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AAP: COVID-19 vaccine recommendation a 'milestone,' more research needed on vaccines in children

by Melissa Jenco, News Content Editor

Update:*The FDA has approved emergency use authorization for this vaccine on 12/11 and the CDC's vaccine committee approved on 12/12. For the latest news on COVID-19, visit https://www.aappublications.org/news/2020/01/28/coronavirus.*

A national vaccine committee recommended authorization of the first COVID-19 vaccine for people ages 16 and older on Thursday, a move the AAP called an important step forward, while also urging more research on vaccines for children and adolescents.

"Today marks another milestone in the pandemic and brings us one step closer to having a vaccine that will be broadly available to physicians, health care workers, and other front-line medical staff," AAP President Sara "Sally" Goza, M.D., FAAP, said in a news release. "This is a light at the end of the long tunnel of this pandemic, which has placed heavy burdens on everyone in the medical community, and we look forward to having a vaccine available to protect everyone who has put their own health and safety at risk in order to care for others."

The Food and Drug Administration's (FDA's) Vaccines and Related Biological Products Advisory Committee (VRBPAC), a group of independent science and public health experts, including several pediatricians, voted 17-4 (with one abstention) to recommend emergency use authorization (EUA) for the vaccine from Pfizer and BioNTech. FDA leaders will consider that recommendation when making its determination whether to approve the EUA in the coming days.

The vote comes as hospitalizations and deaths from COVID-19 have been surging. At the time of the vote, more than 15.5 million people in the U.S. had been infected and more than 291,000 had died, according to Johns Hopkins University.

Vaccine efficacy

The Pfizer-BioNTech vaccine is a messenger RNA vaccine given in two doses 21 days apart. The companies conducted randomized, placebo-controlled trials with more than 40,000 people including 283 adolescents ages

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16 and 17 years.

Data showed 170 people were infected with COVID-19 during the trials, only eight of whom had received the vaccine; 162 received the placebo. The efficacy of 95% was similar across age groups and ethnicities.

Pfizer reported only one severe case of COVID-19 of those vaccinated. Some experts cautioned the small numbers of severe infection limit the conclusions that can be drawn.

Vaccine safety

Safety data on patients with a median of two months of follow-up found mostly mild or moderate systemic reactions. Some of the most common reactions were typical of an immune response, including injection site reactions, fatigue, headache, muscle pain, child, joint pain and fever. Reactions were more common after the second dose and in people in under 55 compared to older participants.

Four cases of Bell's palsy were reported among people who received the vaccine, but it was not clear if the vaccine was the cause. There also were 64 participants who received the vaccine who experienced lymphadenopathy and a report of a shoulder injury either from vaccine administration or the vaccine.

Data on 16- and 17-year-olds showed small percentages of systemic reactions to the overall populations - injection site pain, fatigue, pyrexia, chills and headache. Several VRBPAC members said there wasn't enough data for this group to include it in the EUA.

"We don't know if the benefit outweighs the risk in that two-year age group," said VRBPAC member H. Cody Meissner, M.D., FAAP, professor of pediatrics at Tufts University School of Medicine, who ultimately abstained from the vote.

But others said leaving the teens out of the EUA would delay the opportunity to obtain more information about adolescents and children and some essential workers, who fall into this age group.

Paul Offit, M.D., FAAP, director of the Vaccine Education Center at the Children's Hospital of Philadelphia, said some infected teens have had cardiac anomalies.

"We have clear evidence of benefit," he said of the vaccine. "All we have on the other side is theoretical risk."

In her statement, Dr. Goza said the discussion "underscores the need to keep expanding these trials to the pediatric population so we can collect robust data on this age group.

"Trials in children must keep pace with the tremendous amount of data being generated in adult trials, and this should be initiated safely and as soon as possible so there could be a vaccine authorized for younger children before the next school year begins," she said.

The committee also discussed reports of allergic reactions among two vaccine recipients in the United Kingdom with a history of allergic reactions. FDA officials said Thursday people who are allergic to any of the ingredients should not be vaccinated and they will continue to monitor any reactions.

Vaccine safety will continue to be assessed by Pfizer. In addition, numerous government bodies will be collecting data through traditional surveillance systems, and a new smartphone-based system will be surveying recipients for a year after vaccination.

Next steps

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FDA leaders are expected to issue their own recommendation on the EUA in the coming days. The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) also will be discussing the vaccine and issuing additional recommendations when it meets Dec. 11 and 13. It already has recommended that health care workers and residents of long-term care facilities are vaccinated first.

VRBPAC will meet again Dec. 17 to review an EUA request from Moderna. Once a vaccine receives final approval, it will be distributed to states, each of which has created its own playbook for implementing a vaccination program.

Health and Human Services Secretary Alex M. Azar II, J.D., said Wednesday he expects about 20 million people could be vaccinated by the end of the year, which could grow to 100 million by the end of the first quarter of 2021. By the end of the second quarter, he expects enough vaccine will be available for anyone who wants it.

Resource

- AAP interim COVID-19 guidance
- AAP FAQ on COVID-19 vaccines