COVID-19 Vaccine: Frequently Asked Questions

Vaccine Distribution

Who will be offered the COVID-19 vaccine first?
The Centers for Disease Control and Prevention (CDC) has recommended a tiered approach be used to determine in what order the vaccine will be distributed. The vaccine distribution will be prioritized in the following way:

- Healthcare personnel
- Workers in essential and critical industries
- People at high risk for severe COVID-19 illness due to underlying medical conditions
- People 65 years and older
- General public *(those not in groups listed above)*

The CDC has issued vaccine distribution recommendations to the states, and the Texas Department of Health Services has issued guiding principles regarding the distribution/administration of the vaccines.

General Vaccine Information

Am I required to get a COVID-19 vaccine?
No. A COVID-19 vaccine is not mandatory.

If I've already had COVID-19, would the vaccine be helpful?
Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, people may be advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before.

At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Some early evidence suggests natural immunity may not last very long.

Individuals who are known COVID-19 positive should wait to receive the vaccine until they have recovered from their acute illness and no longer require isolation. There is no minimal interval between infection and vaccination, but current evidence suggests reinfection is unlikely within 90 days, so if an individual wishes to do so, the vaccine may be deferred until the end of the 90-day period.

How were the vaccines tested?
Clinical trials are evaluating investigational COVID-19 vaccines in tens of thousands of study participants to enable the U.S. Food and Drug Administration to determine safety and effectiveness. These clinical trials are being conducted according to the FDA's rigorous standards.

The trials are conducted in three phases.

- **Phase 1** - The vaccine is given to a small number of generally healthy people to assess its safety at increasing doses and to gain early information about how well the vaccine works to induce an immune response in people.
- **Phase 2** - Studies include more people with varying health statuses and from different demographic groups receiving various dosages. These studies provide additional safety information and may provide initial information regarding the effectiveness of the vaccine.
- **Phase 3** - The vaccine is administered to thousands of people in randomized, controlled studies involving broad demographic groups. In a randomized, controlled study, individuals are allocated at random to receive the vaccine and are compared against those in the study who did not receive the vaccine. This phase generates critical information on effectiveness and additional important safety data. It provides additional information about the immune response in people who receive the vaccine compared to those who receive a control, such as a placebo. (FDA)

How does the FDA determine emergency use authorization?
Approval of an emergency use authorization (EUA) request from a vaccine manufacturer enables the FDA to allow the use of unapproved medical products, or unapproved uses of approved medical products, in a public health emergency such as the COVID-19 pandemic. There must be no adequate, approved and available alternatives to a product for the FDA to approve an EUA request.

Vaccine manufacturers are currently conducting extensive clinical trials to generate the information needed by the FDA to determine whether the known and potential benefits outweigh the known and potential risks of a vaccine for the prevention of COVID-19.

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General Vaccine Information cont.

When the final phase of the clinical trial reaches a point that indicates how well a vaccine prevents COVID-19, an independent group called a data safety monitoring board reviews the data. Based on the data and the interpretation of the data by this group, manufacturers decide whether to submit an EUA request to the FDA, taking into consideration input from the FDA.

After the FDA receives the EUA request, its career scientists and physicians, with input from an external advisory committee, evaluate the safety and effectiveness information and decide whether the data support an emergency use authorization of the specific COVID-19 vaccine in the United States.

The FDA informs recipients of a vaccine under an EUA that it has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product. This information is communicated in fact sheets on the FDA website, such as the fact sheet on the approval of the Pfizer vaccine EUA. (FDA)

Will the COVID-19 vaccine be free?

The CDC says that vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.

If I get the COVID-19 vaccine, can I relax the safety precautions I have been taking?

No. The vaccine does not replace the need for safety precautions such as wearing a mask, maintaining a safe distance, washing your hands and limiting gatherings with individuals outside your household.

Vaccine Doses, Safety, Efficacy and Side Effects

Is the COVID-19 vaccine safe for vulnerable populations?

- *Pregnant women*: Women should wait more than two months after taking the second dose of the vaccine to become pregnant.

  As of Dec. 14, 2020, no data is available on the safety of COVID-19 vaccines in pregnant women. If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision.

  - Based on current recommendations from the American College of Obstetrics and Gynecology, if you are planning or trying to get pregnant, you can still get a COVID-19 vaccine. You also do not need to delay getting pregnant after you get a vaccine. Some COVID-19 vaccines will require two doses. If you find out you are pregnant after you have the first dose, you should still get the second dose

- *Breastfeeding*: As of Dec. 14, 2020, no data is available on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion. If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is lactating, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision.

