

# US allows extra COVID vaccine doses for some. Now what?

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In this Thursday, Feb. 25, 2021 file photo, vials for the Moderna and Pfizer COVID-19 vaccines are displayed on a tray at a temporary clinic set up by the New Hampshire National Guard in the parking lot of a high school in Exeter, N.H. The Food and Drug Administration ruled that transplant recipients and other similarly immune-compromised patients can get a third dose of either the Pfizer or Moderna vaccine. But the decision, late Thursday night, Aug. 12, 2021, offers an extra dose only to those high-risk groups—not the general public. Credit: AP Photo/Charles Krupa



Americans at high risk from COVID-19 because of severely weakened immune systems are now allowed to get a third vaccination in hopes of better protection, a policy change endorsed Friday by influential government advisers.

The Food and Drug Administration ruled that transplant recipients and other similarly immune-compromised patients can get a third dose of either the Pfizer or Moderna vaccine. But the decision offers an extra dose only to those high-risk groups—not the general public.

These patients have been clamoring for months for better protection, some of them traveling across state lines or lying to get another dose. About 1.1 million people already have gotten at least a third dose of the Pfizer or Moderna vaccines on their own, the Centers for Disease Control and Prevention revealed, although it's not clear how many did so because they had weakened immune systems.

Advisers to the CDC grappled with exactly who qualifies before unanimously endorsing the FDA's decision.

It's "an important step in ensuring everyone, including those most vulnerable to COVID-19, can get as much protection as possible from COVID-19 vaccination," CDC director Dr. Rochelle Walensky said in a statement after signing off on the recommendation.

Here are some things to know:

#### WHY DO SOME PEOPLE NEED AN EXTRA DOSE?

The Pfizer and Moderna vaccines offer powerful protection for otherwise healthy people, but many who take immune-suppressing medications or have diseases that tamp down their immune systems generally get less benefit from the standard two doses. The CDC cited



one study suggesting about 40% to 44% of people hospitalized for a so-called breakthrough case—infection after vaccination—are among the immune-compromised.

Those hospitalized patients "did all the right things—they're just suffering from a lack of good vaccine protection," said Dr. Camille Kotton of Massachusetts General Hospital, one of CDC's advisers.

# WHO QUALIFIES?

Roughly 7 million American adults are classified as immune-compromised, but the FDA singled out transplant recipients and others with similar levels of immune suppression. The FDA didn't spell out exactly who falls into those other categories, but in new guidance to doctors issued Friday, the CDC listed several categories of people who could qualify, including people with advanced or untreated HIV infections and those with cancers who are receiving certain chemotherapies.

#### ARE THERE AGE RESTRICTIONS?

For now, the new policy allows a third dose of the Pfizer vaccine for children as young as 12 who also meet the high-risk requirement, but adults only for a third Moderna dose. That's because the Pfizer vaccine currently is the only authorized option for Americans under 18. That could change if Moderna's vaccine eventually is allowed for teens.

### WILL I NEED A DOCTOR'S NOTE OR A BLOOD TEST?

The government isn't requiring either—patients will just need to tell the vaccine provider why they're seeking another dose. "We would want to make that as easy as possible," said Dr. William Schaffner, an infectious diseases expert at Vanderbilt University.



#### WHAT WILL A THIRD DOSE COST?

Shots given under FDA's emergency use authorization are free.

#### IS MIX-AND-MATCH ALLOWED?

The government encourages the third dose to be the same as the first two, but doesn't mandate it.

# HOW WELL DOES A THIRD DOSE WORK?

It helps at least some people. Canadian researchers this week reported 55% of transplant recipients given a third dose two months after standard vaccination had good antibody levels compared to 18% who were given a dummy third shot for comparison. Health experts urged these high-risk patients to continue masking and taking other precautions since there's no guarantee a third dose will work.

#### WHAT IF A THIRD DOSE STILL DOESN'T WORK?

It's not a substitute for vaccination, but the FDA has authorized an antibody treatment as a preventive treatment if high-risk patients are exposed to the virus. And it's critical for family members and others close to fragile patients to be vaccinated.

More research is underway to better tease out whether some immunecompromised patients need still other options, such as carefully monitored changes to their medications.

# WHAT IF I HAD THE SINGLE-DOSE JOHNSON & JOHNSON VACCINE?

There's little data on how another dose works in high-risk people who



received that vaccine, although it's likely a small number since fewer than 14 million Americans overall have received the J&J shot. Still, CDC counts at least 90,000 who have gotten another dose on their own.

FDA vaccines chief Dr. Peter Marks said the agency is working to get more information about immune-suppressed J&J patients but that for now, the evidence only backs a recommendation of extra doses for Pfizer and Moderna recipients with fragile immune systems.

# IS THIS A BOOSTER?

Not really, because boosters are for people whose immunity wanes over time and these high-risk groups didn't get enough protection to begin with. They now will qualify for a third dose at least 28 days after their second shot—making a third dose part of their initial prescription. That's similar to how France has handled vaccinations for the immunecompromised since April.

#### WHAT ABOUT BOOSTERS FOR EVERYONE ELSE?

U.S. health authorities insist it's not yet time for booster doses for the general population.

"We believe sooner or later you will need a booster for durability of protection"—but not yet, Dr. Anthony Fauci, the government's top infectious diseases expert, told reporters this week.

The CDC is closely monitoring rates of COVID-19 hospitalizations and deaths, as well as long-running studies of how often vaccinated health workers experience breakthrough infections, especially with the contagious delta variant. That evidence will drive any decision.

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