Duke Perspectives from the

2022 American Academy of Pediatrics National Conference and Exhibition

Complimentary CME

Initial Release Date: **November 7, 2022**
Expiration Date: **May 6, 2023**

Learning Objective

Upon completion, participants should be able to:

- Discuss pertinent new studies presented at AAP and consider ways to apply this information to clinical practice

Developed in collaboration

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CME Information

Target Audience

This activity is intended for pediatricians.

Statement of Need

Healthcare providers need to be aware of timely topics presented at national meetings so that they can incorporate the latest evidence-based treatments into the care of their patients. To that end, we summarize information from select presentations at the 2022 AAP National Conference and Exhibition and gain insight from Jonathan Routh, MD, MPH, FAAP, a pediatric urologist at Duke University School of Medicine, with the goal of helping local and community pediatricians stay abreast of current topics, including COVID-19 vaccines and treatments for children, obesity in children, and mental health. Duke University research is also highlighted.

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Jonathan Routh, MD, MPH, FAAP, has indicated no real or apparent conflicts.

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The American Academy of Pediatrics (AAP) annual National Conference and Exhibition was held in Anaheim, CA, from October 7 to 11, 2022. This publication highlights timely topics in pediatrics presented at the conference. Expert perspective is provided by Jonathan Routh, MD, MPH, FAAP, associate professor of pediatrics, pediatric urologist, and the Paul H. Sherman, MD, Distinguished Associate Professor of Surgery at Duke University School of Medicine.

COVID-19

Pediatric Vaccine Development

During his presentation, Emmanuel Walter, MD, discussed the development of pediatric SARS-CoV-2 vaccines, including dosing, efficacy, and safety profiles.[1] Walter is a pediatrician at Duke University and chief medical officer at the Duke Human Vaccine Institute. He is also a principal investigator at the Duke University site for the Pfizer-BioNTech COVID-19 vaccine trials.

Nearly 15 million cases of COVID-19 infection have occurred in children since the emergence of the SARS-CoV-2 virus, and approximately 18% of all cases now occur in children, Walter told attendees.[2] According to data from the Centers for Disease Control and Prevention (CDC), approximately 1,500 children have died of COVID-19 since 2020, compared with 130 children who die annually of influenza.[3] Additionally, there have been approximately 9,000 reports of COVID-19–related multisystem inflammatory syndrome in children (MIS-C) and more than 72 related deaths.[4]

Clinical Trials in Younger Children

Walter described how the pivotal trials that evaluated the BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) COVID-19 vaccines in adults and older adolescents led to the subsequent adaptation of the vaccines for children and younger adolescents.[1] In a review of data from the vaccine trials in children, Walter explained that initial phase 1/2 dose-ranging studies and monitoring of safety signals in children were followed by phase 3 trials that compared neutralizing antibody titers to those observed in older adolescents and adults, as well as overall initial efficacy against SARS-CoV-2 infection. These data were used to establish safe and effective pediatric doses and dose schedules for different age groups.[1]

For example, after trials determined the safety, optimal dose, and efficacy of the BNT162b2 vaccine for adolescents, a phase 1 dose-escalation study of the vaccine in 48 children aged 5 to 11 years found that a 30-µg dose resulted in mild-to-moderate fever within 7 days in 4 sentinel participants; 1 case of grade 3 fever occurred in the 20-µg group after the second primary shot.[5] Therefore, researchers concluded that a lower 10-µg dose was most appropriate for further evaluation to avoid potential adverse effects. In the phase 2/3 portion of the trial, 2,268 participants aged 5 to 11 years were randomly assigned 2:1 to receive 2 doses of BNT162b2 10 µg or placebo 21 days apart. SARS-CoV-2 geometric mean 50% neutralizing titers were compared with those induced in individuals aged 16 to 25 years. The vaccine induced similar titers as in the older group (geometric mean ratio: 1.04 [0.93 to 1.18]) and was found to be 91% effective against SARS-CoV-2 infection (95% CI, 67.7 to 98.3).[5] A trial of the mRNA-1273 vaccine enrolled 4,016 participants aged 6 to 11 years, who were randomly assigned 3:1 to receive 50 µg or placebo 28 days apart.[6] As with the BNT162b2 vaccine, the study demonstrated a noninferior geometric mean ratio and showed an 88% efficacy against SARS-CoV-2 infection.[6]

