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Panelists tackle COVID-19 unknowns, urge pediatric clinical trial participation

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AAP infectious diseases experts who participated in a virtual town hall called on pediatricians to encourage interested families to sign up for pediatric COVID-19 vaccine trials.

The “unprecedented pace” of the adult clinical trials led to a rapid development of messenger RNA COVID-19 vaccines from Pfizer-BioNTech and Moderna the same year the virus was identified, and pediatric clinical trials need the same willingness from participants, said David W. Kimberlin, M.D., FAAP, editor of the *Red Book*: *2021-2024 Report of the Committee on Infectious Diseases*(COID), 32nd edition (anticipated release in May).

During Thursday’s “Ask the *Red Book*”about COVID-19 town hall, Dr. Kimberlin and COID Chair Yvonne A. Maldonado, M.D., FAAP, addressed a long list of unknowns, including when the COVID-19 vaccine might be available for children.

Pfizer-BioNTech and Moderna are enrolling 12- to 17-year-olds in clinical trials (see resources), but there has been some difficulty identifying participants, Dr. Kimberlin said. “If you are in a city where there is a pediatric study, adolescent study going on, please encourage families to sign up.”

Federal leaders have commented that pediatric clinical studies may not involve tens of thousands of participants but instead use immune bridging, Dr. Maldonado said. “The antibody that’s elicited in children is that similar to what we see in antibody in adults. That could potentially speed up the process of pediatric trials a bit, but (children) are going to lag behind.”

Both pediatricians estimate that the Food and Drug Administration (FDA) could decide on emergency use authorization (EUA) of vaccine in 12- to 17-year-olds in early summer.

In the meantime, immunizing teachers, the elderly and caregivers of children with medical complexity can prevent the spread of disease, Dr. Kimberlin said. “(These are) ways to get children into more normal activities by protecting the adults that are around those children, kind of as a surrogate as we wait for these data.”

Considering the small risk of multisystem inflammatory syndrome in children, clinical trials can examine vaccine safety, immunogenicity and whether immunologic responses skew toward a hyperinflammatory or non-hyperinflammatory state, Dr. Maldonado noted.

“There have not been any signals so far (from data presented during FDA and CDC Advisory Committee on Immunization Practices meetings), but we want to make sure that we know whether there might be any risk of that occurring,” she said.

Another area devoid of pediatric study is monoclonal antibodies and other treatments for children. The FDA granted an EUA for two novel virus-neutralizing monoclonal antibody therapies, bamlanivimab and REGN-CoV2 (casirivimab plus imdevimab), for the treatment of mild to moderate COVID-19 in adolescents and adults in specified high-risk groups.

Dr. Kimberlin said a panel of pediatric experts recently published interim guidance that recommends against routine administration of monoclonal antibody therapy to treat children or adolescents, including those designated by the FDA as at high risk of progression to hospitalization or severe disease. The recommendation was made primarily due to a lack of efficacy or safety data in pediatric patients, lower risk of pediatric severe disease progression and modest efficacy in adults.

Dr. Maldonado and Dr. Kimberlin are eager to see more data from adult clinical trials that can inform whether pediatricians who complete the two-dose COVID-19 vaccine series should quarantine if they are exposed to some who tests positive for the virus. They advised pediatricians who receive the vaccine to continue to follow safety precautions, including using personal protective equipment.

Pediatricians should note that the adult clinical trials did not evaluate whether SARS-CoV-2 can be transmitted by immunized individuals. “It is possible that you could … post-vaccination, asymptomatically acquire wild-type virus infection and still be able to transmit it. And since we don’t know that that does not occur… we need to continue to mask,” Dr. Kimberlin said.

Other discussion highlights:

- **Perils and pitfalls of rapid tests in the office.** Pediatricians should be aware of the type of test they use and its limitations. They should follow up with sick patients — even those with a negative test — who may need continued evaluation
- **Antibodies and immunity to variants.** Regardless of the severity of illness, antibody levels drop off quickly within four to five months. “We don’t even know what your risk is if you contract the old virus again the second time,” Dr. Maldonado said.
- **Ways pediatricians can support schools.** Well-resourced schools have been able to stay open. Pediatricians can be a valuable resource to schools, Dr. Maldonado said. “Your ability to educate families and school districts (can) make a difference.”

“We are all learning together as we proceed through this journey and in this pandemic,” said Anne R. Edwards, M.D., FAAP, AAP chief population health officer, who led the discussion. She said pediatricians often ask how they can support their infectious disease colleagues as the pandemic continues.

“We're going to get there,” Dr. Kimberlin said. “It's remarkable where we are right now. We have these vaccines; we're getting larger supplies of them. We all want it to happen more quickly.”

Resources

- Connecting with the Experts: A COVID-19 Town Hall series
- Pediatric clinical trial details from Pfizer
- Pediatric clinical trial details from Moderna
- AAP members can request a complimentary paperback copy of the Red Book: 2021-2024 Report of the Committee on Infectious Diseases, 32nd edition (shipped in June).