Youngest Kids Can Finally Get COVID Vaccines

After a long wait, the FDA authorizes Pfizer and Moderna vaccines for children as young as 6 months old.

June 20, 2022 By Liz Highleyman

On June 17, the Food and Drug Administration (FDA) authorized the Pfizer-BioNTech and Moderna messenger RNA (mRNA) COVID-19 vaccines for children ages 6 months to 4 years old, finally offering protection to the youngest segment of the population.

The FDA also extended the indication for the Moderna vaccine to include kids ages 5 to 17. The agency previously gave the nod to the Pfizer-BioNTech shot for adolescents ages 12 to 15 in May 2021 and for children ages 5 to 11 in October 2021. The original Pfizer-BioNTech adult indication included people ages 16 and up while the initial Modern indication started at 18.

Earlier in the week, an FDA advisory panel voted unanimously that the benefits of the vaccines for young kids outweigh the risks.

“Many parents, caregivers and clinicians have been waiting for a vaccine for younger children and this action will help protect those down to 6 months of age,” FDA commissioner Robert Califf, MD, said in a statement. “As we have seen with older age groups, we expect that the vaccines for younger children will provide protection from the most severe outcomes of COVID-19, such as hospitalization and death.”

“While COVID-19 affects older and immunocompromised populations more adversely than young children, young children can still suffer severe consequences of COVID-19, including severe illness and death,” he added at a media briefing.

The following day, Rochelle Walensky, MD, MPH, director of the Centers for Disease Control and Prevention (CDC), endorsed an advisory panel’s unanimous recommendation that all children ages 6 months to 5 years should receive a COVID vaccine.

Today marks an important step in our fight against

#COVID19 by making safe & effective vaccines available for children ages 6 months-5 years.

On today's #DirectorDebrief, I discuss the recent recommendation by @CDCgov & the importance of getting children under 5 vaccinated. ⬇

pic.twitter.com/TRgk4RekGd

— Rochelle Walensky, MD, MPH (@CDCDirector) June 18, 2022

"We know millions of parents and caregivers are eager to get their young children vaccinated, and with today's decision, they can," Walensky said in a statement. "I encourage parents and caregivers with questions to talk to their doctor, nurse, or local pharmacist to learn more about the benefits of vaccinations and the importance of protecting their children by getting them vaccinated."

The Pfizer-BioNTech primary vaccine series for infants and toddlers includes three doses, with the first two given three weeks apart and the third given at least eight weeks later. Pfizer initially tested two shots of its low-dose vaccine, but it did not offer adequate protection. The primary series for the Moderna vaccine, which contains a larger amount of mRNA in each shot, involves two doses given one month apart; immunocompromised children can get a third dose at least one month later.

Vaccine Effectiveness

The safety and effectiveness of the Pfizer-BioNTech vaccine for children ages 6 months to 4 years was evaluated in an ongoing, randomized placebo-controlled clinical trial in the United States and other countries.

The researchers assessed the immune responses of 80 babies ages 6 to 23 months and 140 children ages 2 to 4 years who received three 3 microgram vaccine doses, finding that responses were "comparable" to those of people ages 16 to 25 who received two higher-dose shots, according to the FDA.

In terms of clinical outcomes, the number of COVID cases was too low in both the vaccine and placebo groups to reliably calculate vaccine effectiveness. Pfizer estimated that effectiveness was only 28% for two doses, rising to 80% for three doses, but this was based on just a handful of cases.

The Moderna vaccine was evaluated in two ongoing, randomized placebo-controlled clinical trials in the United States and Canada. The researchers assessed immune responses of 490 children ages 6 months to 5 years who received two shots containing 25 mcg of mRNA; 320 children ages 6 to 11 who received two 50 mcg doses; and 340 adolescents ages 12 to 17 who received two 100 mcg does. Here too, responses were "comparable" to those of adults ages 18 to 25 who received two 100 mcg doses.

Looking at clinical outcomes, the researchers analyzed the number of COVID cases occurring at least 14 days after the second dose among approximately 5,400 infants and toddlers who did not have evidence of prior SARS-CoV-2 infection during a time when the omicron variant was predominant. Vaccine effectiveness was 51% for those up to 23 months old but only 37% effective for those ages 2 to 5 years. In the 6 to 11 year age group, the number of COVID cases was too low to reliably calculate vaccine effectiveness. In an analysis of some 3,000 adolescents done before omicron took over, vaccine effectiveness was 93%. This is similar to the effectiveness seen in the main adult clinical trial, but it has decreased in the omicron era.

Vaccine Safety

Turning to safety, the side effects of both vaccines were generally similar but somewhat more varied and frequent with the Moderna shots. The most common adverse events among infants and toddlers who received the Pfizer-BioNTech vaccine were injection site reactions including pain, redness and swelling; fever and chills; headache; decreased appetite and irritability. Children and adolescents who received the Moderna vaccine had the same side effects plus fatigue, swollen lymph nodes, muscle and joint aches, and nausea or vomiting.

A major concern with mRNA vaccines is myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of tissue surrounding the heart), rare but potentially serious side effects seen in some teens and young adults—especially males—who have received the two vaccines in real-world use. However, no cases were seen among young children in either the Pfizer or Moderna trials. In most cases, the condition resolves "with no impact on quality of life," according to the FDA. Pfizer and Moderna, the FDA and the CDC are conduct ongoing safety monitoring.

"As with all vaccines for any population, when authorizing COVID-19 vaccines intended for pediatric age groups, the FDA ensures that our evaluation and analysis of the data is rigorous and thorough," said Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research.

Speaking at the media briefing, Marks said that while the Moderna vaccine leads to somewhat more rapid protection, the Pfizer-BioNTech may induce a stronger response after the third dose. He advised parents to consult their pediatrician to discuss which vaccine to choose.

Vaccine Uptake

While some parents have been eagerly awaiting vaccines for the young children, it's unclear how many will get their children vaccinated.

According to the CDC, 36% of kids ages 5 to 11 have received at least one COVID vaccine dose, and 29% have received both doses, rising to 69% and 59%, respectively, for adolescents ages 12 to 17. But these overall rates hide substantial variation. In San Francisco, for example, 75% of school-age kids and 90% of teens have completed the primary series.

Vaccination rates may end up even lower for infants and toddlers. A Kaiser Family Foundation survey in April found that 18% of parents of children under 5 said they were eager to get their children vaccinated right away, 38% said they would wait and see, 11% would vaccinate their kids only if required and 27% said they will "definitely not" get their children vaccinated. A majority of hesitant parents said they don't have enough information about the vaccines' safety and effectiveness for young children.

"It is now up to the federal government and state and local officials to partner with trusted community-based organizations to ensure vaccines are readily available to all." Infectious Diseases Society of America president Daniel McQuillen, MD, said in a statement. "Vaccination is the best protection against serious illness and death from COVID-19. Parents of children younger than 5 should make a plan to get their kids vaccinated as soon as possible."

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

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