

# Safety and Effectiveness

## Is the vaccine safe and effective?

After a COVID-19 vaccine is authorized by the FDA, many vaccine safety monitoring systems watch for adverse events (possible side effects). This ongoing monitoring can pick up on adverse events that may not have been seen in clinical trials. If an unexpected adverse event is seen, experts quickly study it further to see if it is a true safety concern. Experts then decide whether changes are needed in US vaccine recommendations.

In New York State, an added level of review was established to ensure COVID vaccine safety. Following Emergency Use Authorization by the FDA, experts on [New York State's independent COVID-19 Vaccine Clinical Advisory Task Force](#) thoroughly review vaccine research before recommending any vaccine to New Yorkers. As of March 1, 2021, three COVID-19 vaccines have currently been authorized for emergency use by the FDA and approved by New York State's independent Clinical Advisory Task Force: the Pfizer/BioNTech vaccine, the Moderna vaccine and the Janssen/Johnson & Johnson vaccine.

## Will the vaccine give me COVID?

No. None of the vaccines being studied are made up of materials that can cause disease. For example, the first vaccines authorized for emergency use by the FDA use a small, harmless part of the virus's genetic material called 'mRNA'. This is not the virus. mRNA vaccines teach your body to create virus proteins. Your immune system develops antibodies against these proteins that will help you fight the virus that causes COVID-19 if you are exposed to it. That is called an immune response.

## Are COVID vaccines safe for children?

Currently, the FDA has determined that the Pfizer COVID vaccine meets the standards for effectiveness and safety needed for emergency use authorization for use by children ages 12 and older. Studies will need to be conducted testing COVID-19 vaccines in younger children. To date, no Phase 3 clinical studies of COVID-19 vaccines include children younger than 12

years. Please reach out to your health care provider with specific questions. Additional information can be found on [www.cdc.gov](http://www.cdc.gov).

## **Are COVID-19 vaccines safe for pregnant people?**

As of February 15, pregnant women are currently eligible to receive the COVID-19 vaccine in New York State.

A new study published in the [New England Journal of Medicine](#) reported that COVID-19 vaccines made by Pfizer/BioNTech and Moderna do not appear to pose any serious risk during pregnancy. The research showed that pregnant people did not report having severe reactions more often than people who were not pregnant, except for nausea and vomiting, which were reported slightly more frequently only after dose 2. In addition, pregnancy outcomes for people who had a COVID-19 vaccine during pregnancy were about the same as before the pandemic.

The study, along with existing research showing mRNA vaccines are effective in pregnant and breastfeeding people, suggests that the benefits of the vaccines outweigh the risks, since the CDC says pregnant people with COVID-19 are at increased risk for severe illness and may be at increased risk for adverse outcomes, such as preterm birth. The Johnson & Johnson (Janssen) COVID-19 vaccine uses similar technology to other Janssen vaccine studies that have included pregnant people vaccinated during any trimester. No adverse pregnancy-related outcomes—including infant outcomes—were determined to be related to the vaccine in those studies.

## **If you get a vaccine do you need a negative COVID test beforehand?**

No. [The CDC does not recommend](#) COVID-19 screening tests before getting a COVID-19 vaccine.

## **Is it safe to get a COVID-19 vaccine if I have an underlying medical condition?**

Yes. COVID-19 vaccination is especially important for people with underlying health problems like heart disease, lung disease, diabetes, and obesity.

People with these conditions are more likely to get very sick from COVID-19. Please consult with your health care provider if you have specific questions about the COVID vaccine and your health.

## **If I already had COVID-19 and recovered, do I still need to get vaccinated?**

Yes. CDC recommends that you get vaccinated even if you have already had COVID-19, because you can catch it more than once. While you may have some short-term antibody protection after recovering from COVID-19, we don't know how long this protection will last.

## **Will the vaccine make me sick?**

You may not notice any changes in how you feel after getting the shot. But it's also possible to feel a little "under the weather." This can happen after any vaccine. It is the body's immune response to getting vaccinated and a sign that the vaccine is starting to work.

After the COVID-19 vaccine, you may have:

- A sore arm where you got the shot
- A headache
- Chills
- Fever
- Tiredness

Over the counter pain relievers and fever reducers may help.

You should feel better in a day or two. If you still don't feel well after two or three days, talk to your health care provider.

## **Will the vaccine work against new U.K. coronavirus strain?**

The State Department of Health's Wadsworth Laboratory has confirmed cases of the United Kingdom (U.K.) coronavirus strain, also known as B.1.1.7, in New York State. While evidence indicates that the U.K. variant is more

transmissible (contagious) than other variants, it is not believed to be more resistant to COVID-19 vaccines.

