

COVID-19 vaccines have been approved for kids. Now what?

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U.S. children aged five years and older are now eligible for COVID-19 vaccinations after the Centers for Disease Control and Prevention signed off Tuesday on the Pfizer/BioNTech vaccine that the Food and Drug

Administration authorized for emergency use last week.

Vaccinations for children ages five to 11 are expected to begin immediately, potentially preventing 600,000 cases of COVID-19 by March of next year, according to CDC modeling.

But now that federal approval is secured, the vaccine—and vaccine mandates in particular—may also become a new flash point of debate in a nation polarized by pandemic policies, says William Moss executive director of the Johns Hopkins International Vaccine Access Center and vaccinology lead for the Johns Hopkins Coronavirus Resource Center.

What are some issues that will emerge around a vaccine for children ages five to 11?

A big issue is around mandates. Should there be school mandates after FDA authorization and assuming a CDC recommendation? I'm in the camp, as are a number of other experts, that believes that it is too early to have mandates for this age group. I know Los Angeles County has a mandate and the state of California has said it will mandate the vaccine. But I think it would be best to have more information on this age group before issuing school mandates.

Why do you believe more information is needed to justify mandates for this age group?

There are no concerning safety signals in the trial—the vaccine side effects were very similar to older children and adults. But I think it is early to have school mandates. The emergency use authorization trials for children five to 11 years of age are small, and the FDA requires longer follow-up studies before considering full final approval.

The trial size was relatively small with very short follow up, though the vast majority of adverse events occur within several weeks after the second shot. But the trial certainly was not large enough to assess the risk of myocarditis and pericarditis that had been observed in young men after receiving mRNA vaccines. These cardiac risks are highest within the first week following the second COVID-19 mRNA dose in men 18 to 25 years of age, but it is important to note that most cases have been clinically mild and resolved quickly.

We also don't have good data on how well the vaccines prevent the multi-inflammatory syndrome that had been seen in children, even those with mild COVID-19 disease. But no child developed multisystem inflammatory syndrome in the trial.

Is there enough data to justify the emergency use authorization of this vaccine?

Yes, I think there is enough data for an EUA. But full approval will require more follow-up time.

The Pfizer/BioNTech trial involved 2,268 children between five and 11 years old. Of those, 1,518 received two vaccine doses of 10 micrograms of mRNA spaced three weeks apart. This is one-third the dose used in the adult vaccines. The other 750 children received a placebo vaccine.

The companies reported an efficacy of 91% against symptomatic COVID-19. There were only 19 cases of COVID-19 among trial participants—16 among the 750 children who got the placebo vaccine and only three among the 1,518 children who received the COVID-19 vaccine.

Importantly, there were no severe cases, hospitalization, or deaths of

children in the trial. But again, those are rare outcomes in children and it's a relatively small trial. We will have to continue to monitor the safety of the vaccine in children.

How did the vaccine for children perform compare to the dose given to older kids and adults?

Vaccinated children ages five to 11 had levels of neutralizing antibodies comparable to those of vaccine recipients ages 16 to 25 years who were immunized with two 30 microgram vaccine doses, the full adult dose.

General adverse effects were similar to older children and adults, with pain at the injection site, fatigue, and headache the most commonly reported side effects.

Should children get vaccinated if they've already been infected?

There has been an ongoing discussion about whether the large proportion of children who have already been infected with SARS-CoV-2 should get vaccinated. The general recommendations will be similar to older children and adults based on the fact that natural immunity is of variable magnitude and duration and being vaccinated after that would really provide strong protection.

Do children really need two doses or would one suffice?

There is an interesting discussion on the global scale around whether children should just get a single dose. Some nations have opted to do that. The United States has not.

It's all about trying to balance risk and benefit. We know the risk of myocarditis and pericarditis are higher after a second dose, especially in young males. I think other countries are trying to balance that against the fact that younger children are at a much lower risk of severe COVID. That's still an outstanding question: one dose vs two doses. But here in the U.S., we will go with two doses.

Another outstanding question is the need for booster shots down the road for this youngest age group and for the 12 through 17 group. Will the 5- to 11-year-old children who get two doses be authorized and recommended for a booster dose? I'm not sure that would happen the way it has happened for those 18 years and above. My sense is there may not be a need for booster dose for young children, especially if community transmission goes down. I think it would be harder to make the case for booster doses for young children given their much lower risk of severe COVID-19 if their likelihood of infection is much lower, too.

Does the vaccine prevent children from transmitting COVID-19?

We don't have any evidence from the trial of whether the vaccine prevents transmission of the virus from children. That's similar to the adult trials. They just didn't study that. We can hypothesize that that will be the case because the vaccines can lower the amount of virus and shorten the duration of infection, but that was not formally studied.

Are there expectations for how many five- to 11-year old children will get the vaccine?

The other big issue is what uptake is going to be. A Kaiser Family Foundation survey recently found that basically, a third of parents will have their children vaccinated as soon as it is available, a third said they

would wait and see, and a quarter said they would not get their children vaccinated.

We know that fewer than half of children 12 to 15 are vaccinated despite the fact that the [vaccine](#) has been available to them since May of this year. I anticipate the coverage will be even lower than that for the five- to 11-year-old age group. We'd be lucky to get half.

As with everything in the United States right now, there are very polarized opinions. Some parents are very excited to get their children vaccinated, particularly with the holidays coming up. It's not clear that is going to happen because the short-term demand may exceed supply. This is going to be a different process. There need to be pediatric vials delivered to pediatricians and children's hospitals to distribute the vaccines. We're not going to be seeing big sports stadiums or similar venues used for mass vaccinations.

Provided by Johns Hopkins University

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