Coronavirus Disease 2019 (COVID-19)

Ensuring the Safety of COVID-19 Vaccines in the United States

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The U.S. vaccine safety system ensures that all vaccines are as safe as possible. Safety is a top priority while federal partners work to make a coronavirus disease 2019 (COVID-19) vaccine(s) available.

Clinical Trials

Currently, clinical trials are evaluating investigational COVID-19 vaccines in many thousands of study participants to generate scientific data and other information for the Food and Drug Administration (FDA) to determine their safety and effectiveness. These clinical trials are being conducted according to the rigorous standards set forth by FDA in their June 2020 guidance document, Development and Licensure of Vaccines to Prevent COVID-19 . If FDA determines that a vaccine meets its safety and effectiveness standards, it can make these vaccines available for use in the United States by approval or emergency use authorization.

After FDA makes its determination, the Advisory Committee on Immunization Practices (ACIP) will review available data before making vaccine recommendations to CDC. Learn more about how CDC is making COVID-19 vaccine recommendations.

Vaccine Safety Monitoring

After a vaccine is authorized or approved for use, many vaccine safety monitoring systems watch for adverse events (possible side effects). This continued monitoring can pick up on 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. This monitoring is critical to help ensure that the benefits continue to outweigh the risks for people who receive vaccines.

FDA's June 2020 guidance document also includes important recommendations for ongoing safety evaluation after any COVID-19 vaccine is made available in the United States.

CDC is working to expand 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** [644 KB, 21 pages] — A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. The system also will provide telephone follow up to anyone who reports medically significant (important) adverse events.
- **CDC: National Healthcare Safety Network (NHSN)** — An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS
- **FDA: Other large insurer/payer databases** — A system of administrative and claims-based data for surveillance and research

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 and FDA**: **Vaccine Adverse Event Reporting System (VAERS)** — The national system that collects 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 followed up with specific studies
- **CDC: Vaccine Safety Datalink (VSD)** — A network of 9 integrated healthcare organizations across the United States that conducts active surveillance and research; 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 7 medical research centers to provide expert consultation on individual cases and conduct clinical research studies about vaccine safety
- **FDA and the Centers for Medicare and Medicaid Services: Medicare data** — 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
- **FDA: Sentinel Initiative** — A system of electronic health record, administrative, and claims-based data for active surveillance and research

Members of the military

- **Department of Defense (DOD): DOD VAERS data** — Adverse event reporting to VAERS for the DOD populations
- **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: DOD Electronic Health Record and Defense Medical Surveillance System** — A system of electronic health record and administrative data for active surveillance and research

Veterans

- **Department of Veterans Affairs (VA): 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): IHS VAERS data** — Spontaneous adverse event reporting to VAERS for populations served by IHS and Tribal facilities

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CDC's Vaccine Safety Information

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