

Moderna says its low-dose COVID shots work for kids under 6

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A health worker administers a dose of a Moderna COVID-19 vaccine during a vaccination clinic at the Norristown Public Health Center in Norristown, Pa., Tuesday, Dec. 7, 2021. Moderna says its COVID-19 vaccine works in babies, toddlers and preschoolers. The company announced early findings from a study of children younger than 6 on Wednesday, March 23, 2022. Credit: AP Photo/Matt Rourke, File

Moderna's COVID-19 vaccine works in babies, toddlers and preschoolers, the company announced Wednesday—a development that could pave the way for the littlest kids to be vaccinated by summer if regulators agree.

Moderna said that in the coming weeks it would ask regulators in the U.S. and Europe to authorize two small-dose shots for youngsters under 6. The company also is seeking to have larger doses cleared for older children and teens in the U.S.

The announcement is positive news for parents who have anxiously awaited protection for younger tots and been continuously disappointed by [setbacks and confusion](#) over which shots might work and when. The nation's 18 million children under 5 are the only age group not yet eligible for vaccination.

Moderna says early study results show tots develop high levels of virus-fighting antibodies from shots containing a quarter of the dose given to adults. Once Moderna submits its full data, the U.S. Food and Drug Administration will have to determine if that important marker means the youngsters are as protected against severe illness as adults.

"The vaccine provides the same level of protection against COVID in young kids as it does in adults. We think that's good news," Dr. Stephen Hoge, Moderna's president, told The Associated Press.

But that key antibody finding isn't the whole story. COVID-19 vaccines aren't as effective against the super-contagious [omicron mutant](#)—in people of any age—and Moderna's study found the same trend. There were no severe illnesses during the trial but the vaccine was only about 44% effective at preventing milder infections in babies up to age 2, and nearly 38% effective in the preschoolers.

"Not a home run" but the shots still could be helpful for the youngest children, said Dr. Jesse Goodman of Georgetown University, a former FDA vaccine chief. Goodman said the high antibody levels seen in the study "should translate into higher efficacy against severe infections."

Some parents say even a little protection would be better than leaving their youngest children unvaccinated.

"I don't care if it's even 15 or 20%," said Lauren Felitti of Gaithersburg, Maryland. Her 4-year-old son Aiden, who's at extra risk because of a heart condition, was hospitalized for eight days with COVID-19 and she's anxious to vaccinate him to lessen the chance of a reinfection.

"It was very scary," Felitti said. "If there's a chance that I'm able to keep him protected, even if it's a small chance, then I'm all for it."

Competitor Pfizer currently offers kid-size doses for school-age children and full-strength shots for those 12 and older. And the company is testing even smaller doses for children under 5 but had to add a third shot to its study when two didn't prove strong enough. Those results are expected by early April.

If the FDA eventually authorizes vaccinations for little kids from either company, there still would be another hurdle. The Centers for Disease Control and Prevention recommends who should get them—and Goodman said there may be debate about shots for higher-risk children or everyone under 5.

Vaccinating the littlest "has been somewhat of a moving target over the last couple of months," Dr. Bill Muller of Northwestern University, who is helping study Moderna's pediatric doses, said in an interview before the company released its findings. "There's still, I think, a lingering urgency to try to get that done as soon as possible."

While COVID-19 generally isn't as dangerous to youngsters as to adults, some do become severely ill. The CDC says about 400 children younger than 5 have died from COVID-19 since the pandemic's start. The omicron variant hit children especially hard, with those under 5 hospitalized at higher rates than at the peak of the previous delta surge.

The younger the child, the smaller the dose being tested. Moderna enrolled about 6,900 kids under 6—including babies as young as 6 months—in a study of the 25-microgram doses.

While the study wasn't large enough to detect very rare side effects, Moderna said the small doses were safe and that mild fevers, like those associated with other common pediatric vaccines, were the main reaction.

Hudson Diener, 3, only briefly cried when getting test doses at Stony Brook Medicine in Commack, New York. His parents welcomed the study results and hope to learn that Hudson received the vaccine and not dummy shots.

"We are really hoping to get the answer we're looking for soon so we can take a deep breath," said Hudson's mom, Ilana Diener. Wednesday's news should "hopefully be a step closer for his age group to be eligible for the vaccine very soon."

Boosters have proved crucial for adults to fight omicron and Moderna currently is testing those doses for children as well—either a third shot of the original vaccine or an extra dose that combines protection against the original virus and the omicron variant.

Parents may find it confusing that Moderna is seeking to vaccinate the youngest children before it's cleared to vaccinate teens. While other countries already have allowed Moderna's shots to be used in children as

young as 6, the U.S. has limited its vaccine to adults.

The FDA hasn't ruled on Moderna's earlier request to expand its shots to 12- to 17-year-olds because of concern about a very rare side effect. Heart inflammation sometimes occurs in teens and young adults, mostly males, after receiving either the Pfizer or Moderna vaccines. Moderna is getting extra scrutiny because its shots are a far higher dose than Pfizer's.

The company said Wednesday that, armed with additional evidence, it is updating its FDA application for teen shots and requesting a green light for 6- to 11-year-olds, too. Hoge said he's optimistic the company will be able to offer its vaccine "across all age groups in the United States by the summer."

Moderna says its original adult dose—two 100-microgram shots—is safe and effective in 12- to 17-year-olds. For elementary school-age kids, it's using half the adult dose.

About 1.5 million adolescents have used the Moderna vaccine in other countries, "and so far we've seen very reassuring safety from that experience," Hoge said.

The heart risk also seems linked to puberty, and regulators in Canada, Europe and elsewhere recently expanded Moderna vaccinations to kids as young as 6.

"That concern has not been seen in the younger children," said Northwestern's Muller.

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