How does the vaccine approval process work?

- 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 to approve or not approve a vaccine on data from clinical trials. The data is reviewed by independent experts who are not part of the government or the pharmaceutical companies, and by career scientists and physicians at the FDA who are not politically appointed and who are experts in vaccine safety and effectiveness.

- In a clinical trial, tens of thousands of people are sorted into two groups. One group receives the vaccine. The other group receives 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. If so, it means that the vaccine appears to work in those people. How well the vaccine works is called the vaccine’s “efficacy.”

- The scientists also watch out for unexpected side effects that the vaccine might have caused. This helps determine the vaccine’s “safety.” In general, the fewer and less severe the side effects are, the more the vaccine is considered safe.

- 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 Emergency Use Authorization (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 what’s required for full approval of a product, but it still uses early data gathered from clinical trials.

- A COVID-19 vaccine that receives approval or emergency use authorization from the FDA must also be reviewed by the Governor’s Clinical Advisory Task Force. This group will give an independent opinion on the safety and efficacy of each vaccine before it can be distributed in New York State.

- This group reviewed the data independently and unanimously recommended approval of the Pfizer vaccine on Thursday, December 10; the Moderna vaccine on Friday, December 18; and the Johnson & Johnson/Janssen vaccine on Monday, March 1.

- The Task Force has seven members, including 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.
What does this mean for me as a Mount Sinai employee?

- When a COVID-19 vaccine receives an emergency use authorization, it will take time to produce enough of it to offer it to everyone. Because of this, public health authorities will recommend who should be offered each vaccine first. We expect to follow these recommendations and will not be able to make exceptions to them.

- As of Tuesday, April 6, all Mount Sinai faculty, staff, trainees, and students who work or study onsite at any of our facilities are eligible for vaccination through Mount Sinai, as are all voluntary physicians and patient-facing staff members at voluntary practices. Employees working remotely who live in New York State and are 16 or over are also eligible to enroll on the waiting list for vaccination through Mount Sinai.

- We strongly encourage all Mount Sinai Health System faculty, staff, trainees, and students to get vaccinated as soon as they are eligible. However, at this time, it is not mandatory. That may change as the pandemic progresses—and as we get guidance from the federal, state and city governments—but for now, COVID-19 vaccination is not mandatory.

- Vaccination status will not affect your work assignment. We did not change any work assignments based on COVID-19 antibody status and will not do so based on whether or not you are vaccinated.

- When you get vaccinated, we will cover for you on your unit for the time that the vaccination appointment takes.

- The vaccines will be provided to employees at no cost.

- Some of the vaccines require two doses three to four weeks apart. It is very important that you get both doses to produce an effective number of antibodies. The Pfizer and Moderna vaccines both require two doses. The Johnson & Johnson vaccine requires only one dose.

Who should take COVID-19 vaccines, and what happens afterward?

- Pregnant and breastfeeding persons are encouraged to speak to their health care providers about the potential benefit of vaccination, especially if they are a health care worker or an essential worker, or have underlying medical conditions.

- You should not get the Pfizer, Moderna, or Johnson & Johnson COVID-19 vaccines if you have had a severe allergic reaction (i.e., anaphylaxis) to vaccines or the components of that vaccine. If you have a history of severe medication allergies, please discuss with your health care provider.

- 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 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 continue to 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.

• We don’t yet know how many people need to be vaccinated to reach “herd immunity.” 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.

**COVID-19 Vaccines: Safety and Efficacy**

• Taking these vaccines will not give you COVID-19. None of the COVID-19 vaccines that have received emergency use authorization or are in advanced clinical trials can give you COVID-19.

• The safety and efficacy of each vaccine will be analyzed by three separate groups before Mount Sinai offers them to our staff and patients:
  
  o The U.S. Food and Drug Administration (FDA)
  o 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)
  o The New York State Governor’s Clinical Advisory Task Force, which includes Mount Sinai virologist Adolfo Garcia-Sastre, PhD

• The FDA recommends that if a COVID-19 vaccine is made available, it has to have at least 50 percent efficacy. That means when you test the vaccine in clinical trials, the group of people who got the vaccine has at least 50 percent fewer cases of COVID-19 than the “placebo” group who didn't get the vaccine.

• The FDA reported on December 8 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.

• FDA scientists reported on December 15 that the Moderna vaccine had a similar efficacy rate to Pfizer’s, and that the vaccine’s efficacy rates were similar across genders, age groups, racial and ethnic groups, and groups with comorbidities.
The FDA reported on February 24 that the Johnson & Johnson vaccine had an efficacy rate at preventing moderate to severe COVID-19 of 66 percent worldwide, 72 percent in the United States, and 64 percent in South Africa where a new virus variant has become prevalent. This efficacy rate was similar for all major racial and ethnic groups and all age groups, but the efficacy dropped to 59 percent for groups with comorbidities.

According to the FDA, all three vaccines were nearly 100 percent efficacious at preventing hospitalization and death in the clinical trial populations. This may be the most significant finding of the clinical trials. It suggests that all of these vaccines can sharply reduce the severity of COVID-19 and ease the burden on hospitals.

These efficacy numbers are very high. Under real-world conditions, the effectiveness of the vaccines may turn out to be different. But these data are very promising.

FDA scientists report no significant safety concerns regarding the Pfizer, Moderna, or Johnson & Johnson vaccines.

Like all vaccines, the Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines 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 were common for all three vaccines:
  - Pain at injection site
  - Tiredness
  - Headache
  - Muscle pain
  - Chills
  - Joint pain
  - Fever

These are not all the possible side effects that you may have when taking the vaccine. If you experience any side effects not listed here, tell your health care professional.

More vaccines are in phase 3 trials. More results will be released over the next few months, and we will learn more about these vaccines’ efficacy, side effects, and safety. Because of this, what you hear and read in the news today, and what doctors, scientists, and public health authorities recommend today, may change in the months ahead.

Did the clinical trials for the COVID-19 vaccines include people from the groups most affected by COVID-19, especially Black, Latinx, and older people?

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, Moderna, and Johnson & Johnson 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.

- The FDA reported that 9.7 percent of the patients in Moderna’s trial identified as Black or African American, 20 percent as Hispanic/Latinx, 4.7 percent as Asian, and 0.8 percent as Native American. Also, 25.3 percent were over the age of 65 (compared to 16.5 percent in the general population), and 22.3 percent had at least one high-risk chronic disease, such as diabetes, severe obesity, and cardiac disease.

- In Johnson & Johnson’s worldwide trials, 59 percent of patients were white, 45 percent were Hispanic and/or Latinx, and 19 percent were Black or African American. In their trial in the United States, 74 percent were white, 15 percent Hispanic/Latinx, and 13 percent Black/African American. Forty-one percent of participants in the Johnson & Johnson study had health conditions associated with an increased risk for severe COVID-19.

**Background on Vaccines**

- 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.
The Johnson & Johnson vaccine also instructs your cells to make the COVID-19 spike protein themselves, but it delivers those instructions by using a harmless adenovirus, similar to a common cold virus, rather than using messenger RNA.