The Washington Post *Democracy Dies in Darkness*

Moderna says its coronavirus vaccine for young children is safe, but efficacy is a more complicated picture

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Vaccine maker Moderna announced Wednesday its two-dose pediatric coronavirus vaccine was safe in young children, toddlers and babies in a study. But the effectiveness of the shot in children 6 months to 5 years old was more of a mixed picture because of the challenge presented by the omicron variant.

In a trial of the vaccine, the shot met the main criteria the company and regulators had defined for success, generating immune defenses equivalent to or better than those that protected young adults before the variant emerged, according to a Moderna news release.

But in the face of highly transmissible omicron, the immune defenses mustered by two doses in adults were less robust, particularly in preventing infections — and the same pattern was seen in children, with vaccine efficacy of about 40 percent.

Two years into the coronavirus pandemic, progress toward a pediatric vaccine has been impatiently awaited by parents and pediatricians as children younger than 5 remain the last group not eligible for a vaccine. There are about 19 million children in this age group in the United States.

Moderna said it plans to submit the data on children 6 months to 5 years old to the Food and Drug Administration in the coming weeks. In a briefing Tuesday, company representatives told government officials they planned to file for emergency authorization in mid-April, according to a senior Biden administration official who spoke on the condition of anonymity because they were not authorized to discuss the matter publicly.

The data has not been published or peer-reviewed, and regulators will carefully review the details in coming weeks. A panel of outside experts is expected to be convened to advise the agency on whether to authorize the vaccine. Jacqueline Miller, Moderna's senior vice president of infectious diseases, declined to offer a possible timeline on when shots would be available, noting that those decisions will depend on discussions with the FDA.

"We're optimistic that we can bring the vaccine forward, hopefully reasonably quickly," Miller said.

Children received two shots of a 25-microgram dose, a quarter of the adult dose. The findings reflect the complicated and changing landscape of the pandemic.

"I think what we've got to remember is we have several goals at this stage of the pandemic," said Clarence Buddy Creech, a professor of pediatrics at Vanderbilt University Medical Center and a leader of the trial. "The first continues to be protection of the most vulnerable, and while it's easy to see a grandparent, or someone who is older in that high-risk group, we have to recognize that our children with underlying medical conditions, recent heart surgery or medically fragile children are also at high risk from this virus."

Although the vaccine did not stop every omicron infection — it was not expected to be able to do that — Creech said he was encouraged that protection held up to some extent against mild infections.

"To be able to give a vaccine that will protect against severe disease as well as protect, to a reasonable extent against mild or moderate disease, that's an enormous step forward for us as pediatricians," Creech said.

The original vaccine trials enrolled tens of thousands of participants and waited to see whether participants who received a vaccine were less likely to get sick than those who received a placebo. Those trials showed that, against an earlier version of the virus, the Moderna vaccine was more than 90 percent effective in preventing illness in adults.

To swiftly extend eligibility of the vaccine beyond adults, the children's trials were designed primarily to measure safety and whether the vaccines conjured the same levels of virus-fighting antibodies. When the trial of the Moderna vaccine started, success was defined as immune responses equivalent to what was reported among young adults in the pre-omicron period.

The Moderna trial hit that benchmark in young children. But two doses have turned out to be far less effective against the highly transmissible omicron variant in adults, and that also held true for children. While protection against infection in young children was about 40 percent overall, it was slightly lower in children younger than 2 years old.

Because the children's trial wasn't designed primarily to measure vaccine effectiveness, there are wide statistical uncertainties about the findings on efficacy, but the company said its statistical analysis showed it was above zero.

There were no cases of serious illness or hospitalizations in the trial, which included close to 7,000 children 6 months to 5 years old, making it impossible to detect the vaccine's possible protective effect against the worst outcomes.

Miller, Moderna's senior vice president of infectious diseases, acknowledged it was more challenging to interpret the data than early in the pandemic but said the immune responses provoked in children were similar to adults — and so was their protection against the omicron variant.

She added that the company plans to test a booster dose in children, and is submitting a proposal to regulators to test that four months after children complete their initial series of two shots.

In sharp contrast to the easy path of the first vaccines, children's vaccines have had stops and starts, missing projected timelines and sowing frustration, confusion and impatience among parents and pediatricians.

In December, Pfizer and BioNTech announced that in 2-to-4-year-olds, a two-dose regimen failed to muster an immune response equivalent to the one that protected young adults. The companies added a third shot — and months of waiting — to the trial.

Then, in an about-face in late January, federal officials indicated there could be a path forward for two doses of the Pfizer-BioNTech vaccine, a strategy intended to allow children to start building immunity as officials awaited data on a third dose. But then the FDA said no decision would be made till results on a third dose arrived.

The failure has led some experts to question whether the Pfizer-BioNTech dose is too low, but Pfizer scientists have said they chose the low dose for the youngest children because it caused fewer severe fevers.

The Moderna pediatric vaccine caused fevers above 100.4 degrees in about 1 in every 6 of the youngest children under 2 years old. Among the 2-to-5-year-olds, the rate of fevers was slightly lower. Fevers higher than 104 degrees were rare, reported in just a few children, according to the company. There were no cases of myocarditis or pericarditis, heart inflammation that rarely occurs after messenger RNA vaccination.

James Campbell, a pediatric infectious diseases physician at the University of Maryland School of Medicine who was involved in the trial but learned the findings only when they were made public Wednesday morning, said he was excited about the result. The safety profile of the two doses, he and others said, appears to be similar to other pediatric vaccines, although greater scrutiny of the details will be critical.

Because children are less prone to severe symptoms from covid, the trial would have needed to be much larger and longer to detect whether the vaccine protected against hospitalization or death. Research has shown that adults who mounted an immune response similar to what was found in young children had the greatest protection against severe symptoms and were least protected against very mild or asymptomatic cases. That should hold true in younger children, too, Campbell said.

“There’s been some pushback, if you will, that this might not change the trajectory of the pandemic, or it’s such a mild disease in children, they don’t need to be vaccinated,” Campbell said. “If people would stop comparing it to adult covid and start comparing it to other pediatric diseases, they would say this is very severe. The number of children who die of covid is greater than every other infectious disease.”

Moderna has faced delays with pediatric vaccines. Its shot is authorized only for people 18 and older in the United States, while Pfizer’s shot has been authorized for children as young as 5 years old.

Moderna filed for authorization in teenagers last June, but a regulatory decision has been delayed, in part because of concerns that Moderna’s higher dose may increase the risk of myocarditis in that age group. The company is evaluating the potential of a half-dose for those teens.

The company announced Wednesday it would be submitting updated data in all young age groups and would seek authorization in children 6 to 11 years old, too. That is less likely to spark interest among families, because the Pfizer-BioNTech shot is already authorized for that age group.

Whether parents will be eager for the vaccine remains a question, as uptake among older children has been disappointing, even in the middle of the omicron surge this winter. A recent Kaiser Family Foundation survey of parents of children in this age group found that nearly one-third said they would have their children vaccinated right away and about one-third would wait and see. The remaining parents were split between those who would never get the vaccine for their children, or would only if required.

Children have been spared the worst of the pandemic, suffering lower rates of severe illness and death than older adults. But their hospitalization rates soared to the highest level of the pandemic during the winter omicron surge, according to a recent study from the Centers for Disease Control and Prevention.

During the peak of the omicron variant surge in January, children younger than 5 were hospitalized at five times the rate as during the peak of the delta surge in early September. There was also no reliable way to predict which young children would end up in the hospital, because nearly two-thirds of children who were hospitalized had no underlying medical conditions.

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