

COVID-19 Vaccine Frequently Asked Questions



The Food & Drug Administration is currently reviewing two COVID-19 vaccines (Pfizer and Moderna) for use throughout the United States. While these vaccines will be an important tool to help stop this pandemic, it will take some time to produce enough to vaccinate everyone who is eligible to receive this medication. Initially, with limited quantities available, the vaccine will be distributed to those who live and work in nursing homes, frontline healthcare workers who work in high-risk areas, and other high-risk individuals. Below are common questions and answers related to the vaccine.

How was the vaccine developed and tested?

Before any vaccine can be approved for general use, it must go through a rigorous four phase process to assess its safety and effectiveness in different populations. The vaccine must meet intense safety criteria before completing each phase. Once a vaccine is approved safe for use after phase three, it has been tested on tens of thousands of people and shown to have no significant harmful side effects. Phase four involves continued monitoring and gathering of safety data. This process has been used for decades to approve medications and vaccines.

How do I know the COVID-19 vaccine is safe and effective?

Safety and efficacy are the most important requirements for the vaccine. While these vaccines are being developed as quickly as possible, stringent processes, procedures and standards set by the FDA for all other types of vaccines remain in place to ensure the public's safety. Before the FDA determines whether to approve a COVID-19 vaccine or authorize it for emergency use, it must be rigorously tested in large clinical trials by independent experts to make sure it meets strict safety standards and offers protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.

The current phase three trials have 30,000 to 50,000 participants, much more than is typically required, which demonstrates how safety is a top priority for the FDA and the medical community. After the FDA makes its determination, the Advisory Committee on Immunization Practices (ACIP), will review the data before making a final vaccine recommendation to the CDC. ACIP is an independent advisory board whose job is to monitor vaccines to ensure safety regardless of money, politics, etc. Once in use, the vaccine will continue to be studied under real-world conditions.

What are the FDA's requirements for the safety and efficacy of a COVID-19 vaccine?

The FDA requires 50% efficacy of a COVID-19 vaccine (the vaccines from Pfizer and Moderna have shown 94-95% efficacy in preventing COVID-19 disease during the trial phase) and eight weeks of safety data before it will consider approval of the vaccine.

Why should I get vaccinated?

No one knows for sure how COVID-19 will affect them or others. COVID-19 vaccines are being carefully evaluated and will only be approved if they make it substantially less likely you'll get COVID-19. Based on what we know about other vaccines, experts believe that getting a COVID-19 vaccine will

help keep you from getting seriously ill even if you do get COVID-19, and from infecting others, particularly people at increased risk. Getting vaccinated is one of the most selfless things you can do to protect yourself, your co-workers, our patients and residents, and your family and friends. The more people who get vaccinated, the greater chance we have at controlling this virus and returning to life as we knew it pre-COVID.

Can I get COVID-19 from the vaccine?

NO. You cannot get COVID-19 from the vaccine. None of the vaccines developed in the U.S. use the live virus that causes COVID-19. COVID-19 vaccines work by helping our bodies develop immunity to the virus without us having to get the illness. It typically takes a few weeks for the body to build immunity after vaccination. That means it's possible to become infected with the virus just before or just after you get vaccinated. That's why it's so important to continue to follow all safety precautions.

In some cases, a person may already have COVID-19 when they get vaccinated but are asymptomatic or pre-symptomatic. If they later have symptoms or test positive, it does not mean they got COVID from the vaccine. The goal of the vaccine is to teach your immune system to recognize and fight the virus. If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive for COVID-19 antibodies. Experts are currently looking at how vaccination may affect antibody test results.

What are some of the possible side effects of the COVID-19 vaccine?

Sometimes after vaccination, the process of building immunity can cause symptoms, such as a mild fever and other short-term discomfort (headache, muscle pains, fatigue, chills, and/or pain at injection site). These symptoms are normal and a sign the body is building immunity. Most clinical trial participants who experienced side effects, reported they went away after a day, sometimes sooner. When you receive the second dose of the vaccine, the discomfort may be more pronounced. This is a normal reaction.

If you experience discomfort after the first dose of the vaccine, it's critically important you still receive the second dose a few weeks later for the vaccine to be effective. This does not mean that the vaccine has given you COVID. Rather, it means that the vaccine is causing your body's immune system to create antibodies to fight off the virus. In other words, if you feel some discomfort, then the vaccine is doing its job!

If you experience any side effects, you should call Associate Health at 447-6481. The CDC is also implementing a smartphone-based tool called V-SAFE to check on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you will receive information on V-SAFE. If you enroll, you will get regular text messages and surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

When can I receive the vaccination?

