital Association Board of Trustees.


Dr. Permar


Dr. Patrick

Sallie R. Permar, M.D., Ph.D., Chapter Affiliate member, of Raleigh, N.C., and **Stephen W. Patrick, M.D., M.P.H., M.S., FAAP**, of Brentwood, Tenn., will share the Weill Cornell Medicine's Gale and Ira Drukier Prize in Children's Health Research, which honors innovative work by young investigators.

Dr. Permar is associate dean of physician scientist development, professor of pediatrics, immunology, molecular genetics and microbiology, and founding director of the Children's Health and Discovery Institute at Duke University School of Medicine. She researches the development of vaccines to prevent mother-to-child transmission of neonatal viral pathogens.

Dr. Patrick is associate professor of pediatrics and health policy, and director of the Vanderbilt Center for Child Health Policy at Vanderbilt University School of Medicine. His research focuses on using a public health framework to improve outcomes for infants born to women dependent on opioids.


Dr. Stoll

Barbara J. Stoll, M.D., FAAP, of Houston, was appointed president of the China Medical Board. She assumes the office on Jan. 1.

The Rockefeller-endowed China Medical Board is an independent American foundation. It aims to advance health in China and neighboring Asian countries through strengthening medical, nursing and public health research and education.

Dr. Stoll most recently was the H. Wayne Hightower Distinguished Professor in the Medical Sciences and professor of pediatrics as well as dean of the McGovern Medical School at the University of Texas Health Sciences Center. She is past president of the American Pediatric Society.

Mark L. Wulkan, M.D., FACS, FAAP, of Akron, Ohio, has been appointed chair of surgery at Akron Children's Hospital.

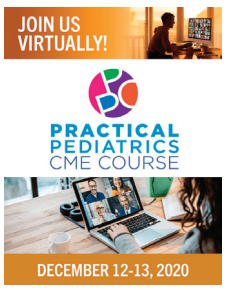
Dr. Wulkan also will serve as professor of surgery and pediatrics at Northeast Ohio Medical University in Rootstown. Among previous roles, he was professor of surgery and pediatrics at Emory University School of Medicine and surgeon in chief at Children's Healthcare of Atlanta.

Fellows in the News acknowledges AAP members' national and prominent awards, honors and appointments. Submit biographical sketch, academic titles, memberships in AAP groups and a high-resolution photo to Trisha Korioth at tkorioth@aap.org; phone 630-626-6791. Publication is at the discretion of AAP News.

Virtual Practical Pediatrics course combines recorded, live sessions

An exciting lineup of renowned faculty, stellar content and the perfect level of interaction awaits you at the Virtual Practical Pediatrics Continuing Medical Education Course.

The course features 18 prerecorded general session lectures (35 minutes each) that can be accessed beginning Nov. 13 plus two live days, Dec. 12-13, that also will be recorded.



Dermatology pre-course lectures, with Kim A. Horii, M.D., FAAD, FAAP, include:

- "Brushing Up On Your ABC's (and DE's) — Melanocytic Nevi (Moles) in Children"
- "Baby You Were Born This Way — Vascular Birthmarks"
- "Pimples Galore: Management of Teenage Acne"

Developmental and behavioral pediatrics pre-course lectures, with Nathan J. Blum, M.D., FAAP, include:

- "Intellectual Disability (ID) and Global Developmental Delay (GDD): Screening, Etiology, and Outcome"
- "Staying Focused on ADHD Management and Outcomes"
- "Transition to Adulthood for Children With Developmental Disabilities: Whose Responsibilities, What Resources?"

