

COVID-19 Vaccine Update

December 14, 2020

Tested, safe, and effective COVID-19 vaccines will help us defeat the virus, get back in control of our lives, and back to the people and places we love.

Scientists had a head start. The vaccines were built upon years of work in developing vaccines for similar viruses.

Tested, safe, and effective. More than 70,000 people volunteered in clinical trials for two vaccines (Pfizer and Moderna) to see if they are safe and work to prevent COVID illness. To date, the vaccines are 95% effective in preventing COVID-19 with no safety concerns. The U.S. Food and Drug Administration (FDA) makes sure the vaccines are safe and can prevent people from getting COVID-19. Like all drugs, the FDA keeps monitoring safety.

There is no COVID in the vaccines—and there are no serious side effects. You may have temporary reactions like a sore arm, being tired, or feeling off for a day or two after receiving the vaccine.

Vaccines will be available to all—for free. Supplies will be limited at first, but you have a spot to take your shot. State and federal public health experts have recommended starting first with vaccinations for those most at risk. More people will be reached when vaccine supply increases throughout 2021.

VACCINE SAFETY

Are there vaccines that are safe and work in preventing COVID-19?

Yes. One from Pfizer has proven to prevent COIVD-19 illness with no safety concerns. It is 95% effective. Another from Moderna is 94.5% effective with no safety concerns, and it is waiting for the federal government to allow its use.

Who makes sure the vaccines are safe and can prevent COVID-19?

The U.S. Food and Drug Administration (FDA) makes sure all food and drugs are safe. The COVID-19 vaccines must pass clinical trials like other drugs and vaccines. The FDA checks the work and approves vaccines only if they are safe and effective. The FDA can get them to people faster through an Emergency Use Authorization. Like all vaccines, the FDA keeps checking safety through the <u>Vaccine Adverse Events Reporting System (VAERS)</u>. Healthcare providers are required to report serious side effects, or if someone gets seriously ill with COVID-19. There is also a smartphone-based health checker called <u>V-SAFE</u> that uses text messaging and web surveys to do health check-ins after people receive a COVID-19 vaccination.

VACCINE DEVELOPMENT and AUTHORIZATION

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) allows the FDA to get a safe COVID-19 vaccine to you quickly during a public health emergency. An independent advisory committee makes sure the vaccines are safe and work before issuing an EUA.

- Pfizer applied for an EUA on November 20, 2020, the advisory committee recommended authorization on December 10, 2020, and the EUA was approved Friday, December 11, 2020.
- Moderna applied for an EUA on November 30, 2020 and the advisory committee will meet on <u>December 17, 2020</u>.

The meetings are public. You can find out about them on the <u>FDA</u> website.

What happens after an EUA is issued?

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices decides who should be vaccinated to make sure the vaccine is safe and works for those who get it.

How do the Pfizer and Moderna vaccines work?

There is no COVID-19 in the vaccines. The Pfizer and Moderna vaccines give your body instructions to make a kind of protein. This protein safely tricks your body into thinking the virus is attacking. Your body then strengthens itself to fight off the real COVID-19 if it ever tries to attack you. Your body gets rid of the small protein naturally and quickly.

How can someone enroll in a clinical trial for a vaccine?

Over 100 vaccines for COVID-19 are under development, and many are in clinical trials that are recruiting participants. People interested in enrolling in a COVID-19 vaccine trial may visit the following website: https://www.coronaviruspreventionnetwork.org/clinical-study-locations/.

VACCINE SHIPPING AND STORAGE

How many vaccines will the state receive?

States will receive very limited supplies at first. The federal government decides how many COVID-19 vaccines each state gets based on the state's population.

How will the vaccine be shipped?

The federal government ships the vaccines and vaccination supply kits to states as soon as they are approved by the FDA and the CDC. For the Pfizer vaccine, 11 hospitals will get shipments after FDA authorization. After the CDC makes its recommendations, vaccines are shipped on dry ice to 42 more hospitals. These hospitals were chosen based on bed capacity, health care workers, and county population.

How will the vaccine be stored?

North Carolina is working closely with providers to safely store vaccines that need ultra-cold storage or frozen storage. Vaccines that need ultra-cold storage will come with packaging and cooling material for places that do not have permanent ultra-cold storage. The Moderna vaccine does not need ultra-cold storage. The state and CDC will deliver training on COVID-19 vaccine storage, handling, and administration.

GETTING VACCINATED

Who will be vaccinated first?

Public health experts say the best way to fight COVID-19 is to first start with vaccinations for those most at-risk, then reach more people as the vaccine supply increases from January 2021 to June 2021.

The first supply will go to a small number of hospitals to vaccinate health care workers at high risk of exposure to COVID-19, like doctors, nurses, and those cleaning areas used by COVID-19 patients. As more vaccines become available, more hospitals and local health departments will vaccinate high-risk health care workers. Hospitals will give vaccines to staff on different days in case they have temporary reactions that may prevent them from working for a day or two.

Long-term care staff and residents are also one of the first groups who will receive a vaccine. Giving vaccinations at nursing homes and most adult care homes and other long-term care settings is being managed by the federal government. However, the vaccines used in long-term care will come from North Carolina's supply.