## **Can I get an allergic reaction from the COVID-19 vaccine?**

People can have allergic reactions to any medication or biological product such as a vaccine. Most allergic reactions occur shortly after a vaccine is administered, which is why the CDC recommends that persons with a history of anaphylaxis (due to any cause) are observed for 30 minutes after vaccination, while all other persons are observed for 15 minutes after vaccination. All vaccination sites must be equipped to ensure appropriate medical treatment is available in the event of an unlikely allergic reaction. The Centers for Disease Control and Prevention recommends anyone with an allergy to "any component" of the vaccine not get the vaccine.

## **Will there be side effects from the vaccine?**

Common side effects that have been observed in clinical studies include fatigue, muscle soreness at the injection site and fever.

## **Is it better to get natural immunity to COVID-19 rather than immunity from a vaccine?**

No. While you may have some short-term antibody protection after recovering from COVID-19, we don't know how long this protection lasts. Vaccination is the best protection, and it is safe. People who get COVID-19 can have serious illnesses, and some have debilitating symptoms that persist for months.

## **How long will vaccine immunity last?**

Researchers do not yet know how long immunity lasts after vaccination. That's why continuing prevention practices like wearing a mask, washing your hands regularly and social distancing will still be important.

## I've heard about "herd immunity." What would it take to get the population to "herd immunity" for COVID-19?

'Herd immunity' happens when enough people have protection from a disease that it is unlikely that the disease will continue to spread. As a result, the virus won't easily spread among the community. Experts do not know what percentage of people would need to get vaccinated to achieve herd immunity to COVID-19. They also do not know how long the vaccine will protect people.

Letting COVID-19 spread through communities naturally would lead to unnecessary infections, suffering and death.

## I tested positive for COVID antibodies. Do I still need the vaccine?

Yes. The CDC recommends that you get vaccinated even if you have already had COVID-19, because you can be infected more than once. While you may have some short-term antibody protection after recovering from COVID-19, we don't know how long this protection will last. Vaccination is the best protection, and it is safe. People who get COVID-19 may have serious illnesses, and some have debilitating symptoms that persist for months.

## Should I get my antibodies checked after getting my COVID-19 vaccination?

No. While some laboratories offer COVID-19 antibody tests, these tests are designed to measure immunity from infection but not from vaccination. Commercially-available COVID-19 antibody tests look for antibodies that are **different** from those made by current vaccines, so you won't get a true picture of your protection.

The CDC recommends that people who have had only 1 dose of a 2-dose COVID-19 vaccine series complete the series regardless of results of antibody testing. Likewise, people who are fully vaccinated against COVID-19 do not need any additional doses of COVID-19 vaccine due to negative or low results of antibody tests.

## **If I get a COVID-19 vaccine, do I still need to wear a mask and social distance?**

Yes. You will need to continue to wear a mask, practice social distancing and good hand hygiene for the foreseeable future as the vaccine gets rolled out in phases.

Experts need more time to understand the protection that COVID-19 vaccines provide before deciding to change recommendations on mask use. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

# **Development**

## **How was the vaccine developed so quickly?**

There are many factors that combined to allow the COVID-19 vaccine to be developed quickly and safely:

- Researchers got a head start on developing a vaccine because the virus that causes COVID-19 is similar to other existing viruses.
- Research about the new virus was shared almost immediately with scientists all over the world, which allowed work to begin on a vaccine right away.
- Some researchers were able to run [phase one and two trials at the same time](#).
- The studies on COVID-19 included a larger number of people than other recent vaccine trials, meaning there were a larger number of people in the trials over a shorter period of time.
- The federal government allowed manufacturing of the most promising vaccines to begin while the studies were ongoing. That means that when it is authorized it can be offered to the public almost immediately.

It's important to note that all vaccine developers are required to go through each stage of the development process and meet all safety and efficacy (how well something works) standards.

## **Who were in the clinical trials?**

Clinical trials for both vaccines that have been authorized for emergency use by the FDA included thousands of men and women representing a wide range

of ages from diverse racial and ethnic backgrounds and with varying degrees of health concerns.

Demographic breakdowns of clinical trial participants can be found here:

- [Moderna Vaccine](#)
- [Pfizer Vaccine](#)
- [Janssen/Johnson & Johnson Vaccine](#)

## **Did the clinical trials include people with comorbidities including diabetes or hypertension?**

Yes. Clinical trials for both vaccines included participants identified as having at least one condition that put them at increased risk of severe complications of COVID-19 including:

- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index  $\geq 30$  kg/m<sup>2</sup>)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

## **Do COVID-19 vaccines contain animal-based ingredients?**

No. The Moderna, Pfizer/BioNTech and Johnson & Johnson/Janssen COVID-19 vaccines contain no human or animal products, preservatives or adjuvants and utilize no ingredients of human or animal origin.

