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FDA and CDC Recommend Moderna and J&J COVID-19 Vaccine Boosters

Many people who received any of the authorized COVID-19 vaccines are now eligible for an additional dose of their choice.

October 21, 2021 By Liz Highleyman

UPDATE 10/21/21: On October 21, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices concurred with the Food and Drug Administration, voting unanimously to recommend Moderna and Johnson & Johnson COVID-19 vaccine boosters. CDC director Rochelle Walensky, MD, MPH, adopted the committee's recommendation. Moderna vaccine recipients who are ages 65 or older, those with underlying health conditions that increase the risk of severe COVID-19 and those with frequent exposure to the coronavirus due to their work or living situation are eligible for a booster six months after their second shot. Anyone who rceived the J&J recipients can get a second shot two months after the first. People may get an additional dose of the same vaccine or select a different brand.

UPDATE 10/20/21: On October 20, the Food and Drug Administration adopted its advisory committee's recommendations to authorize boosters for many people who received the Moderna or Johnson & Johnson COVID-19 vaccines, following a similar authorization for Pfizer-BioNTech recipients last month. Eligible individuals will be able to use a mix-and-match approach, selecting the brand of their choice.

The Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee voted unanimously this week to recommend a third dose of the Moderna COVID-19 vaccine for older adults, those prone to severe disease and those at high risk of exposure to the coronavirus. The advisors went further for the Johnson & Johnson vaccine, recommending a second dose for anyone who received the single shot.

Meeting on October 14, the committee unanimously voted to authorize an additional dose of the Moderna vaccine (also known as mRNA-1273 or Spikevax) after at least six months for adults ages 65 and older as well as for younger adults with underlying conditions that put them at higher risk for severe COVID-19 and those at high risk of exposure due to their occupation or living in an institutional setting. (See the FDA Moderna briefing document here.)

The Moderna vaccine was granted FDA emergency use authorization (EUA) in December 2020 for people ages 18 and older; it has not yet received full approval. The booster is a half dose of the same vaccine, not a new formulation designed to target the latest variants.

According to the Centers for Disease Control and Prevention (CDC), the list of underlying conditions that raise the risk for severe COVID-19 include cancer; chronic kidney, liver or lung disease; certain neurological and mental health conditions; diabetes; HIV; sickle cell disease; smoking and substance use disorders; overweight and obesity; and pregnancy. The FDA and CDC previously recommended a third dose for Pfizer-BioNTech and Moderna vaccine recipients with compromised immune systems.

The FDA authorized a third dose of the Pfizer-BioNTech vaccine (also known as BNT162b2 or Comirnaty) for the same groups last month. In both cases, the committee declined to recommend boosters for everyone. Some members expressed concern about third doses for young people, especially young men, who have a higher—though still very low—risk of myocarditis, or heart muscle inflammation.

In August, the Biden administration announced plans to offer boosters to all adults, but many experts said the proposal was premature, arguing that there's little evidence that young healthy people need another shot at this time. The Pfizer and Moderna mRNA vaccines have shown waning immunity against infection with the highly transmissible SARS-CoV-2 delta variant, but they remain highly protective against severe illness, hospitalization and death. Some experts think the first two mRNA vaccine doses were spaced too close together (three weeks for Pfizer and four for Moderna), and an additional dose six months later could confer stronger and more durable immunity.

Studies have shown that booster shots increase levels of antibodies against the coronavirus, but this effect may only last a matter of months. Antibody levels normally wane after natural infection or vaccination, but memory B cells can produce new ones, and T cells attack cells infected with viruses. B-cell and T-cell responses prevent the coronavirus from multiplying out of control and causing severe illness, but this process takes a few days, which can give the virus time to cause mild illness and spread to other people.

The following day, the advisory committee also unanimously voted in favor of a booster dose for the J&J vaccine. Here, the case was more clear-cut, as several studies and real-world evidence show that the single-shot vaccine does not offer as much protection as the Pfizer and Moderna vaccines. This recommendation applies to all individuals who received the J&J vaccine at least two months after their initial shot. (See the FDA J&J briefing document here.)

Although designed as a more convenient "one and done" vaccine, many experts now think—and some have thought all along—that it should have been a two-dose regimen.

"I think this frankly was always a two-dose vaccine," committee member Paul Offit, MD, of Children's Hospital of Philadelphia, said at the meeting. "It's hard to recommend it as a single-dose

vaccine."

Recent study results showed that a second dose of the J&J vaccine raises its effectiveness into up into the same range as the Pfizer and Moderna mRNA vaccines, and that a longer six-month delay between doses may improve response.

FDA officials cautioned that they did not have time to review the J&J booster data as thoroughly as they usually do. But committee members said they felt compelled to make a recommendation even with limited data rather than leave J&J recipients hanging.

Friday's vote only applies to a second dose of the J&J vaccine, but some doctors have already started to give a Pfizer or Moderna dose to J&J recipients prior to authorization.

The committee reviewed recently released data from a National Institutes of Health trial showing that combining vaccine brands appears safe and feasible. In fact, a dose of one of the mRNA vaccines after a J&J shot led to particularly strong immune responses. But the advisors did not take a stand on a mix-and-match (heterologous) approach at this time.

> This is what we have been waiting for! A study out of NIH shows heterologous COVID-19 booster vaccinations of Moderna, Pfizer, and Johnson & Johnson induce strong humoral immune responses (up to a 76X increase in nAbs) with acceptable reactogenicity profiles. Let's discuss. ????
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> — Chise ?????????????????? BWS GOH (@sailorrooscout) October 14, 2021

The FDA is charged with authorizing vaccines and medications based on the risk-benefit balance for individuals. The full FDA is not required to follow advisory committee recommendations, but it typically does so. The CDC then makes recommendations about how best to use FDA-authorized vaccines, taking a broader view that includes their impact on public health. The agency's Advisory Committee on Immunization Practices will meet on October 21 to discuss the Moderna and J&J booster recommendations. The public can watch the virtual meeting online.

Click here for briefing documents and slide presentations from the FDA advisory committee meeting.
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