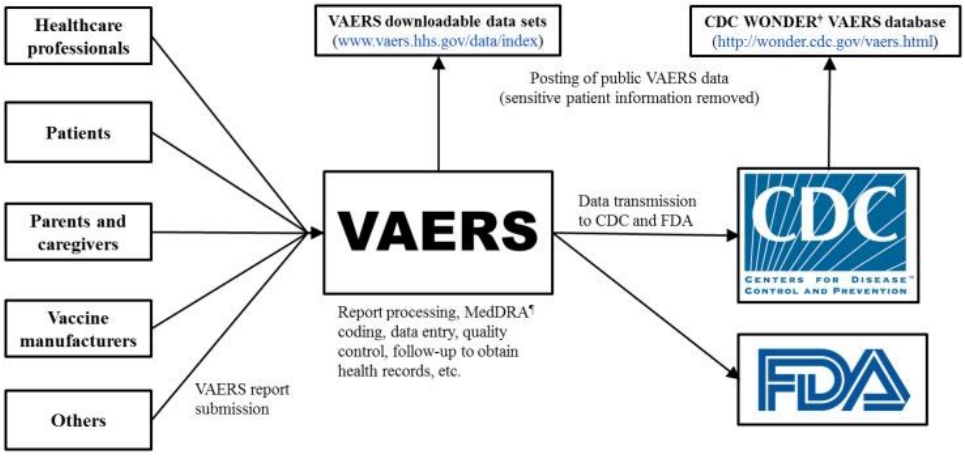
VAERS Safety Signals
Should Not Be Ignored

VAERS OBJECTIVES

- Detect new or unusual vaccine adverse reactions
- Monitor increases in known adverse events
- Identify potential patient risk factors for particular adverse events
- Identify specific vaccine lots associated with increased numbers or types of adverse events
- Assess the safety of newly licensed vaccines

The information collected by VAERS can quickly provide an early warning of a potential safety problem with a vaccine. Patterns of adverse events, or an unusually high number of adverse events reported after a particular vaccine, are called “signals.” If a signal is identified through VAERS, scientist may conduct further studies to find out if the signal represents an actual risk.

CDC states that all recipients should report adverse events to VAERS. This also listed on the back of COVID vaccination card. This is to flag safety signals to the CDC. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/



86% of vaccine injuries/deaths are reported by health care professionals, vaccine manufacturers and entities, only 14% are by the victims themselves.

https://publications.aap.org/aapnews/news/14631

CDC credits VAERS system for providing the safety signals to recall Rotavirus vaccine in 1999. One of the earliest successes in signal detection and assessment in VAERS involved the first rotavirus vaccine, RotaShield®.

Within nine months of its licensure in the United States in August 1998, reports to VAERS raised suspicion of a possible safety problem with intussusception, a type of bowel obstruction, in infants.[1]

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Given the known underreporting of adverse events to VAERS, these findings were concerning enough for CDC to suspend its recommendation for RotaShield® vaccination and initiate further investigation[2]; shortly thereafter the vaccine was withdrawn from the market by the manufacturer[3]. More recently, VAERS detected disproportional reporting for febrile seizures in young children following an inactivated influenza vaccine during the 2010-2011 influenza season[4,5].

**All VAERS reports are kept confidential as required by law. A patient's consent is not required to release medical records to VAERS. In 2012, reports were received from health care providers (41%), manufacturers (29%), other sources (17%) and vaccinees or families (14%). https://publications.aap.org/aapnews/news/14631*

**During the time period 2011-2014, healthcare professionals submitted 38% of U.S. reports, patients and parents submitted 14%, vaccine manufacturers submitted 30%, and others (e.g., friends/acquaintances of the patient, 3rd party reporters who became aware of adverse events from the media, lawyers, etc.) submitted 12% (CDC unpublished data). There is variability in reporter type across different types and brands of vaccines. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/*

The reporting requirements for COVID-19 vaccines are the same for those authorized under emergency use or fully approved. Healthcare providers who administer COVID-19 vaccines are required by law to report to VAERS the following after vaccination:

- Vaccine administration errors, whether or not associated with an adverse event (AE):
  - o If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, VAERS reporting is required.
  - o If a different product from the primary series is inadvertently administered for the additional or booster (third dose), VAERS reporting is required.
  - o VAERS reporting is not required for the following situations:
    - If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)
    - Mixing and matching of booster doses (as of October 21, 2021, mixing and matching of booster doses is allowed)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  - o Death
  - o A life-threatening AE
  - o Inpatient hospitalization or prolongation of existing hospitalization
  - o A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - o A congenital anomaly/birth defect
  - o An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

What are healthcare providers required to report to VAERS?

Healthcare providers are required by law to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

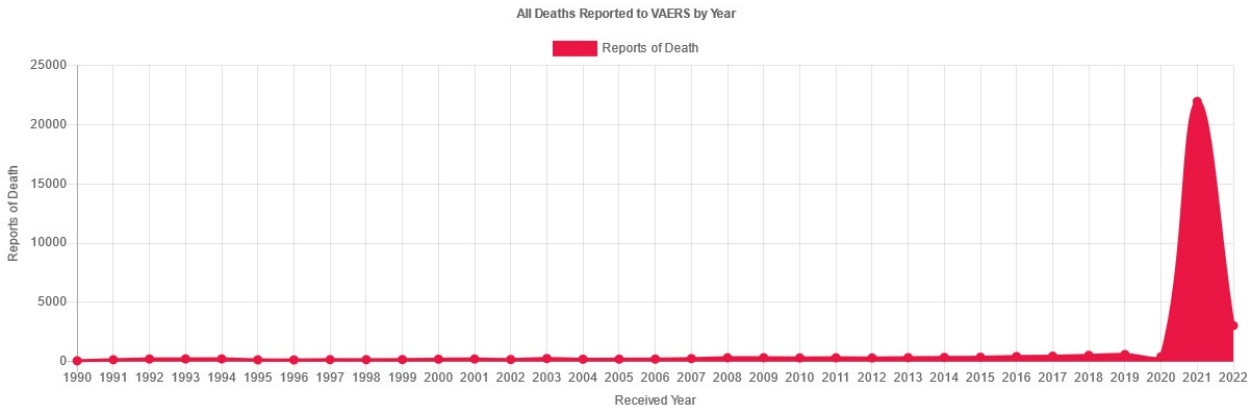
Healthcare providers are strongly encouraged to report:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors

Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

https://vaers.hhs.gov/faq.html

So when you see safety signals like chart below, do not ignore them.



1. *Guillain-Barré syndrome among recipients of Menactra meningococcal conjugate vaccine* https://pubmed.ncbi.nlm.nih.gov/16601664/ **2.** *Centers for Disease Control and Prevention Suspension of rotavirus vaccine after reports of intussusception* https://pubmed.ncbi.nlm.nih.gov/15343145/ **3.** *Centers for Disease Control and Prevention Withdrawal of rotavirus vaccine recommendation.* https://pubmed.ncbi.nlm.nih.gov/10577495/ **4.** *Febrile seizures after 2010-2011 influenza vaccine in young children* https://pubmed.ncbi.nlm.nih.gov/22361303/ **5.** *Data mining for prospective early detection of safety signals in the Vaccine Adverse Event Reporting System (VAERS)* https://pubmed.ncbi.nlm.nih.gov/23657824/