

## Vaccine Adverse Event Reporting System

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The Vaccine Adverse Event Reporting System (VAERS) is a United States program for vaccine safety, co-managed by the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a postmarketing surveillance program, collecting information about adverse events (possible harmful side effects) that occur after administration of vaccines to ascertain whether the risk-benefit ratio is high enough to justify continued use of any particular vaccine. VAERS, the Vaccine Safety Datalink, and the Clinical Immunization Safety Assessment (CISA) Network are tools by which the CDC and FDA monitor vaccine safety to fulfill their duty as regulatory agencies charged with protecting the public. VAERS has limitations, including unverified reports, misattribution, underreporting, and inconsistent data quality. CDC cautions that it is generally not possible to find out from VAERS data if a vaccine caused the adverse event, or how common the event might be.

VAERS has demonstrated its public health importance by providing health scientists with signals about possible adverse events following immunization. In one instance, VAERS detected reports for intussusception over that what would be expected to occur by chance alone after the RotaShield rotavirus vaccine in 1999. Epidemiologic studies confirmed an increased risk, and these data contributed to the product's removal from the US market. In another example, VAERS determined that there may be a potential for a small increase in risk for Guillain-Barre' syndrome (GBS) after the meningococcal conjugate vaccine, Menactra. As a result of this finding, a history of GBS became a contraindication to the vaccine and further controlled studies are currently underway to research this issue. Operation Each year the VAERS receives at least 50,000 reports of adverse events following immunization by more than 10 million vaccines. Higher-priority

uses of the data include reports of death and other serious adverse events, recognizing and detecting adverse effects, and finding unexpected adverse events involving new vaccines. The VAERS data are also used to monitor known reactions to vaccines and for vaccine lot surveillance. Data mining techniques such as empirical Bayes methods can be used to improve the quality of data analysis.

### Use in research and litigation

Many medical researchers make use of VAERS to study the effects of vaccination. VAERS warns researchers using its database that the data should not be used in isolation to draw conclusions about cause and effect.<sup>[5]</sup> Nonetheless, data from VAERS has been used in vaccine litigation to support the claim that vaccines cause autism.

Litigation related to vaccines and autism has led to an increase in VAERS reports filed by plaintiff's attorneys. A 2006 article in *Pediatrics* found that most VAERS reports related to thimerosal, and many related to autism, were filed in connection with litigation, leading the authors to caution that inappropriate reliance on VAERS data may be a source of bias. The study's lead author stated: "Lawyers are manipulating this system to show increases [in vaccine-related adverse events] that are based on litigation, not health research. Paul Offit, chief of infectious disease at Children's Hospital of Philadelphia, wrote: Public health officials were disappointed to learn that reports of autism to VAERS weren't coming from parents, doctors, nurses, or nurse practitioners; they were coming from personal-injury lawyers ... For the lawyers, VAERS reports hadn't been a self-fulfilling prophecy; they'd been a self-generated prophecy.