Q+A: Understanding Vaccine Post-Approval Safety Systems

CVEEP
Fighting Infectious Respiratory Disease

In the U.S., long-standing vaccine safety systems are in place to ensure that vaccine safety is closely monitored at every step, even after a vaccine is approved. These systems include multi-stage clinical trials, ongoing safety studies, regulatory review while a vaccine is being developed, and continuous safety monitoring once a vaccine becomes publicly available. Post-approval monitoring ensures that the vaccine's benefits continue to outweigh any risks and back up demonstrated safety that was seen during clinical trials.

Who monitors vaccines for safety in the U.S.?[1]

Government agencies within the Department of Health and Human Services (HHS), in collaboration with independent health systems and academic researchers, play a key role in ensuring vaccine safety. These agencies include teams of public health experts, physicians, epidemiologists, and researchers. Following the Food and Drug Administration (FDA) approval and once the vaccine becomes available to the public, the Centers for Disease Control and Prevention (CDC), in collaboration with the FDA, monitors its safety through ongoing surveillance.

What systems are in place to make sure vaccines are safe after they become available to the public?

The CDC and FDA both continuously monitor the safety of vaccines through four systems that all work together.[2]

1 Vaccine Adverse Event Reporting System (VAERS)[3]

- VAERS, co-managed by the CDC and FDA, collects reports of possible adverse events—or side effects—after vaccination. VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report, and all reports are accepted and reviewed—no matter how serious the event was or whether it is clear that the event was caused by the vaccine.
- A report to VAERS does not mean that a vaccine caused an adverse event. VAERS is not designed to determine if a vaccine caused a health problem but is especially useful for detecting unusual patterns of adverse events that might indicate a possible safety problem with a vaccine.
- Data collected include: The type of vaccine received, the date of vaccination, when the adverse event began, current illnesses and medications, medical history, history of adverse events following vaccination, and demographic information.
- VAERS is used to assess the safety of newly licensed or authorized vaccines, detect new, unusual, or rare adverse events, monitor increases in known mild side effects, identify potential patient risk factors, recognize administration errors, watch for patterns in adverse event reporting, and serve as the vaccine monitoring system during emergencies.

2 V-safe[4]

- V-safe, run by the CDC, sends you confidential check-ins via text message or email to ask how you feel after vaccination. Even if you don't experience symptoms, completing the check in helps the CDC monitor vaccine safety.
- This system was launched in 2020 to monitor the safety of COVID-19 vaccines and expanded to include RSV vaccines.
- You can participate in V-safe by signing up within 42 days of getting a COVID-19 or RSV vaccine.[5]

Information from these safety monitoring systems is regularly shared with other federal agencies, healthcare providers, vaccine manufacturers, and the public. Below are links to publicly available data for two of these monitoring systems:

VAERS data

V-safe data

3 The Vaccine Safety Datalink (VSD)[6]

- VSD, managed by the CDC, was established in 1990 and uses electronic health record data from participating vaccination sites to detect adverse events in near-real time.
- VSD uses data about the type of vaccine given, the date of the vaccination, other vaccinations given on the same day, and illnesses diagnosed at the healthcare facility to continuously evaluate the safety of vaccines.
- Researchers analyze health record data from member healthcare organizations gathered through weekly rapid cycle analysis to determine if the rates of adverse events following a specific vaccine are higher than the rates of adverse events in a comparison group.

4 The Clinical Immunization Safety Assessment (CISA) Project[7]

- CISA, run by the CDC, is a network of vaccine safety experts from the CDC, research centers, and other partners.
- CISA goes beyond general monitoring to conduct in-depth clinical evaluations of rare or complex adverse events at the individual patient level and provides consultations for healthcare providers with complex vaccine safety questions.
- CISA experts also conduct clinical research studies to better understand vaccine safety and to find preventive strategies for adverse events following immunization.

Why are vaccines monitored for safety after they are approved and recommended?

Like any other medical product, vaccines can have side effects. Most side effects from vaccines are mild, like pain or swelling where the vaccine was given. In some rare cases, side effects can be severe, such as allergic reactions. Ongoing safety monitoring helps the CDC and FDA keep track of reported side effects, notify the public about these side effects, and if needed, remove a product from the market. Robust safety monitoring has strengthened overall vaccine safety in the U.S., leading to improved vaccine production and administration, as well as fewer reported side effects.[8]

Vaccines are thoroughly tested and continuously monitored.
Stay up to date to protect yourself from severe respiratory illness.

[1] https://www.cdc.gov/vaccine-safety-systems/about/monitoring.html
[2] https://www.cdc.gov/vaccine-safety-systems/about/cdc-monitoring-program.html
[3] https://www.cdc.gov/vaccine-safety-systems/vaers/index.html
[4] https://www.cdc.gov/vaccine-safety-systems/v-safe/index.html
[5] https://www.cdc.gov/vaccine-safety-systems/v-safe/access-use.html
[6] https://www.cdc.gov/vaccine-safety-systems/vsd/index.html
[7] https://www.cdc.gov/vaccine-safety-systems/hcp/cisa/index.html
[8] https://www.cdc.gov/vaccine-safety-systems/about/monitoring.html

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