

Updated booster shots, **not original COVID vaccines**, **should be standard**: **FDA panel**

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The U.S. Food and Drug Administration's vaccine advisory panel on



Thursday voted unanimously to recommend that the agency phase out original versions of COVID vaccines for use in the unvaccinated, in favor of updated bivalent booster shots.

Committee members also weighed a proposal to streamline the dosing schedule for COVID vaccines by turning them into annual shots that would likely be given every fall.

However, the committee did not vote on the proposal because many questions remain and more data on exactly who should get those annual shots, and exactly when, is sorely needed.

Still, they agreed that COVID vaccines do need to become more routine, to clear up public confusion and hopefully boost vaccination rates.

Such a move would be critical, given the fact that efforts to get people to get the updated COVID booster shots have fallen far short of expectations. While over 80% of Americans have had at least one dose of the original COVID-19 vaccine, only 16% of those over the age of 5 have gotten the updated booster shots that were approved last August, according to the U.S. Centers for Disease Control and Prevention.

"We can't keep doing what we are doing," said panel member Dr. Bruce Gellin, chief of global public health strategy at the Rockefeller Foundation. "This is a good path forward."

But some committee members said it was too soon to say whether annual doses were needed, as they are for the flu.

"I think we need to see what happens with disease burden," said Dr. Cody Meissner, chief of pediatric infectious diseases at Tufts University School of Medicine, the *New York Times* reported. "We may or may not need annual vaccination."



Dr. Archana Chatterjee, dean of the Chicago Medical School, said she welcomed a chance "to really go back to the <u>drawing board</u>, if you will, and look at the science a lot more closely than we were able to do in the face of a deadly pandemic" two years ago, the *Times* reported.

Unlike the flu, which surges during the winter, COVID has been mutating into new variants and failing to follow a predictable pattern, committee members noted.

"We don't know what's going to happen," said Dr. Eric Rubin, editor-inchief of the *New England Journal of Medicine*. "It's hard to say that it is going to be annual at this point."

"I think this pattern is not necessarily the flu," added Dr. Henry Bernstein, a professor of pediatrics at the Zucker School of Medicine at Hofstra University in New York, *NBC News* reported. "We need to communicate that there is still value in getting vaccines outside the typical influenza window."

But the FDA believes the time is right for annual shots targeting the latest COVID variants, even though Dr. Peter Marks, the agency's top vaccine regulator, acknowledged during the meeting that simplifying the COVID vaccine schedule to be exactly like the flu may not be possible.

Dr. Jerry Weir, director of the Division of Viral Products at the FDA's Office of Vaccines Research and Review, reassured committee members during the meeting that even if COVID vaccines did become an annual affair, an emergency meeting would be called to discuss whether new boosters are needed if a new, dangerous variant suddenly emerged, *NBC News* reported.

So far, the updated bivalent boosters are holding their own against new Omicron variants, including the XBB variant, which now <u>accounts</u> for



roughly half of all U.S. infections.

Several new studies have reported results that, while using incomplete and imperfect data, point to the value of the updated bivalent booster shots. Those vaccines were designed to defend against both the original version of the virus and the BA.5 Omicron subvariant that spread across the United States in the fall.

One report, published in the <u>New England Journal of Medicine</u>, found the bivalent boosters generated stronger protection than the original formulations of booster shots did. The bivalent booster was about 62 percent effective against severe COVID, the study found, compared with the original booster, which was 25 percent effective.

Another <u>study</u>, conducted by the CDC, found the updated booster shot performed as well against the newest Omicron subvariant, XBB.1.5, as it did against BA.5. For adults under 50, a bivalent booster was 48 percent effective against COVID infections caused by XBB.1.5, while it was 52 percent effective against infections caused by BA.5.

And CDC officials told the FDA <u>vaccine</u> advisory committee on Thursday that people who got a bivalent booster saw a 13-fold reduction in the risk of death from COVID compared with unvaccinated people, and a twofold reduction in the risk of death compared with people who were vaccinated but had not received an updated <u>booster</u> shot, the *Times* reported.

More information: Visit the U.S. Centers for Disease Control and Prevention for more on <u>COVID vaccines</u>.

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