AAP News™

J&J COVID vaccine booster recommended by FDA panel

October 15, 2021

Melissa Jenco, News Content Editor

Article type: News

Topics: COVID-19, Influenza, Vaccine/Immunization

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

A federal vaccine advisory panel is recommending a Johnson & Johnson COVID-19 vaccine booster for all adults who received one dose of that vaccine.

The booster would help improve the level of protection provided by the viral vector vaccine, which appears to be lower than the two-dose mRNA vaccines from Pfizer-BioNTech and Moderna.

The panel convened by the Food and Drug Administration (FDA) on Friday voted 19-0 in favor of the Johnson & Johnson booster, which would be given at least two months after the first dose. The recommendation now goes to the acting FDA commissioner for review and possible emergency use authorization. The Centers for Disease Control and Prevention's (CDC's) vaccine committee will discuss boosters when it meets Oct. 20-21.

Johnson & Johnson representatives said Friday they have found a booster given two months after the first dose could improve protection against symptomatic COVID-19 from 70% to 94% without sparking any new safety concerns.

"I think there's more than adequate safety (data) for a two-month boost," said FDA committee member Michael Kurilla, M.D., Ph.D., director of the Division of Clinical Innovation at the National Center for Advancing Translation Sciences. "… And what we've seen so far with their data would suggest some very good activity against variants."

Because the vaccine requires only one dose and does not have onerous storage and handling requirements, it has been touted as an important tool for vaccinating hard-to-reach and vulnerable populations. However, committee members said they view a second dose to be important for protection. They did not restrict the booster to high-risk adults as they did for other COVID-19 vaccine boosters.

"If the vaccine isn't adequate, it should be boosted in everybody," said committee member Eric Rubin, M.D., Ph.D., editor-in-chief of the *New England Journal of Medicine*.

Some expressed concerns that the FDA did not do its typical independent analysis of the data due to time constraints. Still, they felt the evidence was compelling enough to show a benefit from a booster given at least two months after the primary shot.

"It's a public health imperative here," said Acting Chair Arnold Monto, M.D., professor of epidemiology at the University of Michigan School of Public Health. "What we're seeing is this is a group with overall lower efficacy than we have seen with the mRNA vaccines so there is some urgency here to do something."

The decision on Johnson & Johnson boosters came a day after the group recommended a Moderna booster for certain high-risk adults. Those boosters would be half the regular dose and would be given at least six months after the primary series. The FDA commissioner is reviewing that recommendation as well as Friday's Johnson & Johnson recommendation.

Mixing vaccines for boosters

The FDA committee also heard new data from a National Institutes of Health study on using a different booster than the vaccine used in the primary series. All three authorized vaccines were included in the study, although Moderna was studied using a full dose. Participants received boosters at least 12 weeks after their last vaccine dose.

Investigators found neutralizing antibodies increased using any of the three vaccines as boosters regardless of which vaccine was used in the primary series. In addition, the mix-and-match scenarios had as good or better serologic responses as the scenarios using the same vaccine. The team did not find any safety concerns.

The study had several limitations. Investigators have not determined what antibody levels are needed to provide protection. There also are other types of protection that weren't measured. The study was not designed to compare boosters.

Some FDA committee members asked for more data, but others expressed urgency to move forward in allowing mix-and-match scenarios for more flexibility in situations where it may not be easy to get the same vaccine as the primary series or for those who had a reaction to the primary vaccine that would prevent them from receiving the same vaccine.

"In the real world, all these kinds of combinations or extra boosters are already happening," said committee member Ofer Levy, M.D., Ph.D., director of the Precision Vaccines Program at Boston Children's Hospital. "So, I think it's a matter of some urgency for FDA to help sort out what's admittedly a complicated and challenging scenario, but we can't hide from it, and I do think we need to give guidance to the public."

The committee did not vote on mixing and matching boosters. The FDA will continue to look at the issue.