



Common Questions about **Adverse Events That Follow Vaccination**

What is the Vaccine Adverse Events Reporting System (VAERS)?

The Vaccine Adverse Events Reporting System (VAERS) is one of several vaccine monitoring programs that are used to monitor vaccine safety in the United States. The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) established VAERS in 1990 to record and track reactions or adverse events that occur after a vaccine is given to patients.

Anyone can file a VAERS report if they think they or someone they know has had a reaction to a vaccine. VAERS receives reports from health care professionals, parents, and patients.

Doctors and other medical research experts from FDA and CDC analyze the VAERS reports to monitor vaccine safety. Potential safety problems that are detected during regular reviews of VAERS reports are considered to be only a “signal” of a possible safety problem. When the VAERS data “signals” a potential safety problem, the vaccine is thoroughly investigated through other research methods. This is because adverse events reports to VAERS are self-reported and not routinely verified before being entered into the system, thus great caution must be used in interpreting patterns found in the data. Verification studies have shown that most adverse events reported in the VAERS database are not actually caused by an immunization. Rather, the “adverse events” that are shown to be unrelated to an immunization were the result of some other cause, such as a naturally occurring illness.

The rotavirus vaccine is a recent example of how VAERS works. Analysis of VAERS data in 1999 identified that 15 cases of a rare but serious bowel obstruction were reported in association with the rotavirus vaccine (after approximately 1.5 million doses of the newly licensed vaccine had been given to patients). Medical experts are now conducting further studies to better understand the relationship between the bowel obstructions and the vaccine. In the meanwhile, the vaccine has been withdrawn from use in the United States.

The VAERS telephone number is 1-800-822-7967; the Web site is www.fda.gov/cber/vaers; and the email address is vaers@cber.fda.gov.

Are there “hot lots” of vaccines that have been associated with more adverse events than others have? Should parents find the numbers of these lots and make sure their children don’t receive vaccines from them?

The answer to both of these questions is no. Manufacturers produce and distribute vaccines in quantities known as “lots.” Lot sizes vary widely between different types of vaccines and different manufacturers. Samples of each lot are sent to the FDA for tests of safety, potency, and purity before the lot may be given to patients.

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VAERS data can be used to monitor how many adverse events have been reported for each vaccine “lot” approved for use. However, because vaccine lots are not all of the same size, nor distributed and used at the same rate, differences in the numbers of adverse events reported must be interpreted with great caution. Some people have misinterpreted the difference between the number of adverse events in some lots versus other lots as meaning that some lots, i.e. “hot lots,” are more dangerous than others.

FDA officials routinely monitor vaccine lots using VAERS data and other information. With the exception of an early lot of polio vaccine in 1955, which was not fully inactivated, there has never been a “hot lot.”

Members of the public can also view the adverse reaction data in the VAERS database online at www.vaers.org. Currently, however, it is difficult for members of the public to interpret this information because the number of doses created in a given vaccine lot and the actual use, or market share, is considered to be the proprietary information of the manufacturer, and as a result, is not made available to the public. FDA officials do have access to this information, and they use it in their vaccine safety monitoring, but they are not allowed to make proprietary information public.

The perspective of the National Network for Immunization Information is that vaccine manufacturers should release to the public information on the number of doses created and used. Releasing this information to the public, or allowing the FDA to do so, will have an important benefit and is unlikely to put any vaccine manufacturer at a competitive disadvantage in the marketplace. The benefit of releasing the data is that interested members of the public will be able to prove to themselves that there are no “hot lots.”

Are some people more susceptible to adverse reactions than others?

Yes, but it is important to understand that serious adverse reactions to vaccines are very rare. Some people are allergic to a substance present in a vaccine, such as an antibiotic or gelatin stabilizer. These people may experience a severe allergic reaction to the vaccine (that can cause difficulty in breathing, a drop in blood pressure, and sometimes shock); this occurs very rarely approximately (1 out of 500,000 doses).¹ The American Academy of Pediatrics, the Centers for Disease Control and Prevention, and the American Academy of Family Physicians recommend that doctors avoid immunizing a person who has had an anaphylactic reaction to a component of a vaccine. However, people who have had less serious reactions to a vaccine might choose to be vaccinated to avoid the risk of illness or death from vaccine-preventable diseases.

Also, children with a personal or family history of seizures may be at greater risk of having seizures after being vaccinated with the DTP (diphtheria, tetanus, pertussis) vaccine.² However, this vaccine is no longer recommended for use in the United States. The newer DTaP vaccine (which includes the greatly purified acellular pertussis vaccine [aP] as a component) which is now used is far less likely to cause seizures in any children. DTaP is safe and recommended even for children with a family history (siblings or parents) of seizures.

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If one person in a family has an adverse reaction to a vaccine, will other members of the family also have the same reaction? Is there a laboratory test that can identify whether a person might have an adverse reaction to a vaccine before being vaccinated?

There is no single test that can determine whether a person will have an undesired reaction to a vaccine. However, if a person has a serious allergic reaction after a vaccination, he or she may be referred to an allergist who can attempt to determine which component of the vaccine may have caused the reaction. If an allergy to a vaccine component is found in one person, siblings, and children of that person can also be tested for the allergy. However, most reactions are not likely to occur in two members of the same family.

Can vaccines cause permanent adverse events, such as a long-lasting impairment, or death?

Yes, however it is important to understand that the risk of serious adverse events is extremely small (approximately 1 serious event occurs for each 100,000 doses of vaccine given). Most adverse events associated with vaccines are minor and short-lived. Of those few serious adverse events which do occur, only a small proportion result in long-lasting impairment or death. The diseases that vaccines prevent are far more dangerous than the vaccines that effectively prevent them.

Some people believe that certain immunizations can lead to a number of chronic diseases. Many scientific studies have been conducted to investigate these concerns. The results of this research repeatedly point to the conclusion that vaccines do not cause chronic diseases. For example, the Institute of Medicine, an independent research organization that is part of the National Academy of Sciences, reviewed all existing evidence on health problems that occur after vaccination. Their review did not show a cause-and-effect relationship between vaccines and any long-term illness.^{4,5}

- Some scientists, and some parents, are concerned about a possible link between MMR (measles, mumps, and rubella) vaccine and autism. It is not yet known for certain what causes autism, but the best available evidence indicates that autism is a condition that begins before birth (in the first trimester of pregnancy), not after a child is born. The disease is usually diagnosed when children are 18 to 30 months old, which is the period shortly after they receive many of the recommended vaccines. Because of this coincidence in timing, some people have come to believe that the development of autism is somehow associated with the MMR vaccine. With the exception of one research study, whose findings have now been widely refuted, all of the scientific evidence has concluded that vaccines are in no way associated with autism.⁶⁻¹¹
- Similarly, one investigator has suggested that the onset of diabetes might somehow be linked to whole-cell pertussis vaccine, to *Haemophilus influenzae* type b (Hib) vaccine, the new pneumococcal conjugate vaccine, or to the timing of immunizations in general¹² (also see www.