Both vaccines were then evaluated in younger age groups.[7,8] With the BNT162b2 vaccine, dose-ranging studies identified a 3-µg dose as the safest effective dose, but a primary 3-dose strategy was required to confer effectiveness against SARS-CoV-2 infection (75.5% [95% CI, -370 to 99.60].[7] Similar trials were conducted for the mRNA-1273 vaccine in children aged 2 to 5 years and 6 to 23 months, but these

occurred during the omicron variant era.[8] The most effective and safest dosing strategy for this vaccine was found to be 2 doses of 25 µg each, administered 28 days apart for both age groups. Noninferiority to antibody response of older participants was demonstrated in both age groups; efficacy in preventing SARS-CoV-2 infection was 37% in children aged 2 to 5 years and 50% in children aged 6 to 23 months.[8]

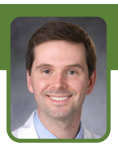
Vaccine-Associated Myocarditis

Rarely, cases of myocarditis have occurred after mRNA COVID-19 vaccination.[1,9] Vaccine-related myocarditis is more common in male adolescents and young adults (aged 12-24 years).[9] Furthermore, the risk of myocarditis increases after the second primary vaccine dose and to a lesser extent after a booster dose.[1,9] Citing data from the Vaccine Adverse Event Reporting System, Walter explained that reported rates of verified myocarditis days 0 to 7 after the second primary dose in males aged 12 to 15 years, 16 to 17 years, and 18 to 24 years were 46.4, 75.9, and 24.1 per 1 million doses, respectively.[9] Rates of myocarditis in females of the same age groups were comparatively lower: 4.2, 7.4, and 3.9 per 1 million doses, respectively.[9]

Presenting symptoms of myocarditis include chest pain, shortness of breath, and palpitations. Vaccine-associated myocarditis responds well to medication, and most patients recover within 90 days of onset, although some cardiac abnormalities have been noted in up to approximately one-half of patients.[10] It is important to keep in mind that the risks of COVID-19 and associated complications (including myocarditis) outweigh the risks of vaccination, Walter said. Extending the dosing interval up to 8 weeks in males in the age groups with a higher risk of myocarditis is one solution.[1] However, if the individual has a high risk of severe COVID-19, it is best to adhere to the recommended 3- to 4-week interval between vaccine doses, he said.

Walter reviewed numerous studies that evaluated the waning effectiveness and immune response to mRNA vaccines over time and pointed out the decline in effectiveness with the evolution of variants from delta to omicron. However, booster shots result in increased effectiveness, he said.[1] The Food and Drug Administration (FDA) authorized the use of the new bivalent booster shots in children as young as 5 years of age on October 12, 2022.[11]

Walter discussed the poor uptake of COVID-19 vaccination among children younger than 12 years: "I think we all know we are not doing so well in the youngest age groups. It's very disappointing." In fact, he said, recent data from the CDC indicate that 35% of children aged 6 months to 17 years "probably or definitely will not get vaccinated."[12] Walter added, "We can develop the greatest vaccines in the world, but we really need to increase parental confidence in COVID vaccines."



Faculty Perspective

Jonathan Routh, MD, MPH, FAAP: Dr. Walter's discussion of these topics outlines the approach to COVID-19 vaccine development in children and answers many questions of relevance to clinical practice. General pediatricians (and the public!) want to know that good science was used in the development of these vaccines and want guidance on how to answer questions that families are going to ask. The dose-ranging studies are important because they explain why the 2- to 5-year-olds and 6-month to 2-year-olds receive lower vaccine doses—because of the risk of fever that emerged in those studies. Similarly, vaccine-induced myocarditis is a frequent topic of discussion, but the actual rate of this reaction is low—less than 0.00008% in vaccinated adolescents and teens. Pediatricians need to know the details so that they can talk to families about the specifics.

