Texas COVID-19 Vaccine Information Statement

TEXAS
Health and Human Services
Texas Department of State Health Services

1. Benefits and risks associated with COVID-19 vaccination

COVID-19 vaccine can prevent COVID-19 disease. Vaccination can help reduce the severity of COVID-19 disease if you get sick.

People who are up to date with COVID-19 vaccination have a lower risk of severe illness, hospitalization, and death from COVID-19 than people who are not up to date. COVID-19 vaccination helps prevent Long COVID – which is a chronic condition that occurs after SARS-CoV-2 infection, can include a wide range of ongoing symptoms, and can last for weeks, months, or even years.

Getting a COVID-19 vaccine helps the body learn how to defend itself from the disease and reduces the risk for severe illness and complications. Additionally, COVID-19 vaccines can offer added protection to people who have already had COVID-19, including protection against being hospitalized if they become infected with COVID-19 again.

Pain, swelling, and redness where the shot is given, fever, tiredness (fatigue), headache, chills, muscle pain, joint pain, nausea, vomiting, and swollen lymph nodes can happen after COVID-19 vaccination.

To date, Centers for Disease Control and Prevention (CDC) has evaluated at least 65 specific safety outcomes, conducted data mining of >60,000 potential outcomes for unexpected concerns, investigated numerous signals and conducted many epidemiological studies. Safety surveillance has identified and characterized the risk of myocarditis after COVID-19 vaccination. No other risks have been confirmed in the current U.S. COVID-19licensed vaccine except those seen with other vaccines (e.g., local and systemic reactions, allergic reactions). CDC, the U.S. Food and Drug Administration (FDA), and vaccine manufacturers continues to monitor the safety of COVID-19 vaccines.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. These risks have been observed most frequently in adolescent and young adult males. The chance of this occurring is low. The FDA has required COVID-19 manufacturers to include this in the “Warning and Precautions” section of their COVID-19 vaccine package insert.

Seek medical attention right away if the vaccinated person experiences chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after COVID-19 vaccination. These could be symptoms of myocarditis or pericarditis. As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

Tell your vaccination provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of COVID-19 vaccine or has any severe, life-threatening allergies
- Has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside of the heart)
- Has had multisystem inflammatory syndrome (called MIS-C in children and MIS-A in adults)

In some cases, your health care provider may decide to postpone COVID-19 vaccination until a future visit or recommend not receiving the vaccine.

People sometime faint after medical procedures, including vaccination.

2. Expedited manner in which COVID-19 vaccine was developed

In December 2020, the FDA issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech and Moderna COVID-19 vaccines. The EUA authority allows the FDA to help strengthen the nation’s public health protections against chemical, biological, radiological, and nuclear threats including infectious diseases, by facilitating the availability and use of medical countermeasures needed during public health emergencies.

Vaccine development and FDA approval (licensure) are a multi-stage process and can take many years, even decades. For details of the process, see How Vaccines are Developed and Approved for Use | Vaccines & Immunizations | CDC and Development & Approval Process (CBER) | FDA. The EUA process is an expedited process, by conducting several stages in parallel, with oversight from the FDA providing safety and efficacy checks.

The FDA issued a *Guidance to Industry – Emergency Use Authorization for Vaccines to Prevent COVID-19* document providing recommendations regarding information and data to be included in a request for an EUA for a COVID-19 vaccine. This document was updated periodically throughout the COVID-19 public health emergency.

Placebo-controlled clinical trials were conducted in over fifteen-thousand participants for each of the COVID-19 vaccines that received EUAs. Several of these vaccines that were initially under EUA are now fully licensed by the FDA. These are Comirnaty®, Spikevax® and Nuvaxovid®.

3. Long-term studies on COVID-19 vaccine

Since 2020, COVID-19 vaccine development has many collaborations among multiple manufacturers and in multiple countries. Safety and effectiveness of the vaccines continue to be monitored and studied by federal agencies (FDA and Centers for Disease Control and Prevention - CDC) and the manufacturers.

It is estimated that approximately 1 billion doses of COVID-19 vaccine doses have been distributed in the U.S. and over 13 billion doses have been administered worldwide.

In reviewing nearly 600 studies on safety of COVID-19 vaccines, the National Academies of Sciences, Engineering and Medicine concluded that evidence supports a causal association between mRNA COVID-19 vaccines and myocarditis. Additional studies are ongoing.

4. Civil liability status of vaccine manufacturers for vaccine-related injuries

U.S. Code Title 42 CHAPTER 6A, SUBCHAPTER XIX, Part 2, subpart b: No vaccine manufacturer shall be liable in a civil action for damages arising from vaccine injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit the program's website at Countermeasures Injury Compensation Program (CICP) | HRSA, or call 1-855-266-2427

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at National Vaccine Injury Compensation Program | HRSA or call 1-800-338-2382 to learn about the program and about filing a claim.

5. Federal Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in vaccines used in the United States. VAERS accepts and analyzes reports of adverse events (AEs) after a person has received a vaccination.

Health care providers are strongly encouraged to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors, whether or not associated with an adverse event

Anyone can report to VAERS. VAERS accepts reports from anyone. Patients, parents, caregivers and healthcare providers are encouraged to report adverse events after vaccination to VAERS even if it is not clear that the vaccine caused the adverse event. Adverse reactions should be reported to VAERS online by visiting the VAERS website at Vaccine Adverse Event Reporting System (VAERS) or call 1-800-822-7967.