

# Moderna to Seek Authorization for COVID Shots for Kids Despite Data Showing Its Vaccine Doesn't Work



Moderna [announced](#) today it plans to seek emergency use authorization for its pediatric COVID-19 vaccine, citing preliminary data showing the two-dose regimen was safe for children under age 6, including toddlers and infants.

Moderna also said the vaccine, when administered at a smaller dose, [produced an immune response](#) in the younger age group similar to the response produced by its vaccine authorized for adolescents and young adults, ages 12 to 17.

Yet, [data show](#) the vaccine may not be effective at reducing severe COVID in children, who make up only a [small percentage](#) of SARS-CoV-2 infections – most of which are [asymptomatic and mild](#).

Moderna [released partial results](#) from its [two pediatric](#)

[clinical trials](#) in 6,900 children showing the mRNA shots were only about 44% effective at [preventing symptomatic infection](#) in children 6 months to 2 years old, and only 37% effective in children aged 2 to 5.

However, Moderna said its pediatric trials were designed to study safety and the immune response, not effectiveness.

“We believe these latest results from the KidCOVE study are good news for parents of children under 6 years of age,” Stéphane Bancel, CEO of Moderna, said in a statement.

“We now have clinical data on the performance of our vaccine from infants six months of age through older adults. Given the need for a vaccine against COVID-19 in infants and young children, we are working with the U.S. FDA and regulators globally to submit these data as soon as possible.” Moderna’s pediatric clinical trials were [conducted](#) using two 25-microgram doses each – a fourth of the adult dose – and during a time period when the Omicron variant was the predominant strain.

Moderna said the safety profile of two pediatric doses was generally “consistent with that observed in children age 6 to under 12, in adolescents age 12 to 17 and in adults.”

Adverse events were mild or moderate and were more frequently reported after the second dose. No cases of myocarditis – a potentially fatal type of heart inflammation linked to mRNA vaccines – were reported, the company said.

Moderna did not report any details on types of side effects except for data on children who experienced fevers. The company said about 15% of children had fevers higher than 100.4 degrees, and 1 in 500 [experienced a fever](#) higher than 104 degrees.

Moderna did not disclose whether children required hospitalization as a result of the fevers or other side

effects.

The company said the majority of COVID cases observed were mild and no severe disease, hospitalizations or deaths were reported among any of the children who participated in the trial, making it [impossible to detect](#) the vaccine's protective effect against the worst outcomes.

"The absence of any severe disease, hospitalization or death in the study precludes the assessment of vaccine efficacy against these endpoints," the company said.

Yet, Moderna said its [efficacy results](#) were statistically significant, and lower efficacy against COVID-19 infection due to Omicron was anticipated based on how the vaccine performs in adults.

According to [The Washington Post](#), the company said its statistical analysis showed vaccine efficacy was "above zero."

"We're optimistic that we can bring the vaccine forward, hopefully reasonably quickly," Jacqueline Miller, Moderna's senior vice president of infectious diseases, told the Post.

Miller said the company plans to test a booster dose in children and is submitting a proposal to regulators to test a third vaccine dose to be administered four months after children complete their initial series of two shots.

## **Moderna's clinical trial failed to show vaccine benefits children**

In an [article](#) on Substack, Alex Berenson, former New York Times reporter and author of "Pandemia," said, "Moderna claimed in its press release that it believes the shots might reduce the risks of COVID in young children, but the trial showed nothing of the sort."

