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AAP: Don’t use COVID-19 vaccine off-label for children

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

While the Food and Drug Administration (FDA) granted full licensure to the Pfizer-BioNTech COVID-19 vaccine Monday, the AAP and FDA are discouraging clinicians from administering the vaccine in an off-label use to children under 12 years.

“The clinical trials for the COVID-19 vaccine in children ages 11 years old and younger are underway, and we need to see the data from those studies before we give this vaccine to younger children,” AAP President Lee Savio Beers, M.D., FAAP, said in a statement. “The dose may be different for younger ages. The AAP recommends against giving the vaccine to children under 12 (years) until authorized by the FDA.”

The FDA’s licensure of the vaccine, which will be called Comirnaty, applies to ages 16 years and older, the group for whom emergency use authorization (EUA) was granted in December 2020. The vaccine will continue to be available under an EUA for adolescents in the 12- to 15-year age group. The AAP strongly encourages all eligible individuals to receive the COVID-19 vaccine, including those who are 12-15 years old.

About 43% of teens ages 16-17 years and 33% of adolescents ages 12-15 years are fully vaccinated, along with 62% of adults, according to Centers for Disease Control and Prevention (CDC) data and an AAP analysis. FDA officials said Monday they hope full authorization of the vaccine will help address concerns among people who have been hesitant.

“This is a pivotal moment for our country in the fight against the pandemic,” Acting FDA Commissioner Janet Woodcock, M.D., said at a press conference. “While this and other vaccines have met the FDA’s rigorous and scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be confident that this meets the FDA’s gold standard for safety, effectiveness, and manufacturing quality that we require for an approved product.”

Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research, said Monday the FDA analyzed thousands of pages of data on individual patients, monitored trial sites and inspected manufacturing facilities before approving the vaccine.

Efficacy data come from 40,000 people, half of whom received the vaccine and half of whom received a placebo. The data show the Comirnaty vaccine is 91% effective in preventing COVID-19 disease, according to Dr. Marks.

Safety was evaluated in 44,000 people, again with half receiving the vaccine. More than half of the participants were followed for at least four months after their second dose and about 12,000 people were followed for at least six months. Pain, redness and swelling at the injection site; fatigue; headache; muscle or joint pain; chills and fever were the most common side effects vaccine recipients reported.

Vaccine packages inserts will contain a warning about a rare risk of myocarditis and pericarditis , especially within a week after the second dose. Males under age 40 have a higher risk than females and older males, according to Dr. Marks. Males ages 12-17 have the highest risk. Most of the affected individuals have responded well to treatment and rest. The FDA will require the manufacturers to continue to evaluate these cases.

The approval comes as the highly transmissible delta variant is causing cases to spike around the country with an average of 133,056 new cases each day, according to the CDC. More than 180,000 new pediatric COVID-19 cases were reported during the week ending Aug. 19, nearly 50% higher than the increase the week before, a report from the AAP and Children's Hospital Association shows. There has been a four-fold increase from about 38,000 new cases since the week ending July 22. Children made up about 22% of all new cases last week.

"We know that with the spread of the delta variant, how contagious it is, more children and more adolescents are getting infected and certainly because more are getting infected, more are becoming significantly ill and becoming hospitalized," Rachel L. Levine, M.D., FAAP, assistant secretary for health at the Department of Health and Human Services, said during a recent FDA stakeholder call. "In addition, these children and adolescents are potentially spreading this disease in their homes and their communities."

The AAP has repeatedly called on health officials to authorize a vaccine for children under 12 years. Pfizer has said it expects to submit data to the FDA on trials in children ages 5-11 years this fall. Dr. Marks said the FDA would move quickly to review it.

"The Delta variant has led to significant increases in the number of children and adults infected with the virus," Dr. Beers said. "While we wait for a vaccine to be authorized for younger children, it's important that everyone who is eligible now get the vaccine. That will help reduce the spread of the virus and protect those who are too young to be vaccinated."

Resources

- Prescribing information for Comirnaty
- Information from the CDC on clinical considerations for COVID-19 vaccines
- CDC COVID vaccination toolkit for pediatricians
- AAP guidance on providing COVID-19 vaccines to adolescents
- Information for parents from HealthyChildren.org on preparing children and adolescents for COVID-19 vaccination