COVID-19 Vaccine Reporting Systems

Updated June 19, 2022

Hundreds of millions of people in the United States have safely received COVID-19 vaccinations. These vaccines have undergone the most intensive safety monitoring in U.S. history that includes both established and new safety monitoring systems.

Results from monitoring show that while some people don't have side effects after getting a COVID-19 vaccine, many people have mild side effects, like pain or swelling at the injection site, headache, chills, or fever. These reactions are normal signs that your body is building protection. COVID-19 vaccines are effective at protecting you from getting sick. CDC recommends COVID-19 vaccines for everyone ages 6 months and older, and boosters for everyone 5 years and older, if eligible.

Safety of COVID-19 Vaccines

The U.S. Food and Drug Administration (FDA) has fully approved the use of the Pfizer-BioNTech COVID-19 vaccine in people ages 16 years and older and has authorized its emergency use for children 6 months to 15 years. The FDA has fully approved the use of Moderna COVID-19 vaccine in people 18 years and older and has authorized its emergency use for children 6 months to 5 years. The FDA has granted Emergency Use Authorizations (EUA) for Johnson & Johnson's Janssen COVID-19 vaccine for people ages 18 years and older.

The Pfizer-BioNTech, Moderna, and J&J/Janssen vaccines were shown to be safe and effective in clinical trials. The trials showed that the known and potential risks and benefits of COVID-19 vaccines outweigh the known and potential risks of becoming infected with COVID-19. Learn more in this video about EUAs.

All COVID-19 vaccines currently authorized or recommended for use in the United States are safe and effective. However, CDC recommends that people who are starting their vaccine series or getting a booster dose get either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). The mRNA vaccines are preferred over Johnson & Johnson's Janssen COVID-19 vaccine in most circumstances. Although mRNA vaccines are preferred, the J&J/Janssen COVID-19 vaccine may be considered in some situations.

COVID-19 Vaccine Effectiveness Research

Before the U.S. Food and Drug Administration (FDA) approves a vaccine or authorizes a vaccine for emergency use, clinical trials are conducted to determine vaccine effectiveness.

After FDA approves a vaccine or authorizes a vaccine for emergency use, CDC and other federal partners continue to assess the vaccine to determine how well it works under real-world conditions.

Such evaluations will help us understand if vaccines are performing as expected outside the more controlled setting of a clinical trial. As vaccine uptake increases nationally, we also try to understand how well the vaccines:

- Perform in specific subpopulations
- Reduce the risk of infection (including infection without symptoms)

- Protect against milder COVID-19 illness
- Prevent more serious outcomes, including hospitalization
- Prevent spread of illness (whether people who have been vaccinated can still spread COVID-19 to others)
- Provide long-term protection (assess duration of protection)
- Protect against changes in the virus (new variants)
- Protect against COVID-19 after the first dose of a 2-dose vaccine because the second dose is sometimes delayed

Several factors can affect real-world vaccine effectiveness, including:

- Population host factors (people not included in clinical trials who may respond differently to the vaccine)
- Virus factors (variants)
- Programmatic factors (adherence to dosing schedules or storage/handling of vaccines)

CDC uses several methods to study all of these factors, as they can all contribute different information about how a vaccine is working.

Vaccine Safety Monitoring

After a vaccine is authorized or approved for use, vaccine safety surveillance systems monitor adverse events and watch for potential safety problems. This continued monitoring can identify adverse events that may not have been seen in clinical trials. If an unexpected adverse event is seen, experts quickly study it further to assess whether it is a true safety concern. Experts then decide whether changes are needed in U.S. vaccine recommendations or clinical guidance. This monitoring is critical to help ensure that the benefits continue to outweigh the risks for people who receive vaccines.

FDA's COVID-19 Vaccines website also includes important recommendations for ongoing safety evaluation after any COVID-19 vaccine is made available under EUA.

CDC has expanded safety surveillance through new systems and additional information sources, as well as by scaling up existing safety monitoring systems.

Expanded Safety Monitoring Systems

The following systems and information sources add an additional layer of safety monitoring, giving CDC and FDA the ability to evaluate COVID-19 vaccine safety in real time and make sure COVID-19 vaccines are as safe as possible:

- CDC v-safe— A smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. **V-safe** uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19 vaccination. **V-safe** also provides second vaccine dose reminders if needed, and telephone follow-ups to anyone who reports medically-attended adverse events. Participants can enroll in **v-safe** after any dose of vaccine, and parents and guardians can enroll on behalf of their children.
- V-safe COVID-19 Vaccine Pregnancy Registry — A registry to collect health information from people enrolled in **v-safe** who receive COVID-19 vaccines shortly before or during pregnancy. This voluntary program helps CDC monitor the safety of COVID-19 vaccines in people who are pregnant.

Existing Safety Monitoring Systems

As people get vaccinated, CDC, FDA, and other federal partners will use the following existing, robust systems and data sources to conduct ongoing safety monitoring:

General public

- CDC & FDA Vaccine Adverse Event Reporting System (VAERS) — The national system that accepts reports from healthcare professionals, vaccine manufacturers, and the public of adverse events that happen after vaccination; reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are further assessed

further assessed.

- CDC Vaccine Safety Datalink (VSD)— A network of nine integrated healthcare organizations across the United States that conducts active surveillance and research using electronic health records; the system is also used to help determine whether possible side effects identified using VAERS are actually related to vaccination.
- CDC Clinical Immunization Safety Assessment (CISA) Project— A collaboration between CDC and seven medical research centers to provide expert consultation on individual cases, assist with vaccine safety surveillance, and conduct clinical research studies about vaccine safety.
- FDA and the Centers for Medicare and Medicaid Services — A claims-based system for active surveillance and research.
- FDA Biologics Effectiveness and Safety System (BEST) — A system of electronic health record, administrative, and claims-based data for active surveillance and research.

Members of the military

- Department of Defense (DOD) VAERS data — Spontaneous adverse event reporting to VAERS for the DOD population.
- DOD Vaccine Adverse Event Clinical System (VAECS) — A system for case tracking and evaluation of adverse events following immunization in DOD and DOD-affiliated populations.
- DOD Electronic Health Record and Defense Medical Surveillance System — Large, linked electronic health records (AHLTA/MHS GENESIS) and administrative data systems for near real-time safety monitoring and research.

Veterans

- Department of Veterans Affairs (VA) Adverse Drug Event Reporting System (VA ADERS) — A national reporting system for adverse events following receipt of drugs and immunizations.
- VA Electronic Health Record and Active Surveillance System — A system of electronic health record and administrative data for active surveillance and research.

Tribal nations

Indian Health Service (IHS) Vaccine Safety Monitoring Systems

Passive Surveillance

- Vaccine Adverse Event Reporting System (VAERS)
  - VAERS functionality permits analysis of adverse events (AE) in IHS system of care
- IHS Safety Tracking & Response System
  - Federal and participating tribal sites
  - Worker-related AEs and vaccine administration errors

Active Surveillance

- IHS Sentinel Survey
  - Biweekly survey of AEs, including vaccine administration errors
  - 58 federal and tribal sites representing IHS Areas
  - Supports reporting to VAERS

Related Pages

› Allergic Reactions after Getting a COVID-19 Vaccine

› Safety of COVID-19 Vaccines

› Developing COVID-19 Vaccines

More Information

CDC's Vaccine Safety Information

Ensuring the Safety of Vaccines in the United States

ACIP Work Groups

COVID-19 Vaccine Safety Publications

Last Updated June 19, 2022