

Questions on the Pfizer COVID-19 Vaccine FDA Authorization

May 11th, 2021

When did the clinical trial for this age group start?

The clinical trial for this age group started last October. The results used for the FDA's authorization are from monitoring the participants through mid-March and each participant was monitored for at least 2 months after the 2nd dose. Like the other clinical trials for these vaccines, monitoring is ongoing.

What did the results show about effectiveness?

Out of 1,110 in this age group who received the placebo, 18 contracted COVID-19. Out of the 1,119 who received the vaccine 0 (yes, zero) contracted COVID-19. In other words, the vaccine protected against COVID-19 disease 100% of the time.

How did they determine COVID-19 infection?

Participants had to report at least one symptom and have a positive polymerase chain reaction (PCR) test.

How else did they show efficacy?

A subset of 190 participants who received the vaccine were tested one month after their second dose and found to have neutralizing antibody levels higher than found in those ages 16 - 25.

What about reactions to the vaccine?

Reactions were similar to what was seen among those ages 16 - 25. They included: about 80% with some pain at the injection site; 10% with a fever after first dose and 20% after second dose; about 60% with some fatigue; about 60% with some headache; and 25 - 30% with some muscle pain. It's important to remember that these reactions are generally signs that one's immune system is working to respond to the vaccine.

What about the vaccine's safety?

Monitoring is ongoing, but so far, no safety signals were seen. In other words, the vaccine is well tolerated and measured to be safe in this age group.

Have other countries authorized this vaccine in this age group?

Yes, Canada did last week.

Why should we consider vaccinating 12 - 15 year olds?

First, it will protect them. Although this age group has generally contracted mild COVID-19 disease, the situation may be evolving. The predominant variant, B.1.1.7 (U.K.), is 50 - 100% more contagious and seems to be disproportionately more contagious among youth and young adults. There is also evidence that this variant causes more severe disease. We are seeing increasing numbers in this age group who are ill enough with COVID-19 to be hospitalized. And even if they contract mild COVID-19, they can contract long-COVID as well as MIS-C (multi-system inflammatory syndrome), a serious complication seen in young people.

Second, the vaccine will protect their families and communities. Especially with the variants, youth increasingly seem to be the vectors of COVID-19 to others, including family and community members who may be more susceptible to severe disease.

Third, the vaccine is our teenagers' ticket to returning to birthday parties, sports, concerts, and school without worry. As a pediatrician and a parent, I feel this vaccine is the best gift we can provide our youth. It is a ticket to a wonderful summer.

When should students stay home from school after the vaccine?

Students can attend school if they feel well enough, are afebrile, and symptoms are limited to those commonly observed following COVID-19 vaccination (e.g. fatigue, headache, chills, muscle pain, injection site redness/soreness) and they do not have symptoms that are more commonly associated with COVID-19 (e.g. cough, shortness of breath, sore throat, or changes in smell or taste). Maine Department of Education guidance on this can be found at: [COVID-19-Educator Vaccines | Department of Education \(maine.gov\)](https://www.maine.gov/education/COVID-19-Educator-Vaccines)

If my child missed the school vaccine clinic, where else can they get vaccinated?

Vaccine Finder for Pfizer vaccine locations

<https://www.vaccines.gov/search/>

Maine Vaccine Finder

<https://www.maine.gov/covid19/vaccines/vaccination-sites>

Other Resources:

EUA Fact Sheet for Recipients/Parents

<https://www.fda.gov/media/144414/download>

EUA Fact Sheet for Providers (37 pages)

<https://www.fda.gov/media/144413/download>