Once the vaccine is available, New York State will prioritize vaccination-based risk factors, public health concerns, and the need to maintain essential services. Because of the limited numbers of vaccine that will be initially available, those living and working in nursing homes and essential

frontline workers will be the first to get vaccinated, followed by other high-risk individuals, the elderly, and those who live in areas with a high prevalence of COVID-19.

While the supply of COVID-19 vaccines will be limited before the end of 2020 and not everyone will be able to get vaccinated right away, quantities will continue to increase in the weeks and months that follow. The goal is for everyone to be able to easily get a COVID-19 vaccine as soon as large quantities are available. The plan is to have several thousand vaccination providers available, including doctors' offices, retail pharmacies, hospitals, and federally qualified health centers.

How will Catholic Health be distributing the vaccine?

Catholic Health's nursing home residents and staff will be vaccinated through a federal Pharmacy Partnership Program in conjunction with Walgreens Pharmacy. Walgreens will be administering the vaccine at Father Baker Manor, McAuley Residence, Mercy Nursing Facility at OLV and St. Catherine Laboure Healthcare Center and the St. Joseph Post-Acute Center.

All other associates and providers will receive the vaccine through a distribution plan established by Catholic Health using outlines developed by the CDC, the New York State Department of Health, and guidance from the Advisory Committee on Immunization Practices (ACIP). To create our vaccination plan, we have assembled a large, multidisciplinary team made of clinicians, logistic and operations specialists, IT leaders, health and safety specialists, HR representatives, Mission leaders, and others to work through the complex details of developing a safe, orderly, and ethical vaccination process for our entire system.

The process involves ordering, securing, storing, tracking, documenting, and preparing the vaccine for distribution, as well as setting up a process for administering the vaccine including dates, times, locations and staffing. Using regulatory compliance and ethical considerations as a guide, our system-wide distribution plan will rely on a tiered approach, administering the vaccine as it becomes available, first to our frontline staff working in high risk areas and then other associates along the risk scale. Because we don't know how much vaccine we will receive and when, it is difficult to estimate when the vaccines will be complete.

How long will the COVID-19 vaccine protect us?

More research is needed to determine how long the vaccine will protect us from COVID-19. The COVID-19 vaccine may be like getting a flu shot, where we need to get vaccinated on a regular basis. Scientists and doctors will continue to study this and how the virus changes in the coming months and years.

Do I still need to get vaccinated if I've already had COVID-19 and recovered?

Yes. 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, called natural immunity, varies from person-to-person, and may not last very long. Both natural immunity and vaccine-induced immunity are important aspects in fighting COVID-19.

Will I still need to wear a mask and avoid close contact with others after I receive a vaccine?

Yes. Even when people receive the vaccine they will not be immediately protected and others who have not been vaccinated are still at risk. While experts learn more about the protection the vaccine provides in real life conditions and whether it's possible for vaccinated people to still transmit the disease to others, it's important we continue to use **all the tools** available to help stop the spread of the virus, like wearing a mask, washing your hands often, and staying at least six feet away from others. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will determine when it is safe to stop wearing a mask.

Will the vaccine be mandated for healthcare workers?

It is unlikely the vaccine will be mandated for healthcare workers, but the best way to protect yourself, our patients and residents, and our community is to get as many people vaccinated as possible.

Can I decline the vaccine? If so, what PPE would I be required to wear and when?

Yes, you may decline the vaccine. PPE requirements will not change based on your vaccination status.

Are there any associates who will be excluded from getting vaccine?

At this time, the vaccine is not recommended for pregnant and breastfeeding woman.

Why are pregnant and breast feeding women excluded from the vaccine?

Pregnant and breastfeeding women were not studied in the original vaccine trials. There are planned and ongoing studies looking at the vaccine in pregnant and breastfeeding women to confirm the vaccine's safety and efficacy in this group as well.

What vaccine will Catholic Health be receiving?

It is likely Catholic Health will receive either the Pfizer or Moderna vaccine. Both require two doses for maximum effectiveness. The first shot starts building protection. A second shot is needed to get the most protection the vaccine has to offer. Both shots must be from the same manufacturer. They cannot be interchanged.

How is Catholic Health involved in the COVID-19 vaccination processes being discussed at the Federal and NYS levels?

Catholic Health has been participating in webinars and in communication with the CDC, the New York State Department of Health and the Healthcare Association of New York State (HANYNS), seeking and obtaining early guidance and clarification on directives in order to administer the vaccine as soon as we are able.

Where can I get more information on the COVID-19 Vaccine?

You may visit the CDC website at www.cdc.gov/coronavirus/2019-ncov/vaccines for more information.

Where can I go in Catholic Health if I have additional questions?

We have created an email address Covid19vaccine@chsbuffalo.org for you to leave additional questions. This FAQ sheet will be updated as more questions and answers become available.

December 11, 2020