

Top Questions Answered About COVID Boosters for Your Patients

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September 24, 2021

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Confusion continues to circulate in the wake of decisions on booster doses of the Pfizer/BioNTech COVID-19 vaccine, all announced within 1 week. Many people — including those now eligible and those who officially have to wait for their shot at a third dose — have questions.

Multiple agencies are involved in the booster decisions, and they have put out multiple — and sometimes conflicting — messages about booster doses, leaving more questions than answers for many people.

On September 22, the US Food and Drug Administration (FDA) [granted an](#) emergency use authorization (EUA) for a booster dose of the [Pfizer mRNA COVID vaccine](#) for those 65 and older and those at high risk for severe illness from the coronavirus, including essential workers whose jobs increase their risk for infection — such as frontline healthcare workers.

Early this morning, the Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky, MD, [overruled advice](#) from the agency's Advisory Committee on Immunization Practices (ACIP) to recommend boosters for essential workers such as those working on the frontlines during the pandemic.

As it stands now, the CDC recommends that the following groups *should* get a third dose of the Pfizer vaccine:

- People aged 65 years and older
- People aged 18 years and older in long-term care settings
- People aged 50 - 64 years with underlying medical conditions

The CDC also recommends that the following groups *may* receive a booster shot of the Pfizer vaccine, based on their individual benefits and risks:

- People aged 18 - 49 years with [underlying medical conditions](#)
- People aged 18 - 64 years at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting

The CDC currently considers the following groups at increased risk for COVID-19:

- First responders (healthcare workers, firefighters, police, congregate care staff)
- Education staff (teachers, support staff, day care workers)
- Food and agriculture workers
- Manufacturing workers
- Corrections workers
- US postal service workers
- Public transit workers
- Grocery store workers

Healthcare professionals, among the most trusted sources of COVID-19 information, are likely to encounter a number of patients wondering how all this will work.

"It's fantastic that boosters will be available for those who the data supports need [them]," Rachael Piltch-Loeb, PhD, said during a media briefing on September 23, held between the FDA and CDC decisions.

"But we're really in a place where we have a lot more questions and answers about what the next phase of the vaccine availability and updates are going to be in the United States," added Piltch-Loeb, preparedness fellow in the Division of Policy Translation and Leadership Development and a research associate in the Department of Biostatistics at the Harvard T H Chan School of Public Health in Boston, Massachusetts.

To provide some initial answers, *Medscape Medical News* spoke with multiple COVID-19 experts.

1. What is the biggest concern you are hearing from patients about getting a booster?

"The biggest concerns are that everyone wants it and they don't know where to get it. In healthcare's defense, the CDC just figured out what to do this morning," said Janet Englund, MD, professor of pediatric infectious diseases and an infectious disease and virology expert at Seattle Children's Hospital in Washington.

"Everyone thinks they should be eligible for a booster...people in their 50s who are not yet 65+, people with young grandchildren, etc.," she added. "I'm at Seattle Children's Hospital, so people are asking about booster shots and about getting their children vaccinated."

Boosters for all COVID-19 vaccines are completely free.

"All COVID-19 vaccines, including booster doses, will be provided free of charge to the US population," the CDC said Thursday.

2. Will patients need to prove they meet eligibility criteria for a booster shot or will it be the honor system?

"No, patients will only need to attest that they fall into one of the high-risk groups for whom a booster vaccine is authorized," said Robert Atmar, MD, professor of infectious diseases at Baylor College of Medicine in Houston, Texas.

Piltch-Loeb agreed. "It is likely to be an honor system. It is very unlikely that there will be punishments or other ramifications...if doses are administered, beyond the approved usage."

3. If a patient who had the Moderna or the Johnson and Johnson vaccination requests a booster, can healthcare workers give them Pfizer?

The short answer is no. "This only applies to individuals who have received the Pfizer vaccine," Piltch-Loeb said.

More data will be needed before other vaccine boosters are authorized, she added.

"My understanding is the Moderna people have just recently submitted their information, all of their data to the FDA and J&J is in line to do that very shortly," said William Schaffner, MD, a professor of preventive medicine and infectious diseases at Vanderbilt University in Nashville, Tennessee.

"I would hope that within the next month to six weeks, we will get information about both of those vaccines," Schaffner said.