Gastroenterology pre-course lectures, with Jenifer R. Lightdale, M.D., M.P.H., AGAF, FASGE, FAAP, include:

- "Milk Intolerance: Is it Lactose, Allergy, IBS … or Superstition?"
- "Neon Babies: Managing Hyperbilirubinemia of the Newborn"
- "Tell Tale Signs of Inflammatory Bowel Disease in Children"

Infectious diseases pre-course sessions, with Jeffrey R. Starke, M.D., FAAP, include:

- "When There's MRSA in the Bursa: Staphylococcus Aureus Infections"
- "Choosing the Best Antibiotic: How an Infectious Disease Consultant Thinks"
- "Childhood Tuberculosis: What the General Pediatric Practitioner Needs to Know"

Sports medicine pre-course sessions, with Amanda Weiss-Kelly, M.D., FAAP, include:

- "Overuse/Overtraining Injuries"
- "The Sports Pre-Participation Exam"
- "Concussion: Developments in Evaluation and Treatment"

Urology pre-course sessions, with Michael A. Keating, M.D., FAAP, include:

- "Abnormal Prenatal Ultrasounds: Before the Cradle and Beyond"
- "Urinary Tract Infections and Reflux: What's New?"
- "The Child Who Wets: What's a Doctor to Do?"

Live sessions on Dec. 12-13 include Q&A sessions for the prerecorded lectures.

On Dec. 12, participate in the Q&A with Drs. Horii, Starke and Weiss-Kelly. After a break, each faculty member will present seminars on dermatology, infectious diseases and sports medicine.

On Dec. 13, participate in a Q&A with Drs. Blum, Lightdale and Keating. After a break, each faculty member will present a seminar on developmental and behavioral pediatrics, gastroenterology and urology.

Earn up to 21.5 AMA PRA Category 1 credits. Register at https://shop.aap.org/2020-practical-pediatrics-cme-course-december/.

New Fellows

Welcome New Fellows
Congratulations on passing the pediatric board exam! As a member and Fellow of the AAP (FAAP), you are part of an exceptional pediatric community. You have access to unmatched opportunities for leadership and quality improvement that will positively impact your care of children and take your career to the next level.

UNDISTRICTED

Mohamed Hamdan, M.D., FAAP
Dubai, Dubai United Arab Emirates

Kathryn Leccese, M.D., FAAP
Traralgon, Victoria Australia

DISTRICT I
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Guilford, CT

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East Lyme, CT

Maine

Amy Barrett, M.D., FAAP
Hampden, ME

Massachusetts

Niyomi Gandhi, M.D., FAAP
Boston, MA

Katherine Harer, M.D., FAAP
Natick, MA

Audrey Marshall, M.D., M.P.H., FAAP
Milton, MA

Abigail Scully, M.D., FAAP
Boston, MA

New Hampshire

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Lebanon, NH

Uniformed Services East

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Washington, D.C.

Vermont

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Essex Junction, VT

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Cortland, NY

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Rochester, NY

Amanda Brown, D.O., FAAP
Brooklyn, NY

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Garden City, NY

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Marco Garcia, M.D., FAAP
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Washington, DC

Theodore Trigylidas, M.D., FAAP
Washington, DC

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Dana Kim, M.D., FAAP
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Mullica Hill, NJ

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Hummelstown, PA

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Kaitlyn Iaccarino, D.O., FAAP
Mechanicsburg, PA

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Sahar Navo, M.D., FAAP
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Huntington, WV

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Charlotte, NC

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Raleigh, NC

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Indianapolis, IN

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Grosse Pointe Park, MI

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Ashleigh Galizio, M.D., FAAP
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Gillian MacLean, M.D., FAAP
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Ruth McWhannell, M.D., FAAP
Toronto, ON Canada

Samantha Witt, M.D., FAAP
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Warapan Nakayuenyongsuk, M.D., FAAP
Omaha, NE

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Deepa Vasireddy, M.D., FAAP
Lafayette, LA

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Priscille Donate, M.D., FAAP
Houston, TX

Monica Fogarty, M.D., FAAP
Austin, TX

Kevin Glinton, M.D., FAAP
Houston, TX

Megan Gribbons, M.D., FAAP
Dallas, TX

Andrea Harris, M.D., FAAP
Corpus Christi, TX

Hannah Kline, M.D., FAAP
Webster, TX

Josue Maldonado, M.D., FAAP
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Marina Masciale, M.D., FAAP
Houston, TX

Lorien Nassi, M.D., FAAP
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Thao Nguyen, D.O., FAAP
Houston, TX

