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CDC panel OKs COVID-19 vaccines; discusses myocarditis, boosters

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

A federal vaccine advisory group signed off Monday on use of the Pfizer-BioNTech COVID-19 vaccine Comirnaty under a full license for people ages 16 years and older. The advisory group also received an update on myocarditis after vaccination and discussed future booster doses.

The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) voted 14-0 in favor of approving Comirnaty, and the CDC director signed off shortly after. The Food and Drug Administration (FDA) granted licensure last week. The vaccine still can be used for adolescents ages 12-15 years under emergency use authorization.

"I can't think of a vaccine for which we have had more efficacy and effectiveness and adverse event data than this vaccine," said ACIP member Sarah S. Long, M.D., FAAP, professor of pediatrics at Drexel University College of Medicine. "And this vaccine is worthy of our recommendation for what it does for us today and worthy of the trust of the American people."

Clinical trials in over 40,000 people found vaccine efficacy to be 91% against symptomatic infection, 100% against severe COVID-19 and 100% against death when looking at cases confirmed with a protocol-approved assay. Observational studies with hundreds of thousands of participants found similar effectiveness.

More than half of the trial 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.

In a discussion weighing the risks and benefits, the CDC estimated that among males ages 16-17 years, every million doses of Comirnaty over the span of a year would prevent 1,540 COVID-19-related hospitalizations, while there may be 73 cases of myocarditis. In males ages 18-24 years, these figures would be 3,150 and 39, respectively.

The licensure of the Pfizer-BioNTech vaccine comes as COVID-19 cases, hospitalizations and deaths are spiking. During the week ending Aug. 26, about 204,000 children and teens were diagnosed with COVID-19, a more than five-fold increase in the past month, according to a report from the AAP and Children's Hospital Association.

Across all ages, there are about 145,000 new cases and almost 1,000 deaths per day, according to the CDC. Hospitalization rates for people ages 18-49 are approaching what was seen last winter during the peak of the pandemic and are largely among those who are unvaccinated. In addition, 23 states have reached at least 80% capacity in their intensive care units.

Myocarditis, pericarditis and anaphylaxis

CDC experts presented updated data Monday on the rare cases of myocarditis, pericarditis and anaphylaxis after either the Pfizer-BioNTech or Moderna COVID-19 vaccines.

Health officials have identified 1,339 preliminary reports of myopericarditis among people under 30 years of age reported to the Vaccine Adverse Event Reporting System. Of those, 742 have been confirmed and 494 are still under review. Among 701 people who have been hospitalized, 95% have been discharged and 73% are known to have recovered. Eighteen are still hospitalized.

A separate analysis of data from the Vaccine Safety Datalink network of health care organizations looked at confirmed cases of myocarditis or pericarditis among people ages 12-39 years within seven days after vaccination with either mRNA vaccine. It found 16 cases per million second doses above what was expected.

"The epidemiology of myopericarditis after COVID-19 vaccination remains consistent with what's been reported in previous updates," said John R. Su, M.D., Ph.D., M.P.H., from the CDC's Vaccine Safety Team. "Primarily, it can be seen among younger males, after dose 2 of mRNA vaccination with symptoms clustering within several days after vaccination."

Dr. Long also noted, "this is not typical myopericarditis."

"Clinicians know that this is unique syndrome," she said. " … The presentation is abrupt onset of chest pain, and the recovery is very rapid."

The latest data on anaphylaxis cases after mRNA vaccination show a rate of five cases per million doses among people ages 12 and older.

Booster doses

Earlier this month, health officials announced they are preparing to offer COVID-19 booster shots to adults as early as Sept. 20, pending regulatory approval.

The CDC presented data Monday showing some reduced efficacy of the Pfizer-BioNTech and Moderna vaccines against COVID-19 infection, which could be due to waning efficacy over time and/or the highly transmissible delta variant. However, protection against severe disease and death remains high.

The committee's COVID-19 vaccine work group said top priority should be to continue to vaccinate those who have not yet been vaccinated. They also stressed the need to ensure vaccines are distributed equitably in the U.S. and available globally.

"I really think we need to remember that really the most important thing we can do with respect to vaccines is to continue to work as hard as we possibly can to encourage more people to get the primary series," said ACIP member Beth P. Bell, M.D., M.P.H., clinical professor in the Department of Global Health at the University of Washington. "That is, I think, in my opinion, the highest priority."

If booster doses are approved, health care personnel, residents of long-term care facilities and adults over 65 years could be among the first to qualify due to their high risk level.

However, it is unclear whether officials will have enough data on safety and immunogenicity to get FDA and CDC approval before Sept. 20. Pfizer officials said Monday they did not expect to have data from their booster dose efficacy trial until late September or October.

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