

Tweaked COVID boosters close but how much will they help?

August 25 2022, by LAURAN NEERGAARD



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COVID-19 vaccines tweaked to better match today's omicron threat are expected to roll out in a few weeks but still up in the air is how much benefit the booster shots will offer, who should get one—and how soon.



Pfizer and rival Moderna both asked U.S. regulators this week to <u>authorize modified versions</u> of their booster vaccine—shots that are half the original recipe and half protection against BA.4 and BA.5, the newest versions of omicron.

The Food and Drug Administration <u>ordered that recipe</u> and now is evaluating what scientists call a "bivalent vaccine," with a decision expected soon.

Dr. Peter Marks, the FDA's vaccine chief, said Thursday that once authorized, the tweaked boosters could help right away—while BA.5 infections still are too high—as well as hopefully blunt yet another winter surge.

Marks told the Associated Press that the new boosters could rev up the immune system to prevent not just serious illness but maybe milder infections, too, like the original vaccines did earlier in the pandemic, before super-contagious mutants emerged.

"The hope here is that by better matching things, not only will we get that benefit or even more, but we'll also have that last for a longer period of time," he said.

WHY DID FDA ORDER A RECIPE CHANGE?

BA.5 currently is causing nearly all COVID-19 infections in the U.S. and much of the world. Current COVID-19 vaccines match the coronavirus strain that circulated in early 2020. And while those vaccinations still offer strong protection against serious illness or death from COVID-19, there's little effectiveness against infection from the wildly mutated omicron family.

The first update to the recipe is an an important but expected next



step—like how flu vaccines get updated every year. True next-generation vaccines are still in development.

"We need to give a clear, forward-looking set of expectations," said University of Pennsylvania immunologist E. John Wherry, who compares vaccine tweaks to periodically updating your computer software.

The gamble is that BA.5, or something similar, still will be circulating through the winter. (Vaccines target the spike protein that coat the coronavirus, and the BA.4 and BA.5 spikes are identical although those strains vary in other ways.)

HOW WERE THE MODIFIED SHOTS TESTED?

Pfizer and Moderna both studied an earlier tweak to their vaccines that targets the original omicron, called BA.1, that hit last winter, as well as even earlier variants.

To evaluate the combo shots, FDA is using data from human testing of the BA.1-tweaked doses plus mice tests of the BA.5-targeted version that Marks said show "a very good immune response."

Human data on the newest tweak will come later in the year, to help assess the value of modified shots—especially whether they offer cross-protection if a new mutant comes along, Marks said. Moderna has started a clinical trial of its BA.5 combo shot; Pfizer and its partner BioNTech expect to open a similar study soon.

WILL THEY WORK BETTER?

No one knows. Dr. Paul Offit, a vaccine expert at the Children's Hospital of Philadelphia and an FDA vaccine adviser, said the antibody



jump from that earlier BA.1-tweaked candidate was "underwhelming."

"What the administration is asking us to do is to accept this bivalent vaccine as significantly better" than another dose of today's vaccine, he said. "It would be nice if there were data to support that."

But while FDA hasn't made a final decision, Marks said there's evidence that the updated boosters are safe and that waiting for more study of their effectiveness would risk another mutant appearing before they could roll out.

They "essentially refresh the immune response," he said. "Granted, it's still a bit of a guess how long it will last but, this is doing our best."

Given how outdated the current shots are, an update makes sense, said Dr. Walter Orenstein of Emory University, a former vaccine director at the Centers for Disease Control and Prevention. While he'd like to see more data, he plans to get the new booster.

WHO SHOULD GET AN UPDATED SHOT?

That's up to the CDC, which called a meeting of its influential vaccine advisers next Thursday and Friday to help decide.

Pfizer wants to open its updated boosters to everyone 12 and older who's already had a primary series of today's vaccine, while Moderna has applied only for adult use. CDC will determine if people at highest risk should go first. Studies of doses for younger children are expected later in the year.

A government rollout plan anticipates that people who've already gotten their initial vaccinations would qualify for one of the new combination shots, regardless of how many boosters they've already had.



WHEN SHOULD THOSE ELIGIBLE GET THE NEW BOOSTER?

Marks is aiming for a very simple message: "It's probably going to be everyone who has not had a booster within the past X number of months should go out and get the booster in a timely manner," he said. Officials still have to decide just how many months, though.

How long to wait after your last vaccine dose or an infection is a critical decision, immunologists agree. That's because if you still have a lot of antibodies in your bloodstream, they'll counteract the brand new antibodies that the vaccine dose is supposed to produce.

So if you already got a booster in July or August and then seek the new combo shot in September, "you'll receive very little additional boosting from that," Penn's Wherry said. He recommends waiting four to six months.

The CDC also will weigh in after after considering how many doses will be available in early September versus later in the fall. The Biden administration has purchased more than 170 million doses.

WILL PEOPLE ROLL UP THEIR SLEEVES AGAIN?

Americans have been reluctant to keep up with COVID-19 vaccinations. While three-quarters of Americans 12 and older have gotten their initial vaccinations, only half got a first booster shot—deemed crucial for the best protection against variants. And just a third of people 50 and older who were advised to get a second booster when omicron arrived did so.

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Citation: Tweaked COVID boosters close but how much will they help? (2022, August 25)



retrieved 11 May 2024 from https://medicalxpress.com/news/2022-08-tweaked-covid-boosters.html

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