Vaccine Adverse Event Reporting System

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History of VAERS

Since the beginning of the 20th century, the United States Congress has passed legislation that ensures the safety and efficacy of vaccines in response to adverse public health events. The topic of vaccine safety became prominent during the mid-1970s with an increase in lawsuits filed on behalf of those presumably injured by the diphtheria, pertussis, and tetanus (DPT) vaccine. One such aspect of legislation is The National Childhood Vaccine Injury Act (NCVIA) of 1986, which requires health professionals and vaccine manufacturers to report specific adverse events that occur after the administration of routinely recommended vaccines to the U.S. Department of Health and Human Services. To implement this law, the Center for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) established the Vaccine Adverse Event Reporting System (VAERS) in 1990 (FDA, 2011). VAERS is a post-marketing safety surveillance program for collecting information about adverse events and possible side effects that occur after the administration of vaccines licensed for use in the United States (VAERS, 2012).

Objectives of VAERS

The primary purpose of VAERS is to detect new, unusual, or rare adverse effects associated with vaccines. In particular, the system is used to monitor increases in known adverse events, to identify potential risks factors for particular types of adverse events, to identify vaccine lots associated with adverse events, and to assess the safety of newly licensed vaccines for general public. By monitoring such events, VAERS helps to identify any important new safety concerns and thereby ensure that the benefits of vaccines are greater than their risks (CDC, 2012).

Reporting Mechanism

VAERS reports can be submitted by anyone, including health care providers, patients, or family members. An adverse event can be reported to VAERS by fax, mail, or online. VAERS accepts all reports on adverse events related to vaccines, including vaccination errors and events that have not been confirmed as being caused by the vaccination itself. Therefore, no proof that the event was caused by a vaccine is required in order for VAERS to accept the report.

Although VAERS accepts all vaccine related reports, VAERS's primary concern is to monitor clinically significant adverse health events following the administration of vaccines. Some of the items required when reporting include the patient's age, state and county, the facility where the vaccine was administered, a description of the suspected adverse event, any prescription medications the patient is taking, the patient's symptoms, as well as the time, course, and duration of symptoms (VAERS, 2012).

Some of the more commonly reported events from vaccination include anaphylactic shock, brachial neuritis, thrombocytopenic purpura, chronic arthritis, and encephalitis.

It is important to note that for any reported event, no cause-and-effect relationship has been established. The VAERS database includes reports of all possible associations between vaccines and adverse events along with potential side effects. Reports of adverse events in the database are not a confirmation that a vaccine caused the event to occur. The database collects reports from all adverse events following vaccination, whether it is merely coincidental or actually caused by a vaccine (VAERS, 2012). VAERS is a passive surveillance system and all it does is collect adverse reports and create a database that will later be used by both CDC and FDA. CDC and FDA monitor the reports received by VAERS and they use the data to design research studies (MMWR, 2004). Reports vary in quality and completeness and sometimes lack details and can include inaccurate information.

Please see the linked flowchart for information about how a report to VAERS of an adverse event following vaccination is investigated and assessed.

Cases Received:

Annually, VAERS receives about 30,000 reports of which CDC and FDA consider 13% to be serious. Serious cases are those that are associated with disability, hospitalization, life-threatening illness, or death. About 85-90% of the reports are described as mildly adverse events such as fever, local reactions, and episodes of crying or mild irritability. VAERS database has received 16,304 adverse reports so far in 2013 (VAERS, 2012).

Successful Cases:

In 1999, VAERS database was used by CDC to conduct epidemiologic studies confirming the risks of RotaShield, a rotavirus vaccine, which was ultimately removed as a product in the US market. From December 1998 to June 1999, VAERS received a total of 10 cases of intussusception and a total of 15 by July 1999. All the cases appeared to be nonrandom in distribution and intussusception occurred after receiving the first dose of RRV-TV and within 1 week after receiving the dose. These early findings prompted CDC to request data from VAERS and initiated two validation studies, a 19-state case-control study and case-series analysis, and a cohort study in 10 managed care organizations. On July 16, 1999 CDC recommended that health-care providers suspend use of licensed rhesus human rotavirus reassortant-tetravalent vaccine (RRV-TV) in response to 15 cases of intussusception (MMWR, 2004).

References

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