Berenson wrote:

*“No children in it had severe COVID, so the company could not evaluate whether the shots actually will have meaningful benefit against serious illness. The shots reduced the risk of COVID from the Omicron variant in children by only about 40%, below the 50% level that regulators had generally called the [minimum level for approval](#) in 2020.*

*“Recall that the major adult trials from Moderna and Pfizer showed a 95% reduction in infections against the original coronavirus variant – a finding that far overstated their real-world effectiveness after a few months. A similar decline from the 40% trial figure Moderna reported would suggest the potential for negative real-world efficacy – or increased infection risk after vaccination – in months.”*

*“Given the weakness of these results and the fact COVID poses almost no risk to kids who are not profoundly ill or morbidly obese, it is not entirely clear why Moderna would try to convince regulators to move ahead,” Berenson said. “Parents have already been very reluctant to have kids aged 5 to 12 take Pfizer’s mRNA jab, and surveys suggest even more resistance for younger kids.”*

Moderna has made it clear it plans to go ahead, Berenson added.

## **Data lacking to justify COVID vaccines for kids**

Florida Surgeon General Dr. Joseph Ladapo on March 7 [issued new guidance](#) formally recommending against COVID vaccines for healthy children, making Florida the first state to break with official guidance from the Centers for Disease Control and

Prevention (CDC).

The CDC [recommends](#) all children over age 5 get the vaccine, despite a [study](#) released last month showing Pfizer's COVID vaccine was only 12% effective against Omicron in children 5 to 11 years old.

According to [The Wall Street Journal](#), children are at an "exceedingly low likelihood of severe illness or death" from COVID.

A recent [study](#) in The Lancet estimated the infection fatality rate of children under 18 at between 0.0023% and 0.0085% – meaning 2.3 to 8.5 of every 100,000 kids who get infected will die, with rates lowest among children 5 to 11.

Between Oct. 3, 2020, and Oct. 2, 2021, the [CDC attributed](#) only 66 deaths to COVID among children 5 to 11. By comparison, the [same number of children](#) died in 2019 from suicide – an "exceedingly rare" event among this age group.

In 2019, there were 969 deaths in the 5 to 11 age group from unintentional injury and 207 from homicide, both of which surpassed the number of deaths attributed to COVID.

Polio paralyzes 1 in 200 children infected with the virus, and the fatality rate for measles ranges between [0.1% and 0.3%](#), while the risk of [hospitalization from the flu](#) for children 5 to 11 is 50% higher than from COVID and a related condition called multisystem inflammatory syndrome (MIS) combined.

MIS is an inflammatory condition often [used as a justification](#) for [authorizing](#) COVID vaccines for children.

Hospitalizations among children [increased](#) while the Omicron variant was the dominant strain in comparison to previous strains, but still remained significantly low – 80% lower than among young adults.

According to Dr. Anthony Fauci, the White House's chief

medical advisor, many children who tested positive for COVID and were admitted to the hospital were actually [hospitalized for other unrelated conditions](#) such as broken bones.

As [The Vault Project reported](#) on March 15, the CDC removed from its data tracker website tens of thousands of deaths linked to COVID, including nearly a quarter of the deaths the agency said had occurred among children.

The CDC said it [made adjustments](#) to the mortality data because the website's algorithm was "accidentally counting deaths that were not COVID-19-related."

The change resulted in the removal of 72,277 deaths previously reported across 26 states, including 416 pediatric deaths – a reduction of 24% to 1,341, the [agency said](#).

The CDC's COVID statistics were used to justify which age groups should receive vaccines and were used by U.S. health agencies to [support the authorization](#) of Pfizer's COVID vaccine for children 5 to 11 years old.

CDC Director Dr. Rochelle Walensky referred to the tracker's death total in November 2021, while pushing for an expert panel to advise her agency to recommend vaccination for all children 5 to 11 years old.

It is unknown whether Moderna will use the CDC's most recent COVID numbers in its risk-benefit analysis presented to U.S. health agencies to determine whether the risks of COVID outweigh the potential risks of its COVID vaccine in children.

The Moderna shot is currently authorized for people 18 and older in the U.S., while the Pfizer/BioNTech vaccine has been authorized for children as young as 5 years old.

Moderna has faced delays with pediatric vaccines and filed for authorization in adolescents last June, but a regulatory decision was delayed due to concerns Moderna's higher dose may

increase the risk of heart inflammation in that age group.