Kriti Puri, M.D., FAAP
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Houston, TX

Grant Shafer, M.D., FAAP
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Emily Wieck, M.D., FAAP
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Chinwe Egbo, M.D., FAAP
Gilbert, AZ

Obinna Egbo, M.D., FAAP
Gilbert, AZ

Melissa Knudson, M.D., FAAP
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Mohamed Nagiub, M.D., Ph.D., FAAP
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Alexandra Tsontakis, M.D., FAAP
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Superior, CO

Kristin Kalita, M.D., FAAP
Denver, CO

Virginia Kee, M.D., FAAP
Fort Collins, CO

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Aurora, CO

Ali Russell, M.D., FAAP
Denver, CO

Michelle Shiffman, M.D., FAAP
Denver, CO

Kaitlin Whelan, M.D., FAAP
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Hafid Mantilla, M.D., FAAP
Nampa, ID

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Elizabeth Beil, M.D., FAAP
Missoula, MT

Nevada
Elizabeth Nakae, D.O., FAAP
Reno, NV

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Albuquerque, NM

Deven McMorrow, M.D., FAAP
Alamogordo, NM

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Francesca Hernandez, M.D., FAAP
Eugene, OR

Gabriel Larson, M.D., FAAP
Portland, OR

Gia Oh, M.D., FAAP
Portland, OR

Uniformed Services West
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FPO, AP

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Zachary Kastenberg, M.D., FAAP
Salt Lake City, UT

Pediatric Surgery Specialty Fellow
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Salt Lake City, UT

Tyson Tidwell, D.O., FAAP
Heber City, UT

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Seattle, WA

Kathryn Sun, M.D., FAAP
Seattle, WA

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San Jose, CA

Joyce Arpilleda, M.D., FAAP
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Michael Avesar, M.D., FAAP
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Arunima Bera, M.D., FAAP
Santa Monica, CA

Lorianne Burns, M.D., FAAP
Sacramento, CA

Vincent Chan, M.D., FAAP
Duarte, CA

Amy Chong, M.D., FAAP
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Rebecca Fink, M.D., FAAP
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Tricia Guadiz, M.D., FAAP
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Tami Inbar, M.D., FAAP
Newport Beach, CA

Pooja Kakar, M.D., FAAP
Los Altos, CA

Jessica Khankhanian, D.O., M.P.H., FAAP
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Shannon Leung, M.D., FAAP
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Laura Nguyen, M.D., FAAP
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Katherine Nielsen, M.D., FAAP
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Chinonso Ogbonnah, M.D., FAAP
Tracy, CA

Shital Patel, M.D., FAAP
San Mateo, CA

Theresa Pattugalan, M.D., FAAP
Elk Grove, CA

Camille Robinson, M.D., FAAP
Chula Vista, CA

Alisa Roda, M.D., FAAP
Jackson, CA

Rocio Rodriguez Valencia, M.D., FAAP
Santa Maria, CA

Sarah Ruberman, M.D., FAAP
Mammoth Lakes, CA

Yamini Sharma, M.D., FAAP
Toluca Lake, CA

Marni Shear, D.O., FAAP
Los Angeles, CA

Sarah Van Camp, D.O., FAAP
Paso Robles, CA

Maramawit Wubeshet, M.D., FAAP
Alameda, CA

DISTRICT X SOUTHEAST

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Birmingham, AL

Florida
Keshawadhana Balakrishnan, M.D., FAAP
Weston, FL

Alrick Drummond, M.D., FAAP
Riverview, FL

Peter Kang, M.D., FAAP
Gainesville, FL

Daniel Ortiz, M.D., FAAP
St. Petersburg, FL

Cristine Santiago, M.D., FAAP
Orlando, FL

Dermatology Specialty Fellow
Jennifer Schoch, M.D., FAAP
Ponte Vedra Beach, FL

Georgia
Fabian Chang, M.D., FAAP
Watkinsville, GA

Michael Fundora, M.D., FAAP
Decatur, GA

Sunita Hemani, M.D., FAAP
Atlanta, GA

Catherine McClure, M.D., FAAP
Covington, GA

Zahidee Rodriguez, M.D., FAAP
Decatur, GA

Sheel Shah, M.D., FAAP
Atlanta, GA

Puerto Rico
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Guaynabo, PR

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Santa Isabel, PR

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Yamila Goenaga, M.D., FAAP
Bayamon, PR

