

An in-depth look at kids and COVID vaccines with Sandra Fryhofer, MD

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In today's COVID-19 Update, AMA Chief Experience Officer Todd Unger discusses what physicians need to know about the recent COVID-19 vaccine authorization for children in the 5 to 11 age group with Dr. Sandra Fryhofer, AMA's liaison to the Advisory Committee on Immunization Practices (ACIP), and a member of ACIP's COVID-19 Vaccine Workgroup.

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Speaker

- Sandra Fryhofer, MD, chair-elect, AMA Board of Trustees; AMA's liaison to the Advisory Committee on Immunization Practices

Transcript

Unger: Hello, this is the American Medical Association's COVID-19 Update. Today, we are discussing what physicians need to know about the recent COVID vaccine authorization for children in the five to 11 age group. I'm joined by Dr. Sandra Fryhofer, AMA's liaison to the Advisory Committee on Immunization Practices, or ACIP, and a member of ACIP's COVID-19 vaccine workgroup. Dr. Fryhofer is also the chair-elect of the AMA Board of Trustees. I'm Todd Unger, AMA's chief experience officer in Chicago.

Dr. Fryhofer, thanks for joining us. Lots to learn here this morning. The FDA authorized and ACIP, with a sign-off from the CDC director, has now expanded its recommendation for the Pfizer COVID vaccine to include children age five to 11. Let's start with some details about the vaccine. Is this vaccine identical to the adult version or is it different?

Dr. Fryhofer: Well Todd, so many parents have been waiting for a COVID vaccine for their kids and now it's here. There are a few minor differences between this new kiddy version and the one for adults. The messenger RNA and its lipid nanoparticle coding are the same. The number of doses and the dosing interval's the same, two doses three weeks apart but the dosing size is different. The dose for kids is smaller. It's a kiddy dose, 10 micrograms, which is one third of the 30 microgram dose for adults and older children. The kid version also uses a different buffer to stabilize it. The kiddy version contains Tris, which is short for tromethamine, as the buffer. PBS, phosphate-buffered saline, is the buffer used for adults. Extra salt, both sodium chloride and potassium chloride, have been removed in the version for kids. These minor changes make the vaccine product more stable at regular refrigerator temperatures for longer periods of time. The kid version vials can be stored unopened in regular refrigerators for up to 10 weeks.

Now, just like the one for adults, the kiddy vaccine contains no preservatives, vial stoppers do not contain latex. To keep them straight, the products are color coded to make them look different. To reduce the risk of mix up the adult vial is purple, the one for kids is orange.

Unger: Well, let's talk a little bit about the research. Can you take us through some of the details about a study that supported this new recommendation?

Dr. Fryhofer: Sure. FDA authorization was based on results from a clinical trial that enrolled about 4,600 children aged five through 11. 3,100 of them received the real vaccine, about 1,500 received placebo. They compared neutralizing antibody titers of five to 11-year-olds who got two 10 microgram kiddy doses to those of 16 to 25-year-olds who got two 30 microgram adult size doses. Doses for both age groups were given three weeks apart. This type of comparison is called immunobridging. The study for the five to 11-year-olds met criteria set by the FDA. Levels of antibodies effectively neutralized both the original virus strain and the Delta variant. The company also conducted a supplemental vaccine efficacy analysis during a time when the Delta variant was prevalent. 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.

Unger: Oh, that's big news and really good news for this age group. When you look at the trial and the trial participants, what is the level of diversity in that group?

Dr. Fryhofer: Well, this part was a little bit disappointing. The pediatric trial included few from historically minoritized groups who we know are at greater risk of bad outcomes from COVID. This really surprised me because the initial phase three trials for adults show diversity in the trial participants but not so for the smaller study in kids. Nearly 80% of the children were white, only 6% were Black. The mean age was eight. 20% had comorbidities putting them at increased risk of COVID. The most common comorbidities were obesity, asthma, neurological disorders and congenital heart disease. 70% of study participants lived in the U.S. We need to keep encouraging vaccine developers to ensure diversity in their trial participants.

Unger: Now, a lot of the discussion has been around how do we get parents to bring their kids in from this age group and is COVID a concern for this age group? We're in a world now where we've had over 700,000 people die from COVID in the U.S. and there are 28 million children in this age group. Can you bring some clarity to the burden of COVID infection for children in this age group and put that into perspective?

Dr. Fryhofer: In children age five to 11, there have been over 1.9 million COVID cases, over 8,300 hospitalizations and nearly 100 deaths since the pandemic began. And if you look at the top 10 causes of death for children in this age group over the last year, COVID comes in number eight. Children age five to 11 make up about 40% of all pediatric COVID cases. Another serious consequence of COVID is MIS-C, multisystem inflammatory syndrome in children. It's most frequent among kids in this five to 11 age group, with more than 2,300 MIS cases so far. Two thirds of MIS-C cases are in Black and Hispanic children. Post COVID conditions can also occur in children, so kids can be long haulers too and not just after severe cases. Children can have persistent fatigue, headaches, sleep problems, trouble concentrating, muscle and joint pain, and cough even after mild COVID infections.

