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FDA panel: Benefits of COVID-19 vaccine for ages 5-11 outweigh risks

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Melissa Jenco, News Content Editor

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Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

A federal vaccine panel said Tuesday the benefits of the Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 years outweigh the potential risks, although some expressed hesitation in recommending it for all children in this age group.

Members of the Food and Drug Administration's (FDA's) Vaccines and Related Biological Products Advisory Committee said they want to protect children from COVID-related infections, hospitalizations and deaths as well as disruptions to their education. However, the risk of myocarditis, though rare, gave some pause.

After a full day of presentations and discussions, the group voted 17-0 with one abstention to recommend emergency use authorization (EUA) of the vaccine for 5- to 11-year-olds. The decision to grant an EUA now goes to the FDA commissioner. The Centers for Disease Control and Prevention's (CDC's) vaccine advisory committee will meet Nov. 2-3 to discuss who should receive the vaccine.

"You never know everything," said Paul A. Offit, M.D., FAAP, director of the Vaccine Education Center at Children's Hospital of Philadelphia. "The question is whether you know enough. I think we certainly know there are many children between 5 and 11 years of age who are susceptible to this disease who could very well be sickened or hospitalized or die from it."

COVID-19's impact on children

Since the start of the pandemic, about 1.9 million children ages 5-11 years have been infected, about 9% of all U.S. cases. More than 8,300 have been hospitalized and 94 have died, according to federal data. The death toll in the past year puts COVID in the top 10 causes of death for this age group.

The pandemic also has taken a toll on children's education and their mental health, prompting the AAP, American Academy of Child and Adolescent Psychiatry and Children's Hospital Association to declare a national emergency in children's mental health earlier this month.

Vaccine trial data on efficacy, safety

If approved, the pediatric vaccine would be given in two 10-microgram doses administered 21 days apart. The dosage is one-third of the adolescent and adult dose.

Clinical trials in children ages 5-11 years found the vaccine to be 90.7% effective in preventing symptomatic COVID-19. The vaccine also met immunobridging success criteria for geometric mean neutralizing antibody

titers and seroresponse rates.

Safety data from the trials, which included more than 3,000 children who received the vaccine, found the most common reactions were pain at the injection site, fatigue and headache. Reactions were mostly mild or moderate. There were no serious adverse events related to the vaccine, including myocarditis or anaphylaxis.

Weighing the risks and benefits

The FDA presented the committee with six modeling scenarios to assess the risks and benefits of COVID-19 vaccines for children. All showed the benefits outweigh the risks with the exception of one scenario where COVID incidence was the lowest.

While there were no myocarditis cases in the trials for children, the rare cases seen in real-world settings loomed over the meeting. The cases have been seen predominantly in males under 30 years after the second dose of mRNA vaccine.

H. Cody Meissner, M.D., FAAP, chief of the Division of Pediatric Infectious Disease at Tufts Medical Center, noted that CDC data show about 42% of children may have had COVID-19, which he said likely means they have some protection.

“We’re getting down to a very small percent of otherwise healthy (5)- to 11-year-old children who might derive some benefit, and we simply don’t know what the side effects are going to be,” Dr. Meissner said.

But other members of the panel noted the low incidence of myocarditis in adolescents after vaccination. In addition, the vaccine given to children would be a lower dose.

“It’s a theoretical risk and it’s an important one, but fortunately no one has died from that that fits that profile,” said Patrick S. Moore, M.D., M.P.H., professor in the Department of Microbiology and Molecular Genetics at the University of Pittsburgh School of Medicine. “If surveillance systems do start seeing severe outcomes and deaths from vaccination, I’m quite confident those surveillance systems will tell us we need to pause like we did with the J&J (Johnson & Johnson) vaccine.”

Mark H. Sawyer, M.D., FAAP, professor of clinical pediatrics in the Division of Infectious Diseases at the University of California San Diego School of Medicine, noted myocarditis historically is less common in this age group than in older groups and more data won’t be available until the vaccine is more widely used.

“I do think we need it as a tool in our armamentarium for high-risk children, for equity issues, for parents who really would like to protect their children and because of the long-term very profound implications of schools being disrupted and the social and educational impact that that’s having,” he said.

Michael G. Kurilla, M.D., Ph.D., director of the Division of Clinical Innovation at the National Center for Advancing Translation Sciences, abstained from the vote saying the immunobridging studies did not convince him the vaccine would provide long-term protection, and he feels children who have been infected don’t need two doses.

“I think the idea of doing under an emergency use authorization, two doses for everybody without any flexibility around this, I think is just not going to go over very well and I don’t think it’s going to give the health care community the options and parents the options to choose what’s best for their children,” he said.

Some vaccine committee members expressed a preference for limiting the vaccine to children with high-risk conditions, which CDC data showed were present in about two-thirds of hospitalized children ages 5-11 years. However, the committee was asked to vote only on whether the benefits outweigh the risks for all children. The CDC will have more latitude to determine whether the vaccine is recommended for a smaller group of children.

Preparing to vaccinate children

Under a plan released by the White House last week, pediatricians will be on the front lines of vaccinating children. The AAP has resources to help pediatricians sign up to be COVID-19 vaccinators and to prepare their practices. Pediatricians can reach out to their state immunization managers to request vaccines for their practices. They also are urged to contact their AAP chapters for assistance.

Resources

- CDC website on vaccinating children ages 5-11 years
- CDC COVID-19 Vaccination Pediatric Operational Planning Guide
- Preliminary overview of Pfizer-BioNTech COVID-19 vaccines
- AAP resources on becoming a vaccinator, preparing a pediatric practice for COVID-19 vaccination and getting paid