NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

COVID-19 Vaccine Update

November 18, 2020

COVID-19 vaccines will help us defeat this virus and get back to the people and places we love. Vaccines imitate an infection, so that our bodies think a germ, like a virus, is attacking and make antibodies that we need to fight if the real germ attacks.

Multiple vaccines for COVID-19 are being developed. Vaccines being tested on thousands of volunteers across the country and globe. These phases are designed to answer questions like:

- Is the vaccine safe?
- Are there any serious side effects?
- What are the most common side effects?
- Is the vaccine effective in preventing illness?

Promising vaccines are being manufactured at the same time they are being tested, so there will be an initial supply ready to go right away when the science shows which vaccines are found to be safe and effective. Once we have a vaccine or vaccines, it will still be some time before it is widely available to everyone. States will receive limited supplies at the start.

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

Yes. As of November 18, 2020, there are two vaccines that are at the end of the last phase of testing in clinical trials with promising results. One is from Pfizer and one from Moderna.

	Pfizer Vaccine	Moderna Vaccine
Preliminary Efficacy Data	• Press release on November 18 reported the final analysis of the Phase 3 trial of Pfizer's COVID-19 vaccine revealed that it is 95% effective in preventing infections –and did not cause any serious safety concerns • The phase 3 trial included over 43,000 participants, 42% with diverse backgrounds.	• Press release on November 16 with preliminary findings of 94.5% effectiveness in preventing illness. The phase 3 trial included 30,000 adult participants, 37% with diverse backgrounds.
Temperature/ Storage	• Requires ultra-cold storage (-75 degrees Celsius). Lasts up to 5 days at refrigerated temperatures	• Requires storage at -20 degrees Celsius (similar to the chickenpox vaccine). Lasts up to 30 days at refrigerated temperatures.
Dosing	• 2-dose schedule, administered 21 days apart.	• 2-dose schedule, administered 28 days apart.
Type of Vaccine	• Both vaccines use mRNA technology from the coronavirus's own genes to trigger people's immune system to produce antibodies against the COVID virus. mRNA vaccines can be made faster than older vaccines and require frozen storage to remain stable	
Safety	• Neither vaccine has had any serious safety concerns in the clinical trials	

Who has to verify that the vaccines are safe and can prevent COVID-19?

The Food and Drug Administration. They can authorize the use of a vaccine under an Emergency Use Authorization.

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) is issued by the Food and Drug Administration (FDA) during a public health emergency to allow the use of new medical products, such as a vaccine, more quickly. An EUA requires the submission of data that demonstrates a vaccine's safety and that it can prevent disease. Before issuing an EUA for a COVID-19 vaccine an independent advisory committee will review the vaccine testing data. This meeting is open to the public. Information about any upcoming meetings is posted by the FDA.

What happens after an EUA is issued?

The Center for Disease Control and Prevention's Advisory Committee on Immunization Practices will review the data and recommend who should be vaccinated based on clinical trial results. For example, it may recommend that a vaccine only be used for a certain age group based on the results of the clinical trials.

How much vaccine will the state receive?

The federal government will determine the number of COVID-19 vaccines each state or jurisdiction will receive initially. The amount of vaccine sent to states will change over time based on who should be vaccinated first , COVID-19 vaccine production and availability, and the size of the state's population. It is expected that more vaccine will become available as time goes on.

How will the vaccine be shipped?

The federal government is coordinating the shipment of the vaccines and vaccination supply kits (e.g., needles, masks) to states. It is possible that vaccines will be shipped to states as soon as they receive FDA authorization so that states have supplies ready once the Advisory Committee on Immunization Practices says which populations can receive the vaccine.

How will the vaccine be stored?

North Carolina is prepared to receive vaccines that require ultra-cold storage or frozen storage as soon as they become available from the federal government. Healthcare systems and other providers with ultra-cold storage have been identified across the state. Vaccine that requires ultra-cold storage will come with packaging and cooling material to meet the storage requirements.

Who will give vaccines?

North Carolina vaccine providers are being enrolled into the COVID-19 Vaccination program based on their ability to reach priority populations. Priority populations include people who are at-risk of exposure (e.g., health care workers) or are at high risk of severe COVID illness. The state will deliver training on COVID-19 vaccine storage, handling, and administration based on federal recommendations and product information from vaccine manufacturers. People will be vaccinated by health care providers in hospitals, clinics, and pharmacies as well as at vaccination events in prioritized settings and in the community.

Will vaccines be tracked? Why?

Many of the vaccines, including the Pfizer and Moderna vaccine, require two doses given a set number of days apart. It is important to know when a person received the first dose of vaccine and which vaccine to ensure they receive the second dose of the same vaccine at the right time. This information is a protected health information. North Carolina will be using a secure data system to track the vaccine called the COVID-19 Vaccine Management System (CVMS).

How much will the vaccines cost?

The COVID-19 vaccine will be available to everyone for free, no matter whether you have health insurance. The federal government will be purchasing the vaccines.