



IMA Public Health Committee - January 10, 2022

Understanding the Vaccine Adverse Event Reporting System (VAERS)

- The Vaccine Adverse Event Reporting System (VAERS) was developed by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) in 1990.
- VAERS was developed to get post-vaccine data from across the country to monitor for rare safety concerns. More common safety concerns are found in clinical trials. However, if a trial studies 40,000 vaccine doses, for example, and a safety event occurs once every 100,000 doses, then the event may not occur in the study. Thus, VAERS allows for continued safety oversight of any vaccine.
- Post-vaccine information may be entered in the VAERS national repository by anyone, including health care providers, vaccine manufacturers, patients, and their families.
- Often the information entered is incomplete and is usually not validated. Vaccine safety experts validate the data when there is a serious event reported. To validate the information, the expert must obtain the medical records and review them to see if the event was likely caused by the vaccine or an unrelated event.
 - For example, if a reported death was from an allergic reaction immediately after vaccination, that death would be determined to be caused by the vaccine. If the death was from a car accident following the vaccine, that death would not be attributed to the vaccine. If a death were from a heart attack, that would be noted for further analysis.
- A common misconception about VAERS is that the high number of reported deaths were *caused* by vaccines. Keep in mind that given the U.S. population of 330 million people, thousands of people are born each day and thousands die every day. In 2017, prior to the pandemic, on average 7,708 American deaths occurred every day.
- For deaths among those who received the COVID-19 vaccine, it is important to note that those people tended to be older and were disproportionately people with underlying medical conditions and their deaths were statistically likely whether vaccinated or not.
- The number of deaths reported to VAERS is *less* than the number expected and the FDA and CDC's review of these deaths has determined that almost all these deaths were unrelated to COVID-19 vaccines.
- 496 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through December 20, 2021. During this time, VAERS received 10,688 reports of death (0.0022%) among people who received a COVID-19 vaccine.
- In reviewing [data from over ten million people](#), comparing vaccinated versus unvaccinated mortality rates, those vaccinated had about 30% the mortality rate of those that were unvaccinated.

Today, the FDA and CDC use several tools to evaluate vaccine safety. VAERS is just one of the tools. The [CDC does not just depend on VAERS](#) to monitor for vaccine safety. V-safe is a new smartphone-based voluntary health check tool. The v-safe program now also has a pregnancy monitoring registry. In addition, the [Vaccine Safety Datalink](#) has been in place since 1990 and is a collaboration between the CDC and nine large health care organizations. The [CISA project](#) is a collaboration between the CDC and seven medical research centers.