Unger: And those long-haul infections we just talked about last week in a different segment, very, very concerning. This question then around whether younger children are less likely to get COVID. What does the data say about that?

Dr. Fryhofer: Children are at least as likely as adults to be infected with COVID but infections in children are less likely to be reported as compared to cases in adults. Zero prevalence in children age five to 11 is about 38%, which is also about what we see in children age 12 to 17. So 38% of children age five to 11 have had COVID in the past. Secondary transmission from children can and does occur both at school and at home. Children can and do transmit COVID to others.

Unger: Those are big numbers and the unreported thing, that's interesting. A lot of kids are sick all the time going to school and there might be confusion with something like the flu. Can you talk about how does COVID infection compare to the flu?

Dr. Fryhofer: We were fortunate last year that we had a very, very, very mild flu season. In fact, there was practically no flu out there and this is probably because most of us were wearing masks and kids were not going to school. But what they did is they compared the risk of flu and COVID and they looked at previous flu seasons. Hospitalization rates for COVID in kids is similar to that for flu in some of those previous seasons but for COVID the hospital stays are longer. A third of all children hospitalized with COVID require ICU admission. Of those hospitalized 68%, that's more than two-thirds, had at least one underlying condition, most commonly chronic lung disease—mainly asthma—and obesity, also neurological disorders and heart disease. But one-third of those hospitalized with COVID did not. One-third of them did not have any underlying medical condition that would predispose them but they got severe COVID anyway.

Unger: You touched on this a little bit before in terms of those kind of severe cases but in terms of racial and ethnic differences, in terms of COVID's impact within this age group, what are the differences that you see?

Dr. Fryhofer: COVID has hit minoritized children in this age group especially hard, with hospitalization rates three times higher for Black, Hispanic and American Indian/Alaska Native children, as compared to white children. Two thirds of cases of MISC, multisystem inflammatory syndrome in children, are in Black and Hispanic children.

Unger: This question of whether to get a vaccine if you've had COVID or not is something that's been floating around and I think in this particular age group it's important to get the facts here. Can kids who've had COVID get vaccinated?

Dr. Fryhofer: Yes. And they should get vaccinated. 9% of children in the clinical trial were already baseline serum positive. They had previously had COVID. Getting vaccinated boosted antibody protection for them a lot. The antibody levels post vaccination in children who had prior infection were higher than in children who had never had COVID. But are antibody levels triggered by previous COVID infection enough to keep them protected from future infection? Probably not. And here's why. Peaks of COVID hospitalizations among children during the Delta wave were in the setting of a seroprevalence of around 40%. In other words, about 40% of these children in this age group had already had COVID. This level of seroprevalence was not sufficient to provide broad protection to children against COVID.

Unger: Well, when you talk about antibody testing, did they discuss testing for antibodies? Could that be helpful in this regard?

Dr. Fryhofer: Antibody testing is not recommended now. There is no established correlate of protection. The available antibody test cannot determine when a person got infected. Antibody tests vary in their sensitivity, especially if it's been more than three months after infection. So you could test positive on some of the commercially available antibody tests if markers of immune response such as neutralizing antibodies have waned. At this time there is no FDA authorized or approved tests that we can use to reliably determine whether a person is protected from infection. So the antibody testing doesn't help us right now.

Unger: Well, that's very clear. Let's talk about side effects. Are we seeing a pretty similar story relative to other age groups?

Dr. Fryhofer: Well, the side effects were pretty much what you would expect, mostly pain, along with redness and swelling at the injection site, fatigue, headache, chills were the main systemic side effects but less fever as compared to those age 16 to 25 who got the adult dose version. So in general, the side effects for kids receiving this lower 10 microgram dose were less than those for older adolescents

and teens who received the adult dose of 30. Symptoms were increased after the second dose. There were no reports of myocarditis in this study but the study was small. Safety surveillance is in place to look for it. Fewer side effects and no cases of myocarditis may be due to the lower dose.

Unger: Okay. What about side effects for kids who have already had COVID? Were they worse or not?

Dr. Fryhofer: No, they were not. Kids who you had prior infection had milder side effects, which to me was a surprise. Rates of local and systemic reactions, as well as adverse events were lower in children who had previously had COVID.

Unger: Myocarditis has been a concern. What should physicians tell parents who are concerned about that?