# **Availability**

## **When should I get the vaccine?**

As soon as it's available to you. The State Department of Health will continue to share information on where and when New Yorkers can get vaccinated as more vaccine doses become available.

## **Who gets the vaccine first?**

New York State began the vaccine distribution process by administering the COVID-19 vaccine in phases based on need and risk. New Yorkers who are more likely to be exposed to the virus, and who are more likely to become seriously ill if they get COVID-19, were offered the vaccine first. Both the federal government and New York State have developed plans to ensure that everyone will be able to get a COVID-19 vaccine as soon as large quantities are available, at no cost no matter where they live.

Currently, all individuals 12+ that reside in the United States are eligible for the vaccine.

## **Will there be more than one vaccine available?**

As of March 1, 2021, three vaccines have been authorized for emergency use by the FDA. More vaccines are expected.

As of December 9, 2020, four vaccines began Phase 3 clinical trials in the U.S.

Phase 3 trials are conducted with large numbers of people to study whether a vaccine is safe and how well it works.

## **How many times will I need to be vaccinated?**

Two of the vaccines currently authorized for emergency use in the U.S. by the FDA — the Pfizer/BioNTech and the Moderna — need two shots to be effective. The Janssen/Johnson & Johnson vaccine requires only one shot.

## **Is the vaccine free?**

Yes. The COVID-19 vaccines will be available at no cost.

## **Will I be required to get a vaccine?**

New York State is not mandating the COVID-19 vaccine.

## Eligibility and Scheduling

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## Are walk-ins accepted or do I need to have an appointment?

Walk-ins are accepted at all New York State-operated mass vaccination sites on a first-come-first-serve basis. You may also choose to schedule an appointment at a New York State operated vaccine site, which you can do by visiting [Am I Eligible](#) or by calling the NYS COVID-19 Vaccination Hotline at [1-833-697-4829](tel:1-833-697-4829). Walk-in policies may be different at other vaccination locations that are not operated by New York State, so it is always a good idea to find out in advance if you will need an appointment.

## What age group is eligible to receive the vaccine?

All individuals 12 years of age and older that reside in the United States are eligible to receive the vaccine. For individuals under the age of 18, the consent of a parent or legal guardian is required.

## I want to schedule an appointment but I am being told there are no appointments available. What should I do?

Due to limited supply from the federal government, it could take some time before you are able to schedule a vaccination appointment. As supply increases, there will be more appointments available. We encourage New Yorkers to be patient. To see available appointments at New York State operated sites, use [New York's scheduling tool](#). To find other appointments, including at locally run vaccination centers and pharmacies, visit [Vaccinefinder.org](https://www.vaccinefinder.org)

## **On the forms I fill out prior to receiving the vaccine, will there be a non-binary gender option?**

Forms generated and maintained by New York State and used at state and local health department vaccine administration sites will include a non-binary gender option.

## **Should I wear a mask when I get vaccinated?**

Yes. Please plan to bring and wear a mask or face covering when you go to get vaccinated.

## **The Am I Eligible pre-screening app says that I'm not eligible, but I believe that I am. What should I do?**

The Am I Eligible app — New York State's pre-screening tool — is not the final say whether or not someone will or will not receive the vaccine. If you believe you are in one of the [eligible categories](#) of New Yorkers, you can call the New York State COVID-19 Vaccination Hotline at 1- 1-833-NYS-4-VAX ([1-833-697-4829](#)), from 7am - 10pm, 7 days a week. After scheduling an appointment, all New Yorkers must complete the [New York State COVID-19 Vaccine Form](#) which includes a self-attestation under penalty of law that the individual is a member of a priority group eligible for vaccination.

## **If I am undocumented will my personal information be shared?**

New York will not transmit any data that could be used to identify the immigration status of any individual. This includes, but is not limited to, name and address. Any data shared will be done so in accordance with New York's robust laws protecting immigration status, and include only aggregated demographic data and dates of vaccine administration and doses. The CDC also agreed that use and access to any data shared from New York will not be shared with any other agency or entity for purposes not related to public health.

## **Can I bring someone to join me on site during my vaccination appointment?**

Yes. You can bring someone to accompany you if you need assistance or if you need someone for the purpose of vaccine consent, for example for a minor under the age of 18.

## **What is the difference between the Pfizer and the Moderna vaccine?**

Pfizer and Moderna vaccines are both “mRNA” vaccines and generate your body’s immunity in similar ways. Both vaccines have similar efficacy and side effects. The biggest difference is that the Pfizer vaccine is approved for those 16 years and older, while Moderna is approved for those 18 years and older.

## **Why am I being asked to bring insurance information? Does that mean I’ll be charged for the vaccine?**

No, there will never be a cost for you to get the vaccine, whether you have insurance or not. It is free. You may be asked to bring insurance information for administration reasons, but this is NOT because you will be charged for the vaccine.