Inpatient and Outpatient Therapeutics

During her presentation, Ibukun Kalu, MD, assistant professor of pediatrics at Duke University School of Medicine, discussed the treatment of COVID-19 in children.[13] The majority of children with COVID-19 can be treated with supportive care, Kalu noted. However, for children with severe symptoms, several therapies are FDA approved or have received emergency use authorization (EUA). She emphasized that the National Institutes of Health (NIH) COVID-19 Treatment Guidelines (www.covid19treatmentguidelines.nih.gov) are an important resource for the management of pediatric COVID-19.

Inpatient Treatment

Remdesivir. Remdesivir has been the "go-to" drug in both children and adults who are hospitalized with severe COVID-19, Kalu said.[13] Remdesivir is a nucleotide analogue prodrug that inhibits viral RNA polymerases, and studies of adults with severe disease have shown that remdesivir results in more rapid recovery.[14] It is FDA approved for hospitalized adults and children aged 28 days and older who weigh at least 3 kg.[15] It should be initiated within 10 days of symptom onset, but Kalu emphasized that ideally, it is started within 1 week of diagnosis.[13,16] She noted that there are no data that demonstrate clear efficacy for children younger than 12 years who do not require oxygen therapy. "In those patients, you could manage them with supportive care, and they will likely be fine," she said. Remdesivir should be used with caution in patients with renal or hepatic disease.[16]

Dexamethasone. A major randomized controlled trial of dexamethasone for the treatment of adult patients hospitalized with COVID-19 demonstrated reduced 28-day mortality rates among those receiving respiratory support.[17] Subsequently, these data were extrapolated to children, Kalu noted. However, there is no documented benefit among patients who do not require oxygen therapy or in infants with viral bronchiolitis unrelated to COVID-19.[17] Given the difficulty of determining whether a child's symptoms are actually due to COVID-19 infection versus another condition at the time of hospitalization, "it's important to try and delineate what you're treating when they come in," Kalu emphasized. "If it is [severe] COVID, dexamethasone would help." Dexamethasone can be used with or without remdesivir and should be used cautiously in patients who are immunocompromised.[18]

Baricitinib. Although immunomodulatory medications are being used in post–COVID-19 syndromes to address inflammation, "most often in pediatric centers, we don't see a lot of immunomodulatory medications used for acute COVID," Kalu told attendees.[13] The JAK inhibitor baricitinib has received EUA for children aged 2 years and older and is one treatment option in patients with severe acute disease and slow improvement after dexamethasone. In the RECOVERY trial of 33 children, treatment with baricitinib resulted in decreased mortality of 13%.[19]

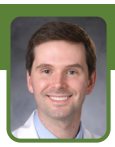
Tocilizumab. The interleukin-6 inhibitor tocilizumab has also received EUA for children aged 2 years and older. Its use should be limited to patients with severe disease after treatment with steroids and respiratory support, Kalu said.[13,20]

Outpatient Treatment

Remdesivir. Remdesivir is used frequently to manage COVID-19 in the outpatient setting. According to the placebo-controlled PINETREE study, remdesivir reduced the relative risk of hospitalization by 87% in adults with COVID-19 symptom onset in the previous 7 days and at least 1 risk factor for severe COVID-19 (HR, 0.13; 95% CI, 0.03 to 0.59; $P = .008$).[21] Of note, only 8 children were included in the study, but other data extrapolated from compassionate use in hospitalized children suggest remdesivir is effective in children, Kalu said. Remdesivir is administered via intravenous infusion, which may limit its availability and use in some settings.[21]

Nirmatrelvir. The efficacy of ritonavir-boosted nirmatrelvir in preventing severe COVID-19 was established in the EPIC-HR trial, which showed an 89% relative risk reduction in symptomatic, unvaccinated adults with a high risk of progression to severe disease ($P < .001$).[22] Ritonavir-boosted nirmatrelvir has received EUA in children aged 12 and older (weighing > 40 kg) with mild-to-moderate COVID-19 who have a high risk of progression to severe disease.[23] The drug must be initiated within 5 days of symptom onset.[23] A main advantage of ritonavir-boosted nirmatrelvir over remdesivir is its oral formulation. However, ritonavir-boosted nirmatrelvir has numerous drug-drug interactions, Kalu pointed out and suggested pediatricians consult the FDA eligibility checklist tool available online (www.fda.gov/media/158165/download).