We hope that by early 2021, health departments and community health centers will start vaccinating other adults with two or more chronic conditions that make them higher risk for getting COVID-19.

As more vaccines become available, vaccinations will be offered to everyone who wants one, including in clinics and drug stores, as well as at vaccination events in communities.

Are children able to get the vaccine?

Children will not receive vaccines until clinical trials are completed to ensure the vaccines are safe and work to prevent COVID illness in children. The Pfizer vaccine can be given to teenagers 16 years old and up now, and they are doing additional studies with children 12 and over.

How will staff and residents in long-term care facilities be vaccinated?

The federal government manages vaccinations for most staff and residents of long-term care facilities. Long-term care facilities include skilled nursing facilities and adult care homes. The federal government has created the Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens to work with long-term care facilities to give vaccinations. They will likely begin vaccinating staff and residents once the Moderna vaccine is authorized.

Are there side effects from the vaccines?

No serious side effects have been reported. But people have reported temporary reactions like sore arms, tiredness, and feeling off for a day or two after receiving the vaccine. These temporary reactions were more common after the second vaccine dose.

Why are two vaccine shots necessary?

The Pfizer and Moderna vaccines require two shots a set number of days apart. You need two doses to build up strong immunity against COVID. The second shot will come about 3-4 weeks after the first. It is important to get two doses of the same vaccine.

If two shots are necessary, how will people know when to get their second shot?

North Carolina will use a secure data system called the COVID-19 Vaccine Management System (CVMS) to make sure you are safe and get your second shot at the right time. When a person gets the first shot, they get information on when to come back for the second and they are asked to make a second appointment. People will also be given a card with information about which vaccine they got for their first dose and the date of that shot. They will receive an email notification with reminders for the second shot. The provider who gave the vaccine may also help with reminders for the second one. State and federal privacy laws make sure none of your private information will be shared. The shot you take and when you need the second is confidential health information that is carefully managed to protect your privacy.

How much will the vaccines cost?

There is no cost. They are free to everyone, even if you don't have health insurance. The federal government is covering the cost.

Do people who have had COVID-19 still need to be vaccinated?

Yes, and it is safe to get vaccinated with the Pfizer vaccine if you have been infected in the past. The vaccine works to protect you against a future infection. You don't need a COVID test before vaccination.

Will people who have been vaccinated still need to wear a mask and avoid close contact with others?

Yes. Everyone should continue using the 3 Ws—wearing a mask, waiting 6 feet apart, washing your hands, and limiting gatherings—until most people are vaccinated. Receiving the COVID-19 shot and following the 3 Ws is everyone's best protection from getting and spreading COVID-19.

Will people who have been vaccinated still need to be quarantined?

Experts are still deciding on whether people who are vaccinated still need to be quarantined if they have been in close contact with someone who has COVID-19.

Should pregnant women be vaccinated?

Pregnant and breastfeeding women may choose to receive the Pfizer COVID vaccine. Pregnant women should talk with their doctors before making the choice. You do not need to take a pregnancy test before you get your vaccine. Women who are breastfeeding may also choose to get vaccinated. The vaccine is not thought to be a risk to a baby who is breastfeeding.

What is the risk of an allergic reaction from the vaccine?

People who have had severe allergic reactions, also called anaphylaxis, to any ingredient in the Pfizer vaccine should not receive that vaccine. People who have had this type of severe allergic reaction to any vaccine or treatment that is injected should not receive the Pfizer vaccine at this time. Vaccine providers will watch patients for 15-30 minutes after vaccination to ensure the patient's safety.

Will I need to sign a consent form to get vaccinated?

No, it is not required for COVID vaccination here in North Carolina.

Does the state require or mandate vaccination?

No. North Carolina has no plan to require people to be vaccinated against COVID-19. It is possible that some employers or schools will require vaccines for their employees or students.

What kind of identification will be required to be vaccinated?

North Carolina does not require an identification card, like a driver's license, to be vaccinated. Some employers could request ID when limited vaccine has to be prioritized, but it is not required.

For how long will the vaccine protect me from COVID?

Since the Pfizer trial just ended, we know that it can protect people from COVID illness for at least two months. We'll know even more about how long the immunity from the vaccine lasts as people have been vaccinated for a longer period of time.

VACCINE DATA

How will the state know who has been vaccinated?

North Carolina will use the COVID-19 Vaccine Management System (CVMS), a free, secure, web-based system provided to all who give COVID-19 vaccinations. It helps vaccine providers know who has been vaccinated with which vaccine to make sure people get the second dose of the same vaccine at the right time. It also helps people register for vaccination at the appropriate time and allows the state to manage vaccine supply. Pharmacies, such as CVS and Walgreens doing vaccinations in long-term care facilities, will not use CVMS to give and manage vaccines. These pharmacies will use their own systems. Your information on vaccination is confidential health information that is carefully managed to protect your privacy. Information will not be shared except in accordance with state and federal law. Any personal information will be taken out prior to sending public health information to the Centers for Disease Control and Prevention (CDC).

What data about vaccinations will be available to the public?

North Carolina will have an online public dashboard to share data on vaccinations. We plan to begin sharing data on vaccinations on December 22. The data in the dashboard will be updated weekly.