

# EHHOP Newsletter

East Harlem Health Outreach Partnership

## Frequently Asked Questions About COVID-19 Vaccines

*From the Mount Sinai Hospital*

### *Is the Pfizer vaccine widely available?*

Not immediately. At first it will be in very limited supply and available to only certain groups of people. It will become available to some parts of the public sometime in early 2021.



### *How will vaccines be distributed?*

Any COVID-19 vaccine that receives an emergency use authorization will be in short supply initially. There won't be enough of it at first for everyone who wants to be vaccinated to get it. Public health authorities will recommend who should be offered each vaccine first. Mount Sinai expects to follow these recommendations and will not be able to make exceptions to them. A group of experts that advises the Centers for Disease Control and Prevention, called the Advisory Committee for Immunization Practices (ACIP), and the New York State Department of Health have both recommended that high-risk health care workers, and residents and staff of nursing homes and other long-term care facilities, be offered the vaccine first. We are waiting for additional guidance before we know exactly which groups of health care workers we can offer vaccines to first. As more vaccine is distributed, it will be offered to additional groups of people, including other essential workers and those who have high-risk medical conditions. After that, as still more vaccines become available, they will be offered to more people.

### *What is an Emergency Use Authorization?*

In the United States, vaccines must be approved by the Food and Drug Administration (FDA) before they can be used. The FDA bases its decision on data from clinical trials. In a clinical trial, the vaccine is given to volunteers—sometimes tens of thousands of them—while others get a placebo, meaning an injection that doesn't contain any vaccine. Scientists observe whether the people who got the vaccine get fewer cases of the disease than those who got the placebo. This means that the vaccine appears to work in those people; this is called the vaccine's "efficacy." The scientists also watch out for unexpected side effects that the vaccine might have caused. This is called the vaccine's "safety." If the clinical trial data shows enough evidence of efficacy and safety, the FDA will approve the vaccine and license it for use in the United States. Sometimes, the FDA will allow a medical product that has not yet been fully approved to be used in an emergency to diagnose, treat, or prevent a serious illness. This is called "emergency use authorization" or "EUA". An EUA may be issued when the FDA determines that the product "may be effective" against the disease based on all the available scientific evidence. This is a lower standard than required for full approval of a product; it uses early data gathered from clinical trials. More information on EUAs is available from the [FDA website](#).

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## *How do I know a vaccine is safe?*

The FDA reviews all vaccines for safety before allowing them onto the market. In New York State, the Governor's Clinical Advisory Task Force will also offer an independent opinion about each vaccine's safety and efficacy. This Task Force, which includes highly respected scientists like Adolfo García-Sastre, PhD, Irene and Dr. Arthur M. Fishberg Professor of Medicine at the Icahn School of Medicine at Mount Sinai, reviewed the data independently and unanimously recommended approval of the Pfizer vaccine on Thursday, December 10.

## *Will taking the vaccine give me COVID-19?*

No. Neither the Pfizer vaccine, nor any of the other vaccines in advanced clinical trials, can give you COVID-19.

## *Are we taking the federal government's word that a vaccine is safe?*

No. The [Advisory Committee for Immunization Practices \(ACIP\)](#), a group of medical and public health experts that advises the Centers for Disease Control and Prevention (CDC), also assesses the safety and efficacy of vaccines. They will also develop recommendations on COVID-19 vaccine use. Additionally, in New York State, the Governor's Clinical Advisory Task Force will independently review the vaccines as they are made available. According to the [Governor's plan](#), "The Task Force's independent review of any federally authorized COVID-19 vaccine will help address publicly reported concerns about the scientific process and rush to market. The Task Force will rely on numerous data sources including public information and the findings of expert third party independent organizations."

## *What do we know about the side effects of the first vaccines?*

Like all vaccines, the Pfizer COVID-19 vaccine can cause side effects. These rarely interfere with daily activities, and often go away with over-the-counter pain medications. It is common to have these types of side effects after a vaccination. They mean your immune system is working and making antibodies as it's supposed to. The following side effects to the Pfizer vaccine are very common, meaning that they may affect more than 1 in 10 people:

- Pain at injection site
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever

Other side effects, like enlarged lymph nodes, were uncommon, affecting up to 1 in 100 people. These are not all the possible side effects you may have when taking the vaccine. If you experience any side effects not listed here, tell your health care professional. Moderna has also released data that suggest their vaccine is safe. We're still waiting for complete data from their phase 3 clinical trials to know more about their side effects.

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## ***How many shots do I have to get if I want to be protected against COVID-19?***

Some of the vaccines that are being developed—including the Pfizer and Moderna vaccines—require two doses three to four weeks apart. It is very important that you get both doses at the recommended times. We do not yet know how long the protection from these vaccines will work. It is possible that you will need to get additional shots in the future.

## ***Should I take the vaccine if I am pregnant or considering pregnancy?***

We don't have enough information about the vaccines and pregnancy just yet. Pregnant people were not included in the clinical trials. Any participant who could have become pregnant was asked to use contraception (birth control) for at least 1-2 months after their second shot. If you are pregnant or are planning on becoming pregnant, we encourage you to talk to your OB/GYN about the vaccine. We are waiting for recommendations from the CDC's Advisory Committee on Immunization Practices and public health authorities on this topic, and will update our advice as soon as we can.