Bebtelovimab (investigational). Bebtelovimab is currently the only available anti–SARS-CoV2 monoclonal antibody that is effective against the omicron variant.[23] It is available under EUA within 7 days of symptom onset for nonhospitalized children aged 12 years and older who weigh 40 kg or more and have a high risk of progression to severe COVID-19 and/or hospitalization.[23]



Faculty Perspective

Jonathan Routh, MD, MPH, FAAP: The manner in which Dr. Kalu broke down therapeutics into categories for hospitalized and nonhospitalized children with COVID-19 and presented the data behind each treatment choice is incredibly useful for busy pediatricians. No human being is ever going to be able to remember everything in this ever-changing field, with new data emerging all the time. When you're dealing with this level of complexity in the middle of a hectic clinic, this is certainly what is needed. Likewise, it's important for pediatricians to refer to the tools available from the NIH and CDC on COVID-19 treatment.

OBESITY

Neighborhood Environment May Not Influence Obesity Outcomes in Youth

Neighborhood environment is not associated with degree of obesity or cardiovascular health outcomes in youth who have already developed severe obesity, a new study finds.[24] Duke University School of Medicine student Shivani Chandrashekaran presented the findings of the study. Senior study author Sarah Armstrong, MD, is the director of the Duke Children's Healthy Lifestyles Program in the Department of Pediatrics.

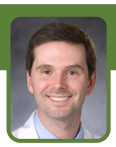
Previous research has demonstrated that neighborhood factors (ie, the "built environment"), such as proximity to fast food restaurants and access to playgrounds and sidewalks, are associated with physical activity, obesity, and cardiovascular outcomes among youth.[24] This study aimed to further characterize associations so that future interventions can be targeted to youth who have an increased risk of poor health outcomes. The study authors noted that during the COVID-19 pandemic, rates of obesity increased among children and adolescents.[24]

The study analyzed data from 248 participants in the Hearts and Parks Trial, which enrolled patients with a body mass index (BMI) greater than or equal to the 95th percentile for sex and age.[24] The average age of participants was approximately 10 years but ranged from 5 to 17 years. More than one-half (52.4%) were girls. Approximately 38% were Hispanic, 39% were White/non-Hispanic, and 17% were Black/non-Hispanic.[24]

Participant addresses were linked to the Child Opportunity Index (COI) at the census tract level.[24] The COI is composed of 29 indicators of neighborhood resources and conditions that affect children. Secondary exposure variables included walkability, green space, access to healthy foods, and commute duration. The study outcomes were BMI relative to 95th percentile for age, submaximal exertion heart rate after the YMCA bench step score, and systolic and diastolic blood pressure percentiles.[24]

Notably, no significant associations were found between composite COI score and any of the outcome variables. Additionally, no association was observed between neighborhood walkability, green space, access to healthy food, or commute duration.[24]

The authors concluded that in a diverse sample of youth who had already developed obesity or severe obesity, neighborhood environment was not independently associated with degree of obesity or cardiovascular health outcomes.[24] They noted: "Treatment of youth obesity should encompass strategies beyond prevention and lifestyle modification, as intensive interventions may be necessary for children and adolescents with severe obesity."[24]



Faculty Perspective

Jonathan Routh, MD, MPH, FAAP: The findings of this study make sense. If a child is already obese, then it may or may not be possible to bend that obesity curve or that outcome curve with relatively straightforward preventive measures—the die may already be cast. At that point, there may already be epigenetic changes as well as entrenched lifestyle issues. A child could have the most wonderful park in the world just outside their window, but if they've been sitting and playing video games for 12 years, they probably still won't access it. This is not to say that the built environment doesn't matter—it does—but its influence may primarily be early on, not late in the game.

