NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

COVID-19 Vaccine Update

December **, 2020

Safe, effective COVID-19 vaccines will be available soon to help us defeat this virus, get back in control of our lives and back to the people and places we love.

Although the vaccines were developed quickly, they were built upon years of work in developing vaccines for similar viruses. Development time was cut without cutting corners.

More than 70,000 people participated in clinical trials for two vaccines to see if they are safe and effective. To date, the vaccines are nearly 95% effective in preventing COVID-19 with no safety concerns.

There is no COVID-19 virus in the vaccine. The vaccine imitates the infection so that our bodies think a germ like the virus is attacking. This creates the antibody defenses we need to fight off COVID-19 if and when the real germ attacks.

Some people may have temporary reactions after being vaccinated, such as swelling from the injection, tiredness or feeling off for a day or two.

A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. Independent state and federal public health advisory groups have determined that the best way to fight COVID-19 is to start first with vaccinations for those most at risk, then reach more people as the vaccine supply increases throughout 2021.

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. Reports so far indicate , the Pfizer vaccine is 95% effective and the Moderna vaccine is 94.5% effective in preventing COVID-19 with no safety concerns.

Who verifies that the vaccines are safe and can prevent COVID-19?

The U.S. Food and Drug Administration (FDA) is responsible for making sure the vaccines are safe and effective. While the COVID-19 vaccines must go through and pass clinical trials like other drugs and vaccines, the FDA can get them to the public faster through an Emergency Use Authorization, as long as the vaccines are found to be safe and effective— and then verified by an independent committee.

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) is issued by the FDA during a public health emergency to allow for the use of new medical products, such as a vaccine, more quickly—but only if research data proves that a vaccine is safe and that it can prevent disease.

An independent advisory committee reviews the vaccine testing data before issuing an EUA for a COVID-19 vaccine. The advisory group has no ties to any company, political administration or individual, and its meetings and findings 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 (CDC) Advisory Committee on Immunization Practices will review the data and recommend who should be vaccinated based on clinical trial results. This ensures that the vaccine is safe and effective for those who get it.

How much vaccine will the state receive?

Once a vaccine is authorized for use by the FDA, states will receive very limited supplies, at first. The federal government will determine the number of COVID-19 vaccines each state will receive. The amount of vaccine sent to states will be based on the size of the state's population.

Who will be vaccinated first?

Independent state and federal public health advisory groups have determined that 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 initial supply of vaccines will go to a small 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 initially receive vaccines. 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.

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 are 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 who are high risk for complications—meaning they have two or more chronic conditions identified by the CDC that make them higher risk for exposure.

As more vaccine becomes available, vaccinations will be offered in a variety of settings to everyone who wants one, including in clinics and pharmacies, as well as at vaccination events in prioritized settings and in the community.

While clinical trials have shown safety and effectiveness for adults, children will not receive vaccines until clinical trials with children are completed to ensure safety and effectiveness.

How will the vaccine be shipped?

The federal government is coordinating the shipment of the vaccines and vaccination supply kits to states. Vaccines will be shipped to states as soon as they receive FDA authorization so that states have supplies ready once the CDC Advisory Committee on Immunization Practices recommends who should receive the vaccine.

How will the vaccine be stored?

We have a plan to store the vaccines safely, so they can be effective. 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. Vaccines that require 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 Moderna vaccine does not require 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?

The federal government is managing vaccinations for most staff and residents of long-term care facilities, however, those doses will come from the state's allotment. Long-term care facilities include skilled nursing facilities, adult care homes, family care homes, group homes and intermediate care facilities for individuals with intellectual disabilities. The federal government, in coordination with the CDC, has created the Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens to vaccinate people in these 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?

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

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

The Pfizer, Moderna and AstraZeneca vaccines 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. The shot you take, and when you need the second dose, is health information that is carefully managed to protect your privacy. North Carolina will use a secure data system called the COVID-19 Vaccine Management System (CVMS) to manage vaccinations. 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, whether or not you have health insurance. The federal government will be purchasing the vaccines.

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

Until we have a vaccine available, the FDA releases information as part of the EUA, and the Advisory Committee on Immunization Practices makes recommendations on how to best use COVID-19 vaccines, the CDC cannot comment on whether people who had COVID-19 should get a vaccine. We don't know enough to say if having had COVID-19 creates natural immunity or how long that may last. Early data suggests that natural immunity from COVID-19 may not last very long, but more studies are needed to better understand.

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

Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using all the tools available to us to help stop this pandemic, like the 3 Ws - wearing a mask, waiting 6 feet apart, washing your hands - , and limiting gatherings. Receiving the COVID-19 vaccination and following the 3 Ws will offer the best protection from getting and spreading COVID-19.

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

Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on whether people who are vaccinated still need to be quarantined if they have been in close contact with someone who has COVID-19.