

Pfizer, BioNTech report COVID-19 vaccine safe, highly effective in 12- to 15-year-olds

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Editor's note: For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>.

Pfizer-BioNTech's COVID-19 vaccine was safe and 100% effective in protecting adolescents ages 12-15 in a phase 3 trial, the companies said Wednesday.

Trial data have not been validated by U.S. health officials, but the companies said they plan to submit them to the Food and Drug Administration (FDA) in the coming weeks so that adolescents can start to be vaccinated.

"It is very important to enable them to get back to everyday school life and to meet friends and family while protecting them and their loved ones," BioNTech CEO and co-founder Ugur Sahin, M.D., said in a [news release](#).

About 2,260 adolescents ages 12-15 years participated in the trial, with roughly half receiving the vaccine and half receiving a placebo. There were 18 cases of COVID-19 reported, all within the placebo group. One month after a second dose, the vaccine elicited SARS-CoV-2-neutralizing antibody geometric mean titers of 1,239.5 in a subset of adolescents, compared to 705.1 in an earlier group of 16- to 25-year-olds, according to the news release.

The companies said side effects were consistent with those seen in older teens and young adults. Since December, the vaccine has been used for people ages 16 and older under emergency use authorization from the FDA.

Pfizer and BioNTech recently began to study their vaccine in children ages 6 months through 11 years. Children as young as 5 have received the vaccine in that trial, and testing will begin in those as young as 2 next week.

Moderna also has been testing its COVID-19 vaccine in children with trials in 12- to 17-year-olds. In mid-March, it announced it was starting a [trial in children ages 6 months through 11 years](#).

The AAP has continued to push for pediatric vaccine trials as children and adolescents make up about 13.4% of cases. More than 3.4 million children have been infected with SARS-CoV-2 and at least 279 have died, according to [data from the AAP and the Children's Hospital Association](#). The pandemic also has taken a toll on [children's mental and emotional health](#), social well-being and their [educational experience](#).

Resources

- [CDC guidance for clinicians on each of the three authorized COVID-19 vaccines](#)
- [AAP FAQs on COVID-19 vaccines](#)
- [AAP interim guidance on COVID-19](#)

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