

CDC vaccine group: Don't delay second doses of COVID-19 vaccine

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

A national vaccine advisory group said Monday it cannot support delaying second doses of Pfizer-BioNTech and Moderna COVID-19 vaccines without more data about the impact on protection.

The issue was one of several the group discussed around expediting vaccine administration during a two-day meeting in which it also approved use of a new single-dose COVID-19 vaccine from Johnson & Johnson.

Vaccine administration challenges

Since COVID-19 vaccination began in December 2020, more than 50 million people have received at least one of the two required doses. While vaccination rates have been improving, states continue to run into challenges like not having enough supply to meet demand, verifying eligibility and distributing vaccine equitably.

The Centers for Disease Control and Prevention (CDC) on Monday asked its Advisory Committee on Immunization Practices (ACIP) to discuss some possible solutions, including delaying a second dose of vaccines so that more people could get a first dose. Currently, Pfizer-BioNTech and Moderna mRNA

vaccines are spaced out by three and four weeks respectively, although the CDC allows up to six weeks in some circumstances.

ACIP members said they do not have enough data to support delaying the second doses, and they worried about leaving people susceptible to infection, especially as variants increase.

“I feel that we really need to go where the randomized trials showed optimal efficacy,” said Pablo J. Sanchez, M.D., FAAP, a board-certified neonatologist and pediatric infectious diseases specialist at Nationwide Children’s Hospital.

The committee also discussed whether people who have been infected with SARS-CoV-2 should get one dose of the mRNA vaccines instead of two. Some studies have suggested a high antibody response from one dose for this population. In addition, the CDC said it has received anecdotal reports of increased reactions to the vaccine in this group.

“I do feel the infection is the prime and the vaccine is the boost and I don’t see any advantage to giving a second dose,” said Grace M. Lee, M.D., M.P.H., associate chief medical officer for practice innovation, Stanford Children’s Health.

However, others said they couldn’t recommend one dose for people with past infection without knowing how long immunity lasts.

“We just don’t know enough about unintended consequences, and there is this issue of how do we know who actually has antibodies and doesn’t have antibodies and what happens with a single dose if you don’t have antibodies,” said Beth P. Bell, M.D., M.P.H., clinical professor in the Department of Global Health at the University of Washington School of Public Health.

ACIP members also discussed the phase 1c priority group that includes people ages 16-64 with an underlying high-risk condition. Committee members generally did not support breaking the group down further by age or prioritizing people with two or more high-risk conditions instead of one. Some also said the CDC’s list of high-risk conditions should be expanded and clarified.

The group did not take a vote on any of these issues. The CDC will take members’ input into consideration but no changes appear imminent.

Johnson & Johnson vaccine

On Feb. 27, the Food and Drug Administration (FDA) **granted an emergency use authorization** to Johnson & Johnson’s single-dose COVID-19 vaccine for people ages 18 and older. The decision followed hours of discussion and approval from the FDA’s vaccine committee. The following day, **ACIP and the CDC director also gave the green light to use the vaccine.**

The Johnson & Johnson vaccine uses a non-replicating adenovirus vector to deliver instructions to cells and trigger an immune response, and its storage and handling requirements aren’t as onerous as the mRNA vaccines. The vaccine can be stored for three months at normal refrigerator temperatures and for two years when frozen.

Clinical trials that enrolled about 44,000 participants in the U.S., South Africa and Latin America reported 85% efficacy against severe/critical disease and 100% protection against hospitalization and death 28 days after vaccination. Efficacy against moderate to severe disease was 66% across all countries and 72% in the U.S.

There were no serious safety concerns in the phase 3 trial. The most common local reaction was injection site pain, and the most common systemic reactions were headache, fatigue and myalgia.

While many have tried to compare efficacy of the Johnson & Johnson vaccine to that of the Pfizer-BioNTech and Moderna vaccines, the CDC said true comparisons cannot be made since the vaccines were tested at different times, in different locations with different circulating variants.

Johnson & Johnson plans to ship 20 million doses of its vaccine by the end of March, part of a larger commitment of 100 million doses in the first half of this year.

Pediatric vaccine trials

The AAP has commended the swift development of a third COVID-19 vaccine while also [urging the Biden administration](#) to speed the enrollment of children in clinical trials.

“While it is heartening to see a third vaccine on the market to help protect our communities against COVID-19, we are not moving fast enough to ensure our children can benefit from these life-saving vaccines,” [AAP President Lee Savio Beers, M.D., FAAP, said in a statement](#). “At the current pace of research, we may not see a vaccine approved for children under age 12 until early next year, which means many children may not benefit from a COVID-19 vaccine until almost a year after one has been available for adults.

“This is hard to fathom given how children have suffered throughout the pandemic in ways both seen and unseen,” Dr. Beers said. “We cannot allow children to be an afterthought when they have shared so much burden throughout this pandemic.”

Johnson & Johnson said it plans to move quickly on trials in adolescents and then will move to younger age groups. It plans to enroll about 3,000 children and adolescents.

Resources

- [CDC information for clinicians on the Johnson & Johnson COVID-19 vaccine](#)
- [AAP FAQ on COVID-19 vaccines](#)
- [AAP interim guidance on COVID-19](#)

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