FDA and CDC Give Green Light to First COVID-19 Vaccine for Kids

Vaccine effectiveness for children ages 5 to 11 was 91%, and serious side effects are rare.

November 2, 2021 By Liz Highleyman

UPDATE: On November 2, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices voted unanimously to recommend the Pfizer-BioNTech COVID-19 vaccine for children ages 5 to 11. The committee agreed that the benefits of the vaccine outweigh the risks for children, and vaccinating kids will also have wider public health benefits. The pediatric vaccine uses a lower dose (10 versus 30 micrograms) and an altered formulation that allows it to be stored longer in a standard refrigerator; children's vials will have an orange cap while adult vials have a purple cap. The recommended regimen is two doses given three weeks apart, the same as the adult schedule. The advisory committee did not weigh in on the issue of vaccine mandates for children to attend school. CDC director Rochelle Walensky, MD, MPH, signed off on the recommendation, and kids could begin receiving their shots within days.

> Today, I endorsed ACIP's recommendation that children 5-11 yrs old should be vaccinated against #COVID19 w/ Pfizer-BioNTech pediatric vaccine. This expands vaccine recommendations to over 28M kids in US & now allows providers to begin vaccinating them.
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> https://t.co/krsXbvsS2p https://t.co/xzgJTvOLWI
>
> — Rochelle Walensky, MD, MPH (@CDCDirector)
>
> November 3, 2021

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On October 29, the Food and Drug Administration (FDA) granted emergency use authorization (EUA) for the first COVID-19 vaccine for children ages 5 to 11. A clinical trial of approximately 4,700 kids in this age group showed that the Pfizer-BioNTech vaccine is highly effective and no serious side effects were reported.

"As a mother and a physician, I know that parents, caregivers, school staff and children have been waiting for today's authorization. Vaccinating younger children against COVID-19 will bring us closer to returning to a sense of normalcy," acting FDA commissioner Janet Woodcock, MD, said in an FDA news release. "Our comprehensive and rigorous evaluation of the data pertaining to the vaccine's safety and effectiveness should help assure parents and guardians that this vaccine meets our high standards."

> Today, we authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of #COVID19 to include children 5 through 11 years of age. https://t.co/Tz0S9s4eyz pic.twitter.com/dc18AWIHKQ
>
> — U.S. FDA (@US_FDA) October 29, 2021

Meeting on October 26, the FDA's Vaccines and Related Biological Products Advisory Committee voted 17-to-0 with one abstention in favor of authorization of the Pfizer-BioNTech vaccine for kids ages 5 to 11, administered as two shots of a lower-dose vaccine given three weeks apart.

This vaccine, also known as BNT162b2 or Comirnaty, was granted emergency use authorization for people ages 16 and older on December 11, 2020, and full approval in August. It was authorized for teens ages 12 to 15 in May and remains under EUA for this age group. The Moderna and Johnson & Johnson vaccines are authorized only for adults ages 18 or older.

Although the committee's ultimate vote appears to reflect near-unanimous approval, it came after considerable debate about the balance of benefits and harms of the vaccine for children.

While kids are much less likely than adults to develop severe COVID-19, the risk is not negligible. As more adults have gotten vaccinated, children account for a growing—though still small—proportion of COVID-19 hospitalizations. Some develop a severe condition called multisystem inflammatory syndrome in children (MIS-C). As of October 17, there have been 146

deaths of children ages 5 to 11 in the United States, according to the FDA. What's more, children can transmit SARS-CoV-2, the coronavirus that causes COVID-19, to vulnerable older people, and concerns about transmission among kids has prevented schools in many cities from getting back to normal.

There's little question the Pfizer-BioNTech vaccine is highly effective for kids. The vaccine is being studied in a clinical trial of children ages 5 to 11 in the U.S., Finland, Poland and Spain. In a preliminary analysis, three cases of COVID-19 occurred among 1,305 vaccine recipients compared with 16 cases among 663 placebo recipients, reflecting a vaccine effectiveness of 90.7%. In addition, an analysis of immune responses in young children showed that they were comparable to those seen in teens and young adults.

In a safety analysis of 3,100 vaccine recipients and 1,538 placebo recipients, no serious adverse effects have been reported in the ongoing study. The most common side effects in children are similar to those seen in teens and adults: injection site pain or swelling, fatigue, headache, muscle or joint pain, fever and swollen lymph nodes. Side effects are generally mild to moderate, resolve after a day or two and are more common after the second dose.

However, rare side effects sometimes don't emerge until a much larger population receives a vaccine in the real world. The Pfizer-BioNTech and Moderna vaccines have been linked to myocarditis and pericarditis (heart inflammation), particularly after the second dose. While the exact risk is unclear—different studies have found varying rates—it appears to be very uncommon. However, the risk is substantially higher for teen boys and young men compared with teen girls and young women. Experts expect that myocarditis rates among younger children will be lower. Most people who developed the condition after vaccination have recovered.

An FDA modeling study estimated that the number of COVID-19 hospitalizations the vaccine would prevent among boys ages 5 to 11 would exceed hospitalizations due to myocarditis when COVID-19 incidence is high (250 versus 156 cases, respectively, per 1 million boys vaccinated). But if COVID-19 incidence is very low, the model predicted the reverse (21 versus 156 cases per million).

While the panel agreed that the vaccine should be available for children at greater risk for severe COVID-19, including immunocompromised kids and those with certain underlying health conditions, some members suggested that all healthy children may not need to be vaccinated, given their chances of COVID-19 complications are so low. In particular, some expressed concern that authorization could pave the way for vaccine mandates for schools.

The FDA is charged with authorizing vaccines based on the risk-benefit balance for individuals. The Centers for Disease Control and Prevention (CDC) then makes recommendations about how best to use FDA-authorized vaccines, taking a broader view that includes their impact on public health.

The CDC's Advisory Committee on Immunization Practices will meet on November 2 to discuss guidelines for vaccinating children. Some experts have urged flexibility, for example, allowing longer spacing between the two doses or a single dose for children who previously had COVID-19.

States and local school districts—not the CDC—are in charge of establishing vaccine mandates. California was the first state to indicate that it will require COVID-19 vaccines for school admission, but only after they receive full FDA approval (not just emergency use authorization). The Oakland Board of Education went further, announcing that children ages 12 and older must be vaccinated by January 1, 2022.

The vaccine dose authorized for children is 10 micrograms—a third of the amount in shots for teens and adults. The kids' vaccine uses a slightly different formulation that can be stored longer in a standard refrigerator (rather than a super-cold freezer), making it easier to administer at pediatricians' offices and clinics. The lower dose produced good immune responses across the 5 to 11 age range, and experts told the New York Times that children near the cusp should not wait until they turn 12 in order to get the higher adult dose.

Click here for briefing documents and slides from the FDA advisory committee meeting.
Click here for more news about COVID-19 vaccines.