- *Older adults*: Currently, people 65 years and older are recommended for early COVID-19 vaccination according to the Advisory Committee for Immunization Practices. Older adults are considered at highest risk for COVID-19 due to increased illness severity and risk of death.

  - Early vaccination for this patient population is highly recommended.

- *Immunocompromised*: Currently, people at high risk for severe COVID-19 illness due to underlying medical conditions are recommended for early COVID-19 vaccination according to the Advisory Committee for Immunization Practices. People with certain underlying medical conditions are at increased risk for COVID-19, therefore it is highly recommended to ensure vaccination within this patient population.

  - Underlying medical conditions include but are not limited to:
    - Cancer, COPD, solid organ transplant recipients, heart failure, coronary artery disease, sickle cell disease, etc.
  - Severe illness is defined as individuals with COVID-19 who may require hospitalization, intensive care or mechanical ventilation.

How many doses of a COVID-19 vaccine will I need?

The Pfizer vaccine is an initial vaccination and a second shot 17 to 21 days later. The Moderna vaccine uses an initial vaccination and a second shot 28 days later. The different vaccine products are not interchangeable; the second dose must be completed with the same vaccine brand as the first.

What are the side effects of the vaccine?

Side effects are expected to be similar to, but perhaps more pronounced than, the side effects some people experience following the flu vaccine. Both Pfizer and Moderna have said their vaccines were "well-tolerated" in clinical trials. Commonly reported adverse effects of the vaccine have been called "mild and nonspecific." These include fever, chills, headache and injection site reactions (soreness/pain, redness, muscle aches). The manufacturers said the vaccines are safe and effective, and that most of the side effects resolved shortly after the shots were administered.

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Vaccine Doses, Safety, Efficacy and Side Effects cont.

Moderna has disclosed some reports among trial participants of "severe" side effects, or those that could impede daily activity. Significant side effects from the first dose included injection site pain, but more felt worse after the second shot — reporting fatigue, muscle and joint pain, and headache, among other symptoms. In the Pfizer trial, participants reported fatigue and headaches after getting the second dose. (The Washington Post, Pfizer and Moderna news releases)

If symptoms worsen or do not resolve after one week, contact your primary care physician and seek medical attention.

FDA documents about the Pfizer vaccine can be found here.

Should I be concerned about having a severe allergic reaction to the vaccine?

1. Those with a history of severe allergic reactions to vaccine components:

Due to reports of anaphylactic reactions experienced outside of clinical trials, persons who have a history of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine should not receive the Pfizer vaccine at this time.

2. Those with a history of severe allergic reactions to other vaccine or injectable therapy:

The CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution but not a contraindication to vaccination. These persons may still receive vaccination, but they should talk with their healthcare provider about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.

3. Those with a history of mild allergic reaction to vaccine or injectable therapy:

A history of mild allergic reaction to a vaccine or injectable therapy (such as hives alone without anaphylaxis), is not a contraindication or precaution to Pfizer-BioNTech COVID-19 vaccination.

In addition, allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, environmental, or latex allergies; oral medications) are not a contraindication or precaution to vaccination with Pfizer-BioNTech COVID-19 vaccine.

Individuals with a history of any severe allergic reaction should be observed for 30 minutes after the vaccination.

How do I report if I had a problem or bad reaction after getting a COVID-19 vaccine?

The Centers for Disease Control and Prevention and the Food and Drug Administration and FDA encourage the public to report possible adverse events to the Vaccine Adverse Event Reporting System (VAERS).

Can I get COVID-19 from the vaccine?

No. It is not possible to get COVID-19 from vaccines. The Pfizer and Moderna vaccines use only a messenger RNA (mRNA) gene, not the actual virus, to trigger a person's immune system to produce protective antibodies against COVID-19. Other vaccines being studied use inactivated virus. None of these can cause COVID-19.

Because the vaccine triggers the immune system to respond as if the actual virus was present a person may experience some side effects similar to those caused by the virus.

What are the efficacy rates of the vaccines and what does that mean?

Vaccine efficacy (VE) measures the proportionate reduction in disease among a vaccinated group in a clinical trial. A VE of 90% indicates a 90% reduction in disease occurrence among the vaccinated group, or a 90% reduction from the number of cases you would expect if they have not been vaccinated.

In clinical trials the Pfizer vaccine has demonstrated a VE of 95%. The Moderna vaccine's VE is 94.5%. (CDC, Business Insider)

Will I have to get the COVID-19 vaccine every year, like the flu shot?

We won't know how long immunity produced by vaccination lasts until we have a vaccine and more data on how well it works.

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