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Moderna reports COVID-19 vaccine for teens safe, effective

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

Moderna's COVID-19 vaccine is 96% effective for adolescents ages 12-17 years after at least one dose and has no serious safety concerns, the [company announced Thursday](#).

The preliminary data come from trials of 3,235 participants who were randomized to receive a vaccine or placebo. Twelve cases of COVID-19 were reported but no additional details were provided.

“Because the incidence rate of COVID-19 is lower in adolescents, the case definition is less stringent than for COVE (the adult study), resulting in vaccine efficacy against milder disease,” the company said in a [news release](#).

The most common side effects include injection site pain, headache, fatigue, myalgia and chills. Moderna said it is discussing its teen data with regulators, but did not provide additional details on a projected timeline for requesting Food and Drug Administration (FDA) approval. It also is continuing to study its vaccine in children ages 6 months to 11 years.

The new data come as the FDA is poised to announce whether it will grant emergency use authorization to Pfizer-BioNTech's vaccine for adolescents ages 12-15. Pfizer also announced this week it plans to request authorization for a vaccine in children [ages 2-11 in September](#) and children under 2 years in the fourth quarter.

Children have been making up an increasing share of new COVID-19 cases, reaching 22.4% last week, according to [data from the AAP and Children's Hospital Association](#). More than 3.78 million children have been infected with SARS-CoV-2 and at least 303 have died. The pandemic also has taken a toll on [children's mental and emotional health](#), social well-being and their [educational experience](#).

President Joe Biden said Tuesday if the FDA approves vaccines for teens, officials will focus on making them available through pediatricians and family physicians. The AAP has been helping pediatricians prepare to administer the vaccine in their practices. It recently updated its [FAQs about COVID-19 vaccines](#) and released new recommendations on [how to prepare](#), [how to implement vaccination](#) in pediatric practices and [how to get paid](#) for vaccine administration.

In addition to addressing vaccines for adolescents, Moderna leaders said Thursday they plan to request full licensure from the FDA later this month. The company also is studying booster doses and the possibility its current vaccine formulation could be stored at refrigerator temperatures for three months instead of one.

Resources

- [AAP guidance on COVID-19 vaccines for children](#)
- [CDC guidance for clinicians on the Moderna vaccine](#)
- [AAP interim guidance on COVID-19](#)
- [To find a COVID-19 vaccine near you, visit <http://vaccines.gov> or text your ZIP code to 438829.](#)

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