COVID-19 VACCINE FREQUENTLY ASKED QUESTIONS

1 HOW DO I KNOW IT'S SAFE?

Each company's application to the FDA includes two months of follow-up safety data from Phase 3 of clinical trials conducted by universities and other independent bodies. In that phase, tens of thousands of volunteers got a vaccine and waited to see if they became infected, compared with others who received a placebo. By September, Pfizer's trial had 44,000 participants; no serious safety concerns have been reported.

CAN I GET COVID-19 FROM THE VACCINE?

No, none of the current leading vaccines (Pfizer, Moderna, AstraZeneca, Janssen) contain whole SARS-CoV-2 virus. They cannot give you COVID-19.

WHAT SHOULD I MENTION TO MY PROVIDER BEFORE I RECEIVE ANY SHOTS?

It is recommended that you inform your vaccination provider about all medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood-thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

HOW DO I REPORT A PROBLEM OR BAD REACTION TO GETTING VACCINATED?

The CDC and FDA encourage the public to report possible side effects (called adverse events) to the <u>Vaccine Adverse Event Reporting System (VAERS)</u>. This national system collects these data to look for adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns of occurrence. Healthcare providers will be required to report certain adverse events following vaccination to VAERS. Healthcare providers also have to adhere to any revised safety reporting requirements according to FDA's conditions of authorized use throughout the duration of any Emergency Use Authorization; these requirements would be posted on FDA's website.

CDC is also implementing a new smartphone-based tool called v-safe to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a v-safe information sheet telling you how to enroll in v-safe. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

5 CAN A CLINICAL TRIAL BE PAUSED IF THERE ARE ADVERSE EFFECTS?

Safety is a top priority during the vaccine approval process. It is not unusual for a clinical trial to be temporarily paused when a possible side effect (called an adverse event) is detected. Clinical trials are designed to pause when an unexpected health event (called a safety signal) is detected so scientists and physicians can investigate potential safety concerns. The approval process for COVID-19 vaccines is no different — safety is always the focus.

ARE THERE OTHER VACCINES THAT WILL PREVENT COVID-19?

There are currently no available vaccines that will prevent COVID-19. However, multiple agencies and groups in the United States are working together to make sure that a safe and effective COVID-19 vaccine is available as quickly as possible. A flu vaccine will not protect you from getting COVID-19, but it can prevent you from getting influenza (flu) at the same time as COVID-19. This can keep you from having a more severe illness. While it's not possible to say with certainty what will happen in the winter, CDC believes it's likely that flu viruses and the virus that causes COVID-19 will both be spreading during that time. That means that getting a flu vaccine is more important than ever.

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IS THERE A RISK SUPPLY WILL RUN OUT BEFORE I GET MY SECOND DOSE?

If you are in the first group of people vaccinated, your booster shot will be set aside for you and won't be given to someone else. Later when supplies are more plentiful, reserves probably won't be necessary. Gen. Gustave F. Perna, the chief operating officer for Operation Warp Speed, the federal effort to speed a vaccine to market, has said that after the first doses are given, the doses earmarked for the second shot will be set aside to be given three weeks later. An additional 500,000 backup doses will also be held in reserve, in case they are unexpectedly needed.

8 CAN I CHOOSE WHICH VACCINE I GET?

This depends on a number of factors, including the supply in your area at the time you're vaccinated and whether certain vaccines are found to be more effective in certain populations, such as older adults. At first, the only choice will be Pfizer's vaccine, though Moderna's could become available within weeks.

HOW LONG WILL IT TAKE TO WORK?

You won't get the full protection from the Pfizer-BioNTech vaccine until about a week after the second dose, based on clinical trial data. The researchers found that the vaccine's protection started to emerge about ten days after the first dose, but it only reached 52 percent efficacy, according to a report in the New England Journal of Medicine. A week after the second dose, the efficacy rose to 95 percent.

I HAD COVID-19-19 ALREADY.
SHOULD I STILL GET VACCINATED?

It's safe, and probably even beneficial, for anyone who has had COVID-19 to get the vaccine at some point, experts said. Although people who have contracted the virus do have immunity, it is too soon to know how long it lasts. So for now, it makes sense for them to get the shot. The question is when. Some members of the CDC advisory committee have suggested people who have had COVID-19 in the past 90 days should be toward the back of the line.

IF I HAVE ALLERGIES, SHOULD I BE CONCERNED?

People with severe allergies who have experienced anaphylaxis in the past should talk to their doctors about how to safely get the vaccine and what precautions to take. The FDA. Has said it would require Pfizer to increase its monitoring for anaphylaxis and submit data on it once the vaccine comes into use. Fewer than one in a million recipients of other vaccines a year in the U.S. have an anaphylactic reaction, said Dr. Paul Offit, a vaccine expert at Children's Hospital of Philadelphia.

Among those who participated in the Pfizer trials, a very small number of people had allergic reactions. A <u>document published by the FDA</u> said that 0.63 percent of participants who received the vaccine reported potential allergic reactions, compared to 0.51 percent of people who received a placebo. In Pfizer's late-stage clinical trial, one of the 18,801 participants who received the vaccine had an anaphylactic reaction, according to <u>safety data published by the FDA on December 10, 2020</u>. None in the placebo group did.

SOURCES

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