COVID-19 Vaccine Reporting Systems

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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.

We know COVID-19 vaccines are safe and effective because of our monitoring systems.

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 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.
- 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

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