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San Juan, PR

Ivonne Iglesias Escabí, M.D., FAAP
Trujillo Alto, PR

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San Juan, PR

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Caguas, PR

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San Juan, PR

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Las Piedras, PR

Darrelle Villarini, M.D., FAAP
San Juan, PR

Classifieds

POSITION WANTED

NORTHEAST

Pediatrician

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Largest Concierge Pediatric Practice in the Country

Concierge Care Pediatric Practice is searching for a third General Pediatrician to join our team!! -Usually see only 3 to 10 patients per doctor per day -Hour long Physicals -Home Visits -PCR lab testing in office -Lifestyle of utmost importance -Very happy and supportive team -Partnership track -Competitive salary and benefits. Please email CV to what20happened @gmail.com.

SOUTHWEST

Full-time Pediatrician
Coastal Georgia

Full-time pediatrician needed for private pediatrics office with three locations all located in or near the beautiful coastal city of Savannah, GA. •Call every sixth week-includes rounding in two area newborn nurseries which are located five minutes from each other •No C sections or NICU, no pediatric admissions •Level 1 trauma w/children's hospital; many pediatric specialists in area including endocrinologists, urologists, hospital based hematology/oncology and infectious disease clinics, orthopedics, pulmonologist, psychiatrists, gastroenterologist, developmental specialists •Four day work week, with exception being the addition of Saturday AM clinic every sixth week when on call. •Competitive compensation with generous monthly incentive bonus• Malpractice coverage •Relocation assistance •Benefits including health, dental, 401k, one-week paid CME and four weeks paid vacation. Please email CV to drkkim@kidsfirstga.com.

NATIONWIDE

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Let us help you find it.

Thinking of making a change? Or just starting your search for a new practice setting? Pediatric Search Partners is a specialized boutique search firm with over 30 years of experience. Our sole focus is serving the pediatricians, pediatric subspecialists, healthcare executives and physician leaders dedicated to providing children's healthcare. Since 2009, we've successfully filled more than 500 searches within leading children's hospitals and healthcare organizations across the nation, each of them with a highly personalized approach. Our passion is matching the physicians and executives who care for children with opportunities they truly care about. For complete details and consideration, please contact: Glenda Smith, Principal, Pediatric Search Partners, Phone: 877-440-3832; Cell: 214-850-3094 or email glenda@pediatricsearchpartners.com.

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Classified Advertisements
Advertisements in the Classified Advertising section of AAP News reach more than 67,000 child health· care professionals and clinicians monthly, AAP News circulation encompasses 85% or all board certified pediatricians. more than 90% of certified pediatric allergists. cardiologists, and surgeons. and more than 9,000 pediatric residents

LINE ADS
Line ads: A line ad is a text ad with no logos. and no paragraph formatting. Cost is calculated by word count. To calculate words, either open Microsoft Word and use the word count function, or count each word as one. Web addresses, e-mail addresses, phone numbers, or fax numbers are all calculated as one word. BC/BE is calculated as one word, but Board Certified/Board Eligible is calculated as four. All line ads are packaged with a job posting at www pedjobs.org. There is *no* print advertising only. There is online advertising only. When placing your ad, the online compatibility allows you to search the job bank of hundreds of CVs.

If you would like information about placing your ad, please call 443.512.8899, ext. 106.

CLASSIFIED DISPLAY
Classified advertising on a set-size basis (1/2 page, 1/4 page, etc.) also is available an AAP News. All display ads are packaged wilh a job posting at www.pedjobs.org. There is *no* print advertising alone. Rate sheets are furnished upon request. Please call 443.512.8899, ext. 106, between the hours of 8:30 am and 5:00 pm Eastern Standard Time for more information.

