COVID-19 vaccine for kids: How we know it’s safe

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With the U.S distributing enough vaccines to immunize the estimated 28 million American children between 5 and 11 years old, pediatricians, family doctors and other physicians may find themselves encountering the question: Is this vaccine safe for my child?

“Safety concerns were the most frequent reason for vaccine hesitancy, but when asked where patients would prefer to get their child vaccinated, their regular physician's office was by far the favorite first choice,” said Sandra A. Fryhofer, MD, during a recent episode of “AMA COVID-19 Update.”

Dr. Fryhofer is the AMA’s liaison to the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) and a member of ACIP’s COVID-19 Vaccine Workgroup.

About half of parents surveyed say they are likely to get their child vaccinated—a number that strongly correlates with whether the parent was vaccinated or not. So, what can pediatricians tell their patients and their parents about the vaccine’s safety?

Over 90% effective against Delta

Food and Drug Administration authorization was based on a clinical trial that enrolled about 4,600 children 5–11. Over 3,000 got the real vaccine and about 1,500 got a placebo.

“Levels of antibodies effectively neutralized both the original virus strain and the Delta variant,” Dr. Fryhofer said. Pfizer-BioNTech “also conducted a supplemental vaccine efficacy analysis during a time when the Delta variant was prevalent,” she added. “There were three COVID cases in the 1,400 children who were vaccinated and 16 cases in the 700 children who received placebo. The vaccine
was more than 90% effective at preventing COVID.”

Why it’s safe

Clinical trials showed that younger children see the same side effects as has been seen in adults and teens: some pain with redness and swelling at the injection site. They also sometimes experienced fatigue headaches and chills.

“Symptoms were increased after the second dose,” Dr. Fryhofer explained. For kids who already had a bout with COVID-19, though, the study showed that the vaccine’s side effects were actually milder.

The 5–11-year-olds saw fewer fevers than those who were between 16–25 years old and received the adult dose of the vaccine. Also, there were no reports of myocarditis in the 3,000 5–11-year-old study participants, but the study was very small.

Also, she said, vaccine-associated myocarditis tends to be mild, seems to respond well to conservative therapy and resolves fairly quickly. The CDC is now doing enhanced surveillance and follow-up of post vaccination myocarditis cases. Patients who experience chest pain, shortness of breath, or palpitations in the first few days after mRNA COVID vaccination should seek medical care, she said.

Patients and doctors should send a report to the CDC Vaccine Adverse Event Reporting System after any suspected case of myocarditis following vaccination.

Dr. Fryhofer said fewer side effects and no cases of myocarditis may have occurred because of the lower dose younger children receive. Children 5–11 will get a 10-microgram dose, compared to the 30-microgram dose that adults and children 12 and older receive.

The American Academy of Pediatrics is on board with vaccinating this age group, along with the American Academy of Family Physicians and the Pediatrics Infectious Diseases Society, said Dr. Fryhofer, chair-elect the AMA Board of Trustees.

Dr. Fryhofer said myocarditis received a lot of discussion at the Food and Drug Administration’s advisory committee meeting and at ACIP. She noted that myocarditis has been a rare occurrence after the second dose of the mRNA vaccines.

“The observed risk is highest in young males age 12 to 29, but COVID infection can also cause myocarditis,” she pointed out. “For adolescents and young adults, the risk of myocarditis caused by COVID infection is much higher than after mRNA vaccination.”
Also, she said, vaccine-associated myocarditis tends to be mild and resolves fairly quickly.

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While severe COVID-19 has been less common in younger children, they can experience long COVID and other complications.

“Children can have persistent fatigue, headaches, sleep problems, trouble concentrating, muscle and joint pain, and cough even after mild COVID infections,” Dr. Fryhofer said, noting that multisystem inflammatory syndrome that has been most frequent in the 5–11 age group over the last year.

There have been more than 1.9 million COVID-19 cases reported in children 5–11, with more than 8,300 hospitalizations and almost 100 deaths since the pandemic’s onset. It was the eighth leading cause of death for children in this younger age group.

In addition to these physical effects, COVID-19 affects children’s quality of life.

“These are huge. School closures and missing school have led to lost in-person learning,” Dr. Fryhofer said. “Getting your child vaccinated is the best way to keep your child from getting COVID and possibly being hospitalized or getting MIS-C or long COVID or spreading it to others.”

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