Arriving Soon: Updated AAP Clinical Practice Guideline for Obesity

Sarah Hampl, MD, an obesity medicine specialist at Children's Mercy Kansas City, provided a preview of the AAP's obesity clinical practice guideline (CPG), anticipated to be published in late 2022.[25]

Hampl began the discussion with a quote from Sarah Armstrong, MD, chair of the executive committee of the AAP section on obesity and professor of medicine at Duke University School of Medicine. "The CPG summarizes what we know about childhood obesity treatment and comorbidity management, and it provides practical, effective recommendations in the context of whole child care [and] nonstigmatizing communication and addresses key social drivers of health."[25]

The CPG is the AAP's first comprehensive guidance in 15 years on the management of obesity, Hampl told attendees. Development included a committee of primary and tertiary care providers, a parent representative, several epidemiologists, policy and implementation science experts, a registered dietitian nutritionist, and a pediatric psychologist.[25] Nearly 16,000 abstracts dating from 2017 were reviewed, and findings of 382 studies were ultimately included. Two technical reports on treatment and comorbidities will be published alongside the CPG.[25]

The main topics covered in the CPG address evaluation of children with obesity, assessment of comorbidities, and evidence-based treatment options.[25] The CPG contains 13 key action statements and 11 consensus recommendations. A detailed algorithm that contains all of the key action statements in one place will accompany the CPG to assist with clinical decision making, Hampl said.[25]

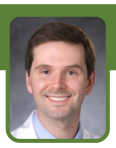
Although the CPG remains embargoed until publication, Hampl provided some takeaways from the CPG. Obesity is a complex chronic disease with structural inequities and can affect a child's emotional and physical health, she said. Thus, comprehensive evaluation of the whole child is important.[25] In the CPG, the committee underscored that obesity is often an indicator of structural inequities, such as unjust food systems, health inequities, and environmental and community factors. Genetics, obesity-promoting environments, and life experiences combined with inequities and structural barriers to healthy living all contribute to overweight and obesity. To assist with overcoming these barriers, the committee recommended that clinicians routinely assess individual structural and contextual risk factors affecting children.[25]

"We now understand to a greater degree that social and other structural determinants of health not only put children at risk of disease, but there are actual physiological impacts of these chronic stressors on children's weight," Hampl told attendees. More information is now known about the effects of weight bias and stigma on children's health and family willingness to pursue treatment, she said.[25]

Importantly, a staged approach to treatment is no longer recommended in the new CPG.[25] "Rather, early diagnosis, evaluation, and treatment of obesity and comorbid conditions is important to optimize children's health outcomes," Hampl explained. "In fact, as we treat children with obesity, we are treating their comorbidities." The CPG will include multiple strategies that can be used individually or in combination to provide intensive tailored treatment. Structured, supervised obesity treatment decreases the risk of current and future disordered eating, she added.[25]

"If you only remember one thing from today's talk, please remember this," Hampl concluded. "Start treatment immediately and deliver it intensively—there is no benefit to watchful waiting."

Faculty Perspective



Jonathan Routh, MD, MPH, FAAP: Obesity rates in the United States (US) are not getting better. Sadly, the rates of obesity and overweight in children and adolescents are on a distinctly upward trend. Thus, what we've been doing hasn't necessarily been working, and the need for this new guideline is clear—it's time for a new approach. I would like to highlight Dr. Armstrong's role in the development of the new guidelines. She is a leader of the Healthy Lifestyles Program, a comprehensive weight management program at Duke Children's, and has been active in the development of these new recommendations.

MENTAL HEALTH

Surge in Patients with Behavioral Health Problems Presenting to Pediatric Emergency Departments

Stephen Rogers, MD, an emergency physician at the Connecticut Children's Medical Center in Hartford, reviewed national data documenting a major recent surge in mental/behavioral health visits to pediatric hospital emergency departments (EDs).[26] Rogers and colleagues analyzed data retrospectively from the Pediatric Hospital Information System that documented 13 million ED visits from 2009 to 2014 at 44 children's hospitals; of these visits, 150,000 resulted in a psychiatric diagnosis.[27] In comparison, data from 2015 to 2021 revealed 18 million ED visits at 49 children's hospitals in the US, with 600,000 visits resulting in a psychiatric diagnosis, representing a substantial increase, Rogers told attendees.[26]

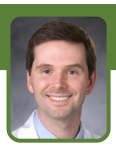
"We know these patients [use] vast resources in already busy pediatric EDs. And most providers, myself included, receive very limited mental and behavioral health training unless we seek it out ourselves," Rogers said. "Therefore, we believe that research, education, and quality improvement need to be a priority for this patient population."[26]

In response to this crisis, Connecticut Children's Medical Center built a separate, 11-bed, ligature-safe unit that has since been expanded to accommodate up to 19 patients.[26] They have a psychiatrist, social workers, behavioral health nurses, and patient care partners on staff, Rogers said.

