NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

COVID-19 Vaccine Update

December 2, 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 are 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 very limited supplies at the start.

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

Yes. As of November 30, 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.

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. The advisory group's purpose is to provide an independent review of vaccine trials. It has no ties to any company, political administration or individual. Advisory group meetings are open to the public. Information about upcoming meetings is posted by the FDA. Pfizer applied for an EUA on November 20, 2020, and the advisory committee will meet on December 10, 2020. Moderna applied for an EUA on November 30, 2020, and the advisory committee will meet on December 17, 2020.

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. The amount of vaccine sent to states will be based on the size of the state's population. Once a vaccine is authorized for use by the FDA, states will receive very limited supplies at first.

Who will be vaccinated first?

To help determine who should get the vaccine first, the North Carolina Institute of Medicine convened an independent COVID Vaccine Advisory Committee. The North Carolina prioritization plan is based on their guidance along with guidance from the National Academy of Medicine on equitable distribution of vaccine and the CDC's Advisory Committee on Immunization Practice. The prioritization plan is based on risk of exposure to and severe illness with COVID-19.

States will receive very limited vaccine supplies at first. Therefore, the initial supply of vaccines will go to a limited number of hospitals to vaccinate health care workers at high risk of exposure to COVID-19 – those who are caring for or cleaning areas used by patients with COVID-19. Because of the limited initial vaccine supply, not all hospitals will receive vaccine initially. As more vaccine becomes available, it will be distributed to more of the state's hospitals and to our local health departments to focus on vaccinating high risk health care workers.

Additionally, long-term care staff and residents are prioritized to receive vaccine. Vaccinations at nursing homes, adult care homes and other long-term care settings are being managed by the federal government. However, the vaccines used in long-term care will come from the state's allotment.

We hope by early 2021 that health departments and community health centers will start vaccinating other adults who are high risk for complications, meaning they have two or more chronic conditions identified by the CDC to increase the risk for severe illness with COVID, and who are at higher risk for exposure. Eventually as more vaccine becomes available, vaccinations will be offered in a variety of settings, including in clinics and pharmacies as well as at vaccination events in prioritized settings and in the community.

Children will not be able to receive vaccine initially as more clinical trials with children are needed to determine safety and effectiveness

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. 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. Eleven hospital sites across the state have been identified that have the greatest capacity for ultra-cold storage for the anticipated Pfizer vaccine. Vaccine that requires ultra-cold storage will come with packaging and cooling material to meet the storage requirements for sites that do not have permanent ultra-cold storage. The state and CDC will deliver training on COVID-19 vaccine storage, handling, and administration based on federal recommendations and product information from vaccine manufacturers.

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

Vaccinations for most staff and residents of skilled nursing facilities and adult care homes are being managed by the federal government, however, those doses will come from the state's allotment. he federal government, in

coordination with the CDC, has created the Pharmacy Partnership for Long-Term Care Program in partnership with CVS and Walgreens to vaccinate people in these long-term settings. These pharmacies will work directly with long-term care facilities to provide vaccines separate from the vaccination efforts being coordinated by the state.

Are there side effects from the vaccines?

We will have more information on the side effects from the Pfizer and Moderna vaccines when the findings from the clinical trials become available. So far, no serious side effects have been reported. However, people have reported side effects like sore arms, fevers, and tiredness 24-48 hours after the vaccine. As a result, vaccinations in prioritized settings, such as hospitals and long-term care facilities may be staggered.

How will people know when to get their second shot?

Many of the vaccines, including the Pfizer, Moderna, and AstraZeneca 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 they received 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 manage vaccines called the COVID-19 Vaccine Management System (CVMS). When a person gets a first dose, they will be given information on when to come back for a second dose and asked to make a second appointment. They will also be given a card with information about which vaccine they got for their first dose and the date of that dose.

How much will the vaccines cost?

The COVID-19 vaccine will be available to everyone for free, no matter whether you have health insurance or not. The federal government will be purchasing the vaccines.

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	Pfizer Vaccine	Moderna Vaccine	Astra-Zeneca 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 and November 30 with preliminary findings of 94.5% effectiveness in preventing illness. • The phase 3 trial included 30,000 adult participants, 37% with diverse backgrounds.	• Press release on November 23 with preliminary findings of 62-90% effectiveness in preventing COVID-19 illness depending on the dosing regimen. The data from the trials included over 22,000 adult participants.
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.	• Requires refrigerated storage at 2 to 8 degrees Celsius. Lasts at least 6 months at refrigerated temperatures.
Dosing	• 2-dose schedule, administered 21 days apart.	• 2-dose schedule, administered 28 days apart.	• 2-dose schedule, administered at least 1 month apart
Type of Vaccine	• The Pfizer and Moderna 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 require frozen storage to remain stable		• Vaccine uses another virus to carry COVID genes into the cells to trigger people's immune system to produce antibodies against the COVID virus.
Safety	• Neither vaccine has had any serious safety concerns in the clinical trials		• No serious safety events related to the vaccine have been confirmed. • A serious inflammatory condition in one participant paused global trials in September. FDA authorized restarting the US trial on October 23.