Dr. Fryhofer: There was a lot of discussion about this at FDA's advisory committee meeting and at ACIP. The good news is there were no cases of myocarditis in the more than 3,000 children age five to 11 vaccinated during the clinical trial. Myocarditis has occurred rarely following mRNA vaccines, usually within a few days after the second dose. The observed risk is highest in young males age 12 to 29 but COVID infection can also cause myocarditis. For adolescents and young adults, the risk of myocarditis caused by COVID infection is much higher than after mRNA vaccination. The rates of vaccine associated myocarditis previously reported are based on data from adults and adolescents who received the higher adult dose of 30 micrograms, not the pediatric dose of 10 micrograms. The 10 micrograms dose given to five to 11-year-olds is one-third of the dose given to those 12 and older.

Again, there were no cases of myocarditis in the clinical trial for five to 11-year-olds who received this lower vaccine dose. Also, vaccine associated myocarditis seems to be mild and tends to resolve pretty quickly. Most patients respond well to conservative management and seem to completely recover. CDC is now doing an enhanced surveillance to make sure they do. Until now, COVID vaccine has not been available for children age five to 11, so the reality is rate of myocarditis after mRNA vaccination in children age five to 11 is unknown. People receiving mRNA COVID vaccine, especially young males under 30, should be aware of this rare risk of myocarditis. They should seek care if they have chest pain, shortness of breath or palpitations. And please report any possible cases to VAERS, CDC's Vaccine Event Reporting System. CDC will continue close safety surveillance.

Unger: Now I know a lot of parents out there are eager to get their children vaccinated who are in this age group and given the kind of differences in the dosing you outlined earlier. When you have a young person kind of on the bubble, about to turn 12, should they get vaccinated now with the lower dose or should they wait for their birthday and get the higher dose? Any question about would the higher dose be more effective for someone like that?

Dr. Fryhofer: Well, this actually came up at the FDA's VRBPAC meeting. Someone asked this question and a Pfizer representative showed data that neutralizing titers in five to 11-year-olds who received a 10 microgram dose were just about the same as titers in 16 to 25-year-olds who received a 30 microgram dose. So, no need to wait. Go ahead and get vaccinated. So, go for it.

Unger: All right. Well, now the question is how do we get folks in there? How likely do you think parents will be to get children in this age group vaccinated?

Dr. Fryhofer: About half of parents say they're likely to get their child vaccinated and it's no big surprise that intent to vaccinate strongly correlated with the parent's vaccination status. 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.

Unger: And that makes sense. Pediatricians obviously are going to be very supportive to getting vaccinating children in this age group. Talk a little bit more about that.

Dr. Fryhofer: The American Academy of Pediatrics is on board, so is AAFP and the Pediatrics Infectious Disease Society. Their liaisons at our ACIP meeting all spoke out in favor of this vaccination and encouraged ACIP to recommend the vaccine. AAP says the vaccine will help make it safer for children to celebrate holiday gatherings and to resume normal childhood activities. The pediatricians are standing by to talk with families about the vaccine and to administer the vaccine to children as soon as possible. And I think internists and others are ready to talk to parents and encourage them to vaccinate their children as well.

Unger: Given some of the things that we talked about earlier in terms of the dosing, is there a concern about supply in terms of is there enough of this new vaccine for the five to 11-year-olds?

Dr. Fryhofer: There is enough vaccine. In fact, the U.S. government has purchased enough vaccine for all 28 million children in the U.S. age five to 11. News reports say that Pfizer actually started packing and shipping the vaccine for kids as soon as FDA authorized it and about 15 million doses were actually shipped out before the CDC director signed off on ACIP's recommendation. Of course it wasn't administered but they were trying to get it to the locations where that vaccine would be administered. But it still may take a few days to get it to pharmacies and pediatricians offices and then into little arms and little thighs.

Unger: Really is kind of a miracle. I mean, if you were to think about where we were a year ago, to think that we could be in this position now where that kind of distribution, testing all moving so smoothly. Any final thoughts as you think about all of the details that we've covered today?

Dr. Fryhofer: Well, we've talked a lot about the many physical effects of COVID but we have to remember the COVID effects on quality of life. These are huge. School closures and missing school

have led to lost in-person learning. ACIP has thoroughly reviewed the evidence and recommends Pfizer's COVID vaccine for children age five to 11. 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. The timing of having a vaccine for kids available for the holidays, it's very exciting. I encourage parents to get their children vaccinated. Having this vaccine available is great news for the 28 million children age five to 11.

Unger: It really is. Thank you so much Dr. Fryhofer, for all of these details about immunizing children in this five to 11-year age group. What good news.

That wraps up today's COVID-19 Update. Thanks Dr. Fryhofer, as always, for sharing your expertise and the details. For updated resources on COVID-19, visit ama-assn.org/COVID-19. Thank for joining us. Please take care.

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