PLACING AN AD
To confirm an insertion order, send classified ad copy with payment to

American Academy of Pediatrics
2225 Old Emmorton Road. Suite 201
Bel Air, MD 21015
E-mail ad copy to: rhonda.beamer@wt-group.com

Ad copy may be sent via e-mail in a Word-friendly format or be typewntten. No handwritten or telephone (verbal) orders will be accepted.

DEADLINE
The deadline for placing a classified ad in AAP News is the 1st of the month preceding month of issue. Example: January 1st for the February issue.

TERMS
Please note, payment must accompany order. No ads will be placed without prior payment. Make checks payable to: American Academy of Pediatrics. Visa, Master-Card, American Express, and Discover are accepted. Ads will not be placed until payment is collected. An advertiser may cancel an ad without refund.

REPLYING TO A CONFIDENTIAL BOX AD
To reply to an ad with a confidential box number (box #000), please use the following address: Pediatrics Classified Ads. 2225 Old Emmorton Road, Suite 201, Bel Air, MD 21015

CLASSIFIED ADVERTISING POLICY
Although the American Academy of Pediatrics believes classified advertisements published in AAP News are from reputable sources, the Academy reserves the right to revise or reject advertising copy that is inconsistent with the publication's standards. All advertising is subject to approval

Ads in AAP News must be relevant to the practice of medicine. The Academy does not investigate offers made in classified ads and assumes no responsibility concerning them. In consideration for acceptance of an advertisement for publication, the agency and advertiser agree to indemnify and hold the American Academy of Pediatrics harmless against any losses or expenses arising out of publication of such advertisements, including and without limitation, those resulting from claims based on the contents, claims, or subject matter of such adverttsements. Every effort is made to avoid mistakes, but the Academy cannot accept responsibility for printing or clerical errors.

Without limiting the American Academy of Pediatrics' terms, conditions, and policies, the American Academy of Pediatrics, in accordance with Department of Justice guidelines:

- Prohibits any job posting that requires U.S. citizenship or lawful permanent residence in the U.S. as a condition of employenl, unless otherwise required in order to comply with law, regulation, executive order, or government contract.

- Prohibits any job requirement or criterion in connection with a job posting that discriminates on the basis or citizenship status or national origin.

For complete EEO guidelines please refer to the following resource: http://www justice.gov/crt/osc/

CONTACT INFORMATION
The Walchli Tauber Group. Inc
Attn: Rhonda Beamer
2225 Old Emmorton Road
Suite 201
Bel Air, Md. 21015
Phone: 443.512.8899, ext 106
Fax: 443.512.8909

BEST CHILDREN'S HOSPITALS U.S.News & WORLD REPORT RANKED IN 5 SPECIALTIES 2020-21

HIGH-VOLUME, HANDS-ON TRAINING BY WORLD-RENOWNED FACULTY.

The Children's Hospital at Montefiore (CHAM) offers an extremely wide variety of educational opportunities for medical students interested in pediatrics. The department oversees the education and training of subspecialty fellows in 17 fellowship programs. Diversity, equity and inclusion are integrated into many of our educational initiatives, including our PARADE (Pediatric Advocacy, Rights and Diversity Education) curriculum. Our faculty members have been nationally and internationally recognized for their contributions to the field of pediatrics and form one of the highest-rated medical student rotations ever assembled.

PROGRAM HIGHLIGHTS AND OPPORTUNITIES

- Our 50-plus-year-old Social Pediatrics program trains pediatricians with special interests in advocacy, health policy, community and public health.
- The residency program partners with Montefiore's school health program, the largest in the United States, providing primary and preventive care to children in elementary through high school.
- Our LEADER (Leadership, Engagement, and Diversity in Education and Residency) Program is a trainee-driven program that fosters academic excellence and cultural humility while building a diverse pediatric workforce.

www.cham.org/education

Contact us at 718-741-2426 or racholon@montefiore.org.

Children's Hospital at Montefiore is consistently ranked nationally by *U.S. News & World Report* in areas including Cancer, Gastroenterology and Gastrointestinal Surgery, Neonatology, Nephrology, and Neurology and Neurosurgery.

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The Children's Hospital at Montefiore

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