

A pediatrician explains how Pfizer's COVID-19 vaccine was tested for safety and efficacy

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Elementary school children in the United States will soon have one more layer of protection to keep them safe from COVID-19.

On Oct. 29, 2021, the Food and Drug Administration authorized emergency use of the Pfizer-BioNTech COVID-19 vaccine for children ages 5 to 11. The move came days after a tense and careful deliberation of its key scientific advisory committee, on Oct. 26, 2021, in which members voted 17-0 to authorize the Pfizer shot, with one abstention.

The next necessary step in the process is for the [Centers for Disease Control and Prevention](#) to issue its guidance on how to use the vaccine in this age group, based on the FDA's authorization. The CDC's Advisory Committee on Immunization Practices is scheduled to meet on Nov. 2, 2021, and the agency's official recommendation is expected as soon as later that day. Rollout of the Pfizer shots for children ages 5 to 11 will likely begin days after.

Once the CDC issues its recommendation, the [28 million eligible U.S. children in this age group](#) will have the opportunity to receive the Pfizer shot through health departments, medical institutions, doctor's offices and pharmacies, as well as school and community-based sites.

The FDA authorization comes after months of pediatric clinical trial investigation involving about 4,500 children ages five to 11. Pfizer released new data on Oct. 22, 2021, stating that its vaccine is almost [91% effective at preventing COVID-19](#) in that age group, with similar tolerability and antibody responses to that seen in older [age groups](#).

Moderna has also [released preliminary results](#) showing that its low-dose vaccine is safe and produces a strong immune response in children ages six to 11 years. It plans to submit data to the FDA for review soon.

As a [pediatrician specializing in infectious diseases](#), I have worked closely on many aspects of the COVID-19 response at the University of Virginia. I have helped care for children with severe COVID-19 and also observed the burden of the pandemic on children and their families.

Vaccines, which work by teaching your immune system to make disease-fighting antibodies without giving you the actual disease, have emerged as the most important tool that we currently have to prevent severe COVID-19.

Here's how the COVID-19 vaccine was tested for efficacy and safety on children and how access to these shots could alter the impact of COVID-19 for American kids.

The risks of COVID-19 in school-age children

The FDA advisory committee openly grappled with the risks and benefits of the vaccine and the weightiness of the decision for younger children. Ultimately, it concluded that parents should be presented with the option to vaccinate their kids against COVID-19. One committee member—Centers for Disease Control and Prevention vaccine expert Amanda Cohn—noted that COVID-19 was the eighth-highest killer of kids in the 5–11 age group over the past year. She pointed out that children are continuing to be hospitalized and to die or otherwise suffer adverse long-term effects from a largely vaccine-preventable disease.

As of Oct. 21, 2021, more than [6 million](#) American children have tested positive for COVID-19. Cases in children rapidly increased during the delta variant surge, which coincided with the opening of in-person school across much of the country. Children now account for a quarter of [new weekly cases](#).

While severe disease and hospitalization from COVID-19 are far more rare in children than in adults, intensive care admission and the need for invasive ventilation do occur in children. There have been over [1.9 million](#) COVID-19 cases in children ages five to 11, with [nearly 100 deaths](#).

[Rates of COVID-19 hospitalization](#) among children and adolescents rose to the highest rates ever in August and September 2021, with [over 8,300](#) children in the 5-11 age group hospitalized since the beginning of the pandemic. Many children hospitalized with COVID-19 have underlying medical conditions, but [one-third](#) of them [do not](#).

Additionally, more than [5,200 children](#) have been diagnosed with the rare but serious condition called multisystem inflammatory syndrome in children, or MIS-C, in the weeks after COVID-19 infection. MIS-C can cause inflammation of the heart, brain, skin, gut and other organs, requiring hospitalization and often intensive care. The syndrome [most commonly occurs in children 6 to 11 years](#) of age.

The pandemic has also harmed children's [social, emotional](#) and [mental well-being](#) and [delayed their education progress](#). Safe and effective vaccines are one of the most promising ways that children can be protected from COVID-19, prevent spread and have as little disruption as possible in their schooling and everyday life.

COVID-19 vaccine development for children

Before use in the [general public](#), all vaccines go through rigorous phases of testing starting with pre-[clinical studies](#) in the laboratory and in animals. Then they must go through three phases of clinical studies in people, allowing investigators and regulators to evaluate the vaccine's safety at each stage before moving on to test it in larger numbers of people.

Once a vaccine is shown to be safe and effective in adults, trials move on to children, who may differ in their reactions and immune response to vaccines. Going down stepwise by age, Pfizer studied children [ages 12 to 15](#) before the younger age groups. The FDA expanded its emergency authorization of the Pfizer COVID-19 vaccine to include that age group

in May 2021. In adolescents ages 12 to 18, the vaccine was shown to [reduce hospitalizations by 93%](#) from June through September 2021.

Even after vaccines are authorized or approved for use, monitoring for safety continues. This allows very rare side effects not seen in large late-phase trials to be detected and investigated. Safety surveillance with the COVID-19 vaccines following authorization in adults and older adolescents ages 16 and up quickly identified a rare increase in inflammation of the heart known as myocarditis following COVID-19 vaccines, particularly in young males. Most patients [responded well](#) to supportive care and rapidly improved. [Myocarditis](#) can also occur with COVID-19 or as a complication of [multisystem inflammatory syndrome](#).

The Pfizer trial for those under age 12 began with three different doses; ultimately, researchers determined the optimal dosage for children ages 5 to 11 to be [one-third](#) of the dose given to adults and adolescents and administered as a two-shot regimen three weeks apart.

No serious side effects related to the vaccine, and no cases of myocarditis were reported. The [Pfizer data](#) also showed that the vaccine in that age group seems to provide similar high levels of protective antibody responses to those seen in older age groups. And the antibodies produced demonstrated an ability to neutralize the delta variant.

Next steps

Ongoing studies will continue to follow vaccinated children closely for safety and to provide more insight into the durability of immunity. The results of the Pfizer vaccine trial for the younger two age cohorts, those two to five years and six months to two years, are expected [later this year](#). Testing of the Moderna and Johnson & Johnson vaccines in clinical trials in children is also underway.

Given that the pediatric clinical trial data show the overall benefits outweigh risks in this age group, I look forward to being one step closer to offering the COVID-19 [vaccine](#) to newly eligible [children](#) and their families if the CDC recommendations make this possible.

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