Rogers also discussed suicide screening and prevention and presented sobering facts on suicide in younger populations. Citing CDC data, he noted that suicide became the second leading cause of death among 10- to 34-year-olds in 2014.[28] Alarmingly, in 2020, suicide became the 10th leading cause of death *among 5- to 9-year-olds*, a trend never seen before.[28] Data from the 2019 State Youth Risk Behavior Surveys show that 19% of high school students have seriously contemplated suicide in the past year, and 9% have attempted suicide in the same time frame.[29] "We've got to figure out how to identify these kids and get them the help they need," Rogers said.

In 2019, The Joint Commission established that healthcare institutions, including EDs, must screen for suicide risk as a requirement for accreditation. Rogers explained that his institution uses the Ask Suicide-Screening Questions 4-question (ASQ-4) tool.[26] "We screened over 30,000 patients with that screener. Our compliance rate is 91%," he said. The ASQ-4 and other tools for suicide prevention in the ED are available through the NIH (www.nimh.nih.gov/research/research-conducted-at-nimh/asq-toolkit-materials).

Faculty Perspective



Jonathan Routh, MD, MPH, FAAP: Mental and behavioral health among children and adolescents is a huge problem in the post-pandemic era. Resources are highly variable depending on the state in which you happen to live, and not every facility is able to build a dedicated pediatric unit as described (particularly in Certificate of Need states such as North Carolina). The reality is that on any given day, EDs have critically (mentally) ill children who are a threat to themselves and to others; some may have been in the ED for more than a month because they are too unsafe to be moved to a regular floor. This is a crushing problem in pediatric EDs and pediatric hospitals overall.

Pediatricians Can and Should Talk About Mental Health

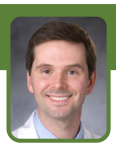
Johanna Bergan, former executive director of Youth MOVE National, delivered the 2022 Stockman Lecture and offered a patient perspective on mental health discussions in pediatric clinical practice.[30] Youth MOVE National is a youth leadership organization that prioritizes the mental health of young people.

She encouraged pediatricians to engage patients in discussions about mental health and offer help when needed. "If TikTok is currently answering my mental health questions and giving me my best ideas to find support, I should definitely be able to talk about mental health with my pediatrician," she told attendees.[30]

From a patient's perspective, pediatricians play a crucial role in youth mental health, Bergen explained. "Your ability [as a pediatrician] to validate, refer, connect, recommend, and network are all superpowers that you hold for youth and their family," she said. "Knowing that you care about helping them identify and access specialty mental healthcare can be such a stress relief."[30]

Bergen acknowledged that pediatricians often feel that they lack the vocabulary and qualifications to engage in mental health conversations with their patients.[30] "First of all, young people are already talking about mental health way more than you can possibly imagine," she said. "The narrative and willingness to talk about anxiety, depression, and mental health in general has changed and shifted so much in the last 10 years."

She also addressed other sources of hesitancy among pediatricians in addressing mental health. "Sparking the conversation about emotional health does not immediately saddle you with a requirement and need to fix everything. It can be as simple as starting the conversation and beginning a process to identify additional mental health resources," she explained.[30]



Faculty Perspective

Jonathan Routh, MD, MPH, FAAP: The current US system to deal with mental health turns out to not be a system at all, but a patchwork quilt that isn't keeping everyone warm. Innovation, by necessity, arises from that. Everyone is aware that kids' mental health is an issue in the pandemic era. This lecture acknowledged that, with a nod to the fact that pediatricians cannot necessarily run a busy pediatric practice, handle COVID, take care of obese children, and oh, by the way, fix kids' mental health issues. We need other alternatives, and community support is a big part of that. However, it is crucial that pediatricians continue to be engaged on this issue and continue to be willing to start what can be a challenging conversation.

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