Vaccine manufacturers and vaccine administrators are required to report to VAERS any adverse event following COVID-19 vaccination that involved hospitalization, prolongation of existing hospitalization, life-threatening illness, permanent disability, congenital deformity, or death. These reports were required to be submitted whether or not the adverse event was believed to be related to the vaccination. These mandatory requirements proved highly successful as in 2021, VAERS received over a million reports of adverse events compared to approximately 50,000 reports received in previous years. However, because these reports are required to be submitted regardless of the plausibility of the vaccine causing the event, not all of the reports involve an outcome caused by the vaccine. Also, vaccine recipients, parents and caregivers are encouraged to submit reports to VAERS. Most adverse events reported are not categorized as serious. The most commonly reported adverse events include headache, fevers and pain at the site of infection.

The robust reporting to VAERS related to the COVID-19 vaccines makes an analysis of events using raw numbers in comparison to previous years unreliable. A more suitable analysis is to use the reporting rate for particular adverse event in VAERS and compare it to the background rate in the general population. While this calculation has limitations as well, it was used successfully to identify several safety signals related to COVID-19 vaccines, including Guillain Barre Syndrome (GBS), thrombosis with thrombocytopenia (TTS) following the Janssen COVID-19 vaccine, and myocarditis and anaphylaxis following the Pfizer-BioNTech and Moderna COVID-19 vaccines. Information on selected adverse events after COVID-19 vaccines are available here.

Additional Background on VAERS:

VAERS (consisting of safety reports submitted by healthcare providers, patients, parents and other members of the public) serves as the nation's established "early warning" system for post licensure vaccine safety for both routine immunizations and COVID-19 vaccines by providing public health professionals with valuable information to assess possible safety concerns. This data is especially useful for rapidly detecting unusual or unexpected patterns of adverse event (AE) reporting that might signal a possible safety problem with a vaccine. Some of the limitations of VAERS include the lack of a control group - and reports may contain inaccurate or incomplete data. Thus, VAERS is not designed to assess causality, but rather for hypothesis testing. If VAERS monitoring identifies a potential safety signal, additional scientifically rigorous active surveillance studies or investigations can be conducted through BEST (Biologics Effectiveness and Safety) and the CMS (Center for Medicare and Medicaid) systems. The CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) Project can also be utilized for this purpose as well.