COVID-19 Vaccines in Tribal Communities

Several vaccines are currently undergoing clinical trials and two vaccines - Pfizer/BioNTech mRNA vaccine and the Moderna mRNA vaccine received Emergency Use Authorization (EUA) by the Federal Drug Administration (FDA) in December 2020.

There are at least 10 different vaccines currently in Phase III clinical trials. This means that the vaccines have shown promise in preliminary studies and are now being tested in controlled trials with voluntary participants across a wide variety of communities.

Some Native Americans have participated in these clinical trials, though they make up a very small percentage of total participants. It is extremely important to ensure that the vaccines are safe and effective among Native peoples, in order to reduce the burden of disease. Data have shown that Native Americans and other minority populations have been disproportionately impacted by COVID-19 disease, and it is essential that the vaccines are effective among Native populations. The role of Native American participants in clinical vaccine trials is extremely important.

Vaccine Trial Approval Processes in Tribal Communities

The process for approving vaccines will vary depending on the community. There are typically two layers of consent standard in research within Native Nations: 1) Community consent, and 2) Individual participant consent. Study staff are trained in research ethics to ensure that the community is informed about and approves of the study, and that all participants understand the risks and benefits of the study and that participation is voluntary.

Ensuring the Safety of COVID-19 Vaccines

The clinical trial process, which all vaccines must go through, is very thorough and ensures that only safe and effective vaccines are licensed for use. The COVID-19 vaccine development has occurred at a more rapid pace than typical for vaccine development, due to a large amount of funding from the government, research, and private organizations.

Maintaining Safety, Avoiding Delays

No steps in the clinical trials are being skipped, but for the sake of time some steps have been completed at the same time.

All vaccines in clinical trials will still be required to complete all phases of testing before they can be approved for use.

Normally there is a delay between the time when a vaccine is approved and when it can become available for use. Due to the urgency of COVID-19, the federal government has approved manufacture of doses of leading vaccine candidates currently being tested in clinical trials. These vaccines will only begin to be distributed after receiving the EUA. If a vaccine does not get approved by the FDA, it will not be distributed or used.

Warp Speed

Warp Speed is an effort led by the US government to support the rapid development of safe and effective vaccines, treatments, and tests to help fight COVID-19. One main goal is to have hundreds of millions of doses of a safe and effective vaccine ready for use in 2021. Warp Speed efforts also include development of better testing and treatment for COVID-19. Coordinated efforts and high investment will increase the speed of development without lowering safety standards.

Who will Receive the Vaccine First?

Supply of vaccines will be limited at first, but more vaccines will be available throughout 2021. Tribal governments are prioritizing specific groups of individuals to offer the limited doses of vaccine, including:

- People with underlying health conditions that put them at a heightened risk for COVID-19 disease.
- People with essential or high-risk community roles, such as healthcare workers or those working in nursing homes, police officers, and teachers.

At first, COVID-19 Vaccines May Not Be Available for Children

Vaccine trials do not currently include children younger than 12, so use of the vaccine is not recommended for young children, though this could change in the future.

COVID-19 Vaccines Will Be Available at No Cost to the Public

Doses of vaccine will be purchased with US taxpayer dollars and will be given to the public at no cost. Healthcare providers may still charge a fee for providing the shot, but most public and private insurance companies will cover the fee so that there is no cost. For individuals without health insurance, the government has created a fund to cover these fees.
How Do Vaccines Protect against COVID-19?
Vaccines work to prevent disease by training our bodies to recognize and fight off germs, including viruses. After getting a vaccine, our bodies start to produce antibodies which are specialized proteins that stick to and help fight germs, such as viruses. Vaccines cannot cause disease in the body.

The COVID-19 vaccines in development are mRNA vaccines. mRNA vaccines are a new approach to vaccines. They use the code that tells our cells which proteins to build. The mRNA vaccine for COVID-19 tells our body how to build a protein that is found on the surface of the coronavirus, called the spike protein. This triggers our body to start producing antibodies that target the spike protein which then protect us when we get infected with the real virus. No pieces of the real virus are contained in the vaccine. The vaccine cannot cause you to get sick with COVID-19.

Emergency Use Authorization (EUA) and the COVID-19 Vaccine
Emergency Use Authorizations (EUAs) allow the FDA to make a product or drug available in an emergency, as long as there are some data to show that it is safe and effective. The requirements for an EUA are:

- A public health threat exists
- There is reason to believe that the product will be effective in diagnosing, preventing, or treating the illness
- The known or potential benefits outweigh the risks
- There are no adequate, approved, or available alternatives

History of EUAs in the United States
The authority to grant EUAs dates back to federal laws passed in 1938 and to the Project BioShield Act of 2004, which was a part of bioterrorism preparedness activities following 9/11. The first EUAs were granted in response to a pandemic influenza in 2009 that included an EUA for the use of oseltamivir (Tamiflu) in infants.

The FDA has granted EUAs for products related to diagnostic tests, personal protective equipment, medical devices, drugs, and biological products (like convalescent plasma) in response to COVID-19.

FDA has Specific Requirements for EUAs related to COVID-19 Vaccines
The FDA released specific guidance on the EUA process for both of the currently-available COVID-19 vaccines, including a minimum efficacy of 50% (which both vaccines have substantially exceeded) and a minimum length of follow-up of trial participants to make sure the vaccine is safe. The FDA also requires that the vaccine companies provide data on the production, manufacturing process, quality controls, and supply chain for the vaccine.

For more information: CDC.gov/coronavirus

Effective January 19, 2021
Source: Centers for Disease Control