Pfizer’s COVID-19 vaccine OK’d for ages 12–15: What doctors must know

MAY 13, 2021

Sara Berg, MS
Senior News Writer

What’s the news: This week, the Food and Drug Administration (FDA) deemed the Pfizer-BioNTech COVID-19 vaccine safe and effective for children 12–15 years old, granting it emergency use authorization (EUA). The Pfizer-BioNTech SARS-CoV-2 vaccine is the first in the U.S. to get EUA for this younger population.

Following this decision, the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) met to discuss the use of the vaccine in adolescents. After deliberation, ACIP determined that the Pfizer-BioNTech COVID-19 vaccine was safe and effective for younger individuals and CDC Director Rochelle Walensky, MD, MPH, signed off on the Committee’s recommendation on May 12th, indicating that vaccine providers could begin vaccinating this population right away.

In a clinical trial of more than 2,200 adolescents, Pfizer’s vaccine was found to be 100% effective. It will be administered in two doses, three weeks apart—the same regimen that people 16 and older have been receiving. The side effects for this age group were consistent with those seen adults. They include pain, redness and swelling of the arm that received the shot as well as chills, tiredness, muscle pain, fever and headache.

“The recommendation approved today by the Advisory Committee on Immunization Practices supporting the use of the Pfizer-BioNTech COVID-19 vaccine in individuals age 12–15 years of age brings us one critical step closer to our nation’s goal of achieving widespread vaccination among the U.S. population,” said AMA President Susan R. Bailey, MD.
Additionally, the CDC updated its clinical considerations for vaccine administration indicating that COVID-19 vaccines can be given along with other routine vaccines instead of waiting 14 days. With rates of routine immunizations having decreased during the pandemic, the hope is that this will help boost immunization rates.

Discover eight things physicians and patients need to know about the Pfizer vaccine.

**Why it’s important:** Adolescents can get seriously ill from COVID-19 and they can also spread the coronavirus to others. About 1.5 million American children 11–17 years old were diagnosed with COVID-19 in between March 2020 and April 2021, according to the CDC. Since the pandemic began, nearly 500 people 17 and younger have died from COVID-19 in the U.S.

“We know that adolescents 12 years of age and up are at risk of severe illness from COVID-19 and can contribute to transmission of COVID-19 to others,” said Dr. Bailey. “Having safe and effective vaccine available to this age group will help them return to normal activities and help protect more people from the spread of COVID-19.”

By allowing those 12 and up to get a COVID-19 vaccine, it will help accelerate the country’s efforts to reduce infections and is another step toward returning to some form of normalcy. This also comes at a time when many parents are fully vaccinated against COVID-19 while their children are not, which has introduced another complexity as families learn to live amid a pandemic that’s on the wane but still a huge public health threat.

While the first shots will be administered this week, vaccine distribution and administration plans will vary by state. Parents and guardians can rest easy knowing that the FDA and CDC, including ACIP, completed thorough reviews of all available data to determine the safety and efficacy of the Pfizer-BioNTech vaccine for children 12–15.

Pfizer continues to study two doses of the vaccine among healthy children ages 6 months to 11 years. Moderna and Johnson & Johnson are also testing their vaccines in younger age groups.

Read about the new CDC tools that aim to ease COVID-19 vaccine hunt.

**Learn more:** The FDA has updated its fact sheet for physicians and other health professionals administering the Pfizer COVID-19 vaccine to include information for children 12 to 15 years old.

The CDC also offers information for physicians and other health professionals on the Pfizer-BioNTech COVID-19 vaccine overview and safety.

The Biden administration believes the supply of vaccines to physician offices will increase and they want physicians to register to become a COVID-19 vaccination provider. If you are part of a health
system, reach out to your health system point of contact about whether your system is already enrolled or would be interested in enrolling. If you are a physician in independent practice and are interested, contact your state or local immunization program.

Studies have found that a doctor’s strong recommendation “is closely correlated with vaccination,” the CDC says. Meanwhile, 30% of adults now hesitant to get vaccinated against COVID-19 say they would be likelier to do so if the vaccine were offered to them “during a routine medical visit,” says the agency.

The AMA has developed frequently-asked-questions documents on COVID-19 vaccination covering safety, allocation and distribution, administration and more. There are two FAQs, one designed to answer patients’ questions, and another to address physicians’ COVID-19 vaccine questions.