## ***Should I take the vaccine if I have severe allergies?***

There have been reported cases in the United Kingdom of people who had allergic reactions after getting the Pfizer vaccine. These cases are being reviewed. For now, we recommend that if you have a history of allergies that are severe enough to require you to carry an epinephrine auto-injector (EpiPen), please talk to your primary care provider before taking the vaccine.

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## ***If I already had COVID-19, should I get vaccinated?***

If you have had COVID-19 and recovered, it is still worthwhile to get a COVID-19 vaccine. While most people are protected from getting COVID-19 again after they've recovered, we don't know how long that protection lasts.

## ***If I get vaccinated, can I stop wearing masks and socially distancing?***

If you get a vaccine, you should still protect yourself by wearing a mask and social distancing. We don't know how effective the vaccine is going to be. It's possible, for example, that the vaccine will protect you from getting very sick with the virus, but it will not prevent you from spreading the virus to other people. Until we have a better idea of that and know how many people are going to receive it, you should still practice social distancing, wear a face mask, and wash your hands often and well. We're going to have to do all of this for a little while longer until we know more and until the pandemic is more under control.

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## *Do the clinical trials for COVID-19 vaccines include people from the most affected groups?*

Yes. While vaccines work the same in people of different races or ethnicities, it is important to make sure vaccines are tested in diverse population groups before they are released. The phase 3 clinical trials conducted by Pfizer and Moderna included significant numbers of participants from the population groups most at risk for COVID-19. In Pfizer's U.S. trial, 13.1 percent of participants are Hispanic/Latinx, 10.1 percent are Black, 5.5 percent are Asian American, and 1 percent are Native American. About 45 percent of U.S. participants are 56-85 years of age. For comparison, in the most recent estimates by the U.S. Census Bureau, 18.4 percent are Hispanic/Latinx, 12.8 percent are Black, 5.7 percent are Asian American, and 0.9 percent are Native American. The Census uses slightly different age groups than the drug companies, but says that 27.4% of Americans are between ages 55 and 84. Moderna did not report precise numbers for its trial, but said that of its 30,000 U.S. trial participants, more than 6,000 participants, or 20 percent, identify as Hispanic or Latinx, and more than 3,000 participants, or 10 percent, identify as Black or African American. Moderna also said that its trial included more than 7,000 Americans, or 23.3 percent, over the age of 65 (compared to 16.5 percent in the general population), and more than 5,000 Americans, or 16.7 percent, who are under age 65 but have high-risk chronic diseases, such as diabetes, severe obesity, and cardiac disease.

## *How well do the first vaccines work?*

The FDA reports that the vaccine made by Pfizer had an efficacy rate of 95 percent. That means that under the controlled conditions of the company's phase 3 trial there were 95 percent fewer cases of COVID-19 in the group of people who got the vaccine compared to the group of people who got the placebo. A second vaccine, made by Moderna, also has an efficacy rate of 94 to 95 percent, according to preliminary data released by the company. These are very high efficacy numbers, meaning the vaccines worked well in these trials. Under real-world conditions, the effectiveness of the vaccines may turn out to be different. But this data is very promising.

## *How do the COVID-19 vaccines work?*

Vaccines expose us to pieces of either a bacteria or a virus. Our body mounts an immune response by making antibodies against those pieces. Antibodies are proteins that fight germs like viruses and bacteria by latching onto and disabling them. The goal is that our body will then recognize those pieces and use the antibodies to fight off any future exposure to the real bacteria or virus. There are several different types of vaccines. Traditional vaccines include pieces of the virus in them. This causes your immune system to react by making antibodies against those pieces. The Pfizer and Moderna vaccines are called "messenger RNA" vaccines. They do not contain pieces or proteins from the virus. Instead, they contain instructions for your cells, called "messenger RNA." This messenger RNA tells your cells to make the COVID-19 spike protein themselves. Once your cells make the spike protein, your immune system will make the antibodies that fight COVID-19 and protect you from getting sick from this virus.

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## *What is “herd immunity” and when will we get there?*

Herd immunity means that enough people in a community are immune to a disease that the disease can't spread easily among them. That helps protect people who are not immune—for example, those who can't be vaccinated for some reason—from getting sick. In the case of COVID-19, we don't yet know how many people need to be vaccinated to reach herd immunity. But we are likely still far away from that point.

## *How do I know what vaccine information online is accurate?*

There is a lot of information on the internet about vaccines, and it can be difficult to know which sites to trust. Mount Sinai is providing a tool called [NewsGuard](#), which is a browser extension you can download that will help determine which information about vaccines and other health topics is accurate.

## *I've heard some really hard to believe things about COVID-19 vaccines. How can I find out if they're true?*

There are a lot of myths on the internet about COVID-19 vaccines. Mount Sinai is working with a company called NewsGuard to provide the most accurate information. If you've heard something that sounds questionable and want to know if it's true or not, you can look it up in NewsGuard's report on the [top COVID-19 vaccine myths](#).