Congressional Research Service
Informing the legislative debate since 1914

INSIGHT

The Vaccine Adverse Events Reporting System: Understanding the Data

January 16, 2025

In general, vaccines undergo rigorous testing for safety through clinical trials before they are licensed (i.e., approved) or authorized for use by the Food and Drug Administration (FDA). These trials, which can involve thousands of patients, are designed to identify any major safety concerns with the vaccines. FDA licenses vaccines if they are determined safe for their intended use. Once a vaccine is on the market, federal agencies monitor vaccine safety through complementary systems such as the Vaccine Adverse Events Reporting System (VAERS) to help identify any rare or new safety issues that occur.

VAERS is a monitoring system for reported adverse events following vaccination jointly operated by FDA and the Centers for Disease Control and Prevention (CDC). An "adverse event" is any health problem that happens after a vaccination. Using the VAERS system, anyone—including clinicians and the general public—can submit a report of an adverse event following vaccination. Under federal laws and regulations, health care providers and vaccine manufacturers are required to report certain adverse events that occur following vaccination. For Coronavirus Disease 2019 (COVID-19) vaccines, there have been additional VAERS reporting requirements through FDA and CDC that changed over time.

CDC makes data on initial VAERS reports publicly available through its WONDER database. This CRS Insight provides an overview of how to understand publicly available VAERS data, its limitations, and the evidence usually required to determine whether a vaccine *caused* or contributed to a certain adverse health event.

Understanding VAERS Data

CDC and FDA monitor VAERS reports and use the information to determine whether to conduct further studies and investigations on the reported cases. VAERS serves as an early warning system to help detect possible new safety issues with vaccines, providing some of the earliest information on potential safety issues with newly introduced vaccines.

VAERS is a passive reporting system, meaning it relies on individuals to send reports. VAERS is not designed to determine if a vaccine *caused* a specific adverse health event. Instead, VAERS is meant for detecting unusual or unexpected patterns of adverse event reporting that might indicate a potential safety problem with a vaccine that warrants further investigation. CDC and FDA can follow up on reported

Congressional Research Service
https://crsreports.congress.gov
IN12486

cases to gain further information and can use other vaccine safety monitoring systems, such as the Vaccine Safety Datalink or the Clinical Immunization Safety Assessment project, to further investigate potential issues first detected through VAERS. CDC and FDA provide information on potential adverse events to health care providers and the public.

Why VAERS Data Alone Cannot Determine if a Vaccine Caused a Specific Adverse Health Event

Sometimes vaccination coincides with a subsequent serious adverse health event and then results in a report to VAERS. Without rigorous further study, it is not possible to determine if the vaccine *caused* the adverse health event, or that the vaccine somehow contributed (e.g., through improper administration) to the outcome.

Establishing causation often involves establishing statistical *association* at a population level as one step. Determining statistical association between a certain type of vaccine and a subsequent adverse health event requires additional information that is not available in the public VAERS database:

- **Total actual cases of a specific adverse health event that occurred following vaccination:** As mentioned, VAERS relies on user-submitted reports, which means the data are inherently incomplete. Not all people who experience a specific adverse health event following vaccination report to VAERS, especially for minor events (e.g., fever, soreness). In addition, the publicly available data include only the initial report, rather than any follow-up information used in CDC and FDA reviews. Therefore, the information in the public VAERS database may not provide a complete or verified picture. Rigorous studies often rely on actual medical diagnoses or other validated information rather than submitted reports.
- **The total population that received the vaccine:** While the VAERS database includes data on the total number of reported adverse health events that followed receipt of a certain vaccine type, it does not include information on the total population that received the vaccine. Information regarding how many people received the vaccine is necessary to determine the *rates* or the proportion of the vaccinated population that experienced the adverse health event. CDC generally does not collect data on the actual total U.S. population that received any specific vaccine, except for COVID-19 vaccines where enhanced reporting requirements were in place. (CDC uses data from its national immunization survey to *estimate* population-level vaccination rates.)
- **The normal or "background" rates of the adverse health event in the population:** In order to determine if the rates of an adverse health event are higher than usual following vaccination, information on the normal rates or "background rates" of the adverse health event in the general population is needed. This information is not available in the VAERS public database.

CDC studies usually combine VAERS data (validated after case review) with other data to explore associations between certain vaccines and adverse health events. These studies are generally intended to be viewed alongside other evidence and note any limitations for interpreting results.

Establishing a causal relationship between a certain vaccine and a subsequent adverse health event generally requires many forms of evidence. Federal agencies have previously commissioned independent vaccine safety reviews that assess the totality of available evidence on recommended vaccines, for example, a review in 2012 that was augmented in 2014 and 2021. A review for COVID-19 vaccines was published in 2024. These reviews can involve two kinds of studies: (1) evidence of statistical associations between vaccination and specific adverse health events in the population and (2) mechanistic

evidence—such as from laboratory research, medical records, or clinical research with patients—that explore potential relationships between vaccination and subsequent adverse health events. For these reviews, expert panels compile and assess available studies to determine whether the totality of high-quality evidence indicates a causal relationship between a specific vaccine and a certain adverse health event. These reviews have found some conclusive evidence of very rare safety issues associated with specific vaccines. For some potential rare adverse events linked to vaccines, the expert panels lacked sufficient evidence to draw conclusions about causality; studying rare safety issues with vaccines is methodologically difficult.

Author Information

Kavya Sekar
Analyst in Health Policy

Disclaimer