Overview of COVID-19 Vaccines

Which Vaccines are Currently Available in the US?

Three vaccines are currently available in the US: Pfizer/BioNTech mRNA vaccine, the Moderna mRNA vaccine, and the Johnson & Johnson viral vector vaccine received Emergency Use Authorization (EUA) by the Federal Drug Administration (FDA). Several other vaccines are currently undergoing clinical trials, but are not yet available to the public.

As of February 27, there are two additional vaccines currently in Phase III clinical trials in the United States. This means that the vaccines, which were shown to be safe and effective in previous clinical trials, are now further being tested in controlled trials with large numbers of 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 within Native communities. 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; because of the Native Americans who volunteered to be in the vaccine clinical trials we know that the COVID-19 vaccine is safe and effective to use within Native communities.

Vaccine Trial Approval Processes in Tribal Communities

The Vaccine approval process varies 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 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 developmen 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 stacked (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. This way, the vaccines can be distributed immediately upon receiving the FDA approval. 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 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 have have the opportunity to offer doses of the vaccine to specific individuals based on priority, 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.**
- **Native language speakers or traditional and cultural practitioners**

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 are Available at No Cost to the Public

Doses of vaccines will be purchased with US taxpayer dollars and are given to the public at no cost, though healthcare providers may still charge a fee for providing a shot. Most public and private insurance companies will cover that fee so that there is no cost, and individuals without health insurance will still be able to get COVID-19 vaccines at no cost.

How Do Vaccines Protect against COVID-19?

Vaccines work to prevent disease by creating immune protection in our bodies. After getting a vaccine, our bodies start to produce antibodies which are specialized proteins that stick to and help fight germs, such as viruses. The COVID-19 vaccines cannot give a person COVID-19.

Two of the methods currently being used in vaccines are an RNA vaccine and an mRNA vaccine. The RNA vaccines are made from lab-made pieces copied from SARS-CoV-2, not the actual virus. This type of vaccine is simpler and quicker to make, and so they could be produced faster than other types of vaccines. mRNA vaccines are a relatively new approach to vaccines, but they have been ressearched for decades. They use the code that tells our cells which proteins to make, and the mRNA vaccine builds the outer spike protein of the coronavirus so that the body reacts to the protein to create antibodies. No pieces of the real virus are contained in the vaccine.

The Johnson & Johnson vaccine is a viral vector vaccine. Viral vector vaccines use a modified version of a different, harmless virus to deliver important instructions to our cells. This allows our body to produce tools needed to fight 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 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 devises, 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 COVID-19 vaccines, including a minimum efficacy of 50% (which both vaccines have substantially exceeded) and a minimum period of safety follow-up after submission. The FDA also requires that the vaccine companies provide data on the production, manufacturing process, quality controls, and supply chain for the vaccine.

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For more information:
CDC.gov/coronavirus

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