4. When are the "mix-and-match" vaccine study results expected to come out?

"We expect that data from the study will be available in the coming weeks," said Atmar, who is also national coprincipal investigator of a [mix-and-match booster trial](#) launched in June 2021.

5. Are side effects of a booster vaccine expected to be about the same as what people experienced during their first or second immunization?

"I'm expecting the side effects will be similar to the second dose," Englund said.

"The data presented yesterday at ACIP suggests that the side effects from the third shot are either the same or actually less than the first two shots," said Carlos del Rio, MD, distinguished professor of medicine, epidemiology and global health and executive associate dean of Emory University School of Medicine at Grady Health System in Atlanta, Georgia.

"Everyone reacts very differently to vaccines, regardless of vaccine type," said Eric Ascher, MD, a family medicine physician at Lenox Hill Hospital in New York City. "I have had patients (as well as personal experience) where there were none to minimal symptoms, and others who felt they had a mild flu for 24 hours."

"I expect no side effects greater than what was felt with you prior doses," he said. "The vaccine is very safe and the benefit of vaccination outweighs the risks of any mild side effects."

6. Is it unethical to give a booster to someone outside the approved groups if there are doses remaining at the end of the day in an open vial?

"Offering a booster shot to someone outside of approved groups if remaining doses will go to waste at the end of the day seems like a prudent decision, and relatively harmless action," said Faith Fletcher, PhD, assistant professor at the Center for

Medical Ethics and Health Policy at Baylor College of Medicine.

"However, if doses continue to [fall in the laps](#) of unapproved groups, we must evaluate the vaccine systems and structures that advantage some groups and disadvantage others," she added. "We know that the distribution of Covid-19 vaccines has not been equitable — and some groups have been left behind."

"I am not an ethicist and there are many competing concerns that this question addresses," Atmar said. For example, "there is not a limitation of vaccine supply in the US, so that using left-over vaccine to prevent waste is no longer a major concern in the US."

It could be more of a legal than ethical question, Atmar said. For an individual outside the authorized groups, legally, the FDA's EUA for boosting does not allow the vaccine to be administered to this person, he said.

"The rationale for the restricted use in the EUA is that at this time the safety and risks associated with such administration are not known, and the benefits also have not been determined," Atmar said. "Members of the ACIP raised concerns about other individuals who may potentially benefit from a booster but are not eligible and the importance of making boosters available to them, but from a legal standpoint — I am also not a lawyer, so this is my understanding — administration of the vaccine is limited to those identified in the EUA."

7. What is the likelihood that one shot will combine COVID and flu protection in the near future?

It is not likely, Englund said. "The reason is that the flu vaccine changes so much, and it already has four different antigens. This is assuming we keep the same method of making the flu vaccine — the answer could be different if the flu vaccine becomes an mRNA vaccine in the future."

Companies such as [Moderna](#) and [Novavax](#) are testing single-dose shots for COVID and influenza, but they are still far from having anything ready for this flu season in the United States.

8. Is there any chance a booster shot distributed now will need to be redesigned for a future variant?

"Absolutely," Englund said. "And a booster dose is the time we may want to consider re-engineering a vaccine."

9. Do you think the FDA/CDC limitations on who is eligible for a booster was in any way influenced by the World Health Organization call for prioritizing shots for the unvaccinated in lower-resource countries?

"This is absolutely still a global problem," Piltch-Loeb said. "We need to get more of vaccine to more countries and more people as soon as possible, because if there's anything we've seen about the variants it is that...they can come from all different places."

"That being said, I think that it is unlikely to change the course of action in the US," she added, when it comes to comparing the global need with the domestic policy priorities of the administration.

Atmar was more direct. "No," he said. "The WHO recommends against boosting of anyone. The US decisions about boosting those in this country who are eligible are aimed toward addressing perceived needs domestically at the same time that vaccines are being provided to other countries."

"The philosophy is to address both 'needs' at the same time," Atmar said.

10. What does the future hold for booster shots?

"Predicting the future is really hard, especially when it involves COVID," del Rio said.

"Having said that, COVID is not the flu, so I doubt there will be need for annual boosters. I think the population eligible for boosters will be expanded...and the major population not addressed at this point is the people that received either Moderna or J&J [vaccines]."

Kelly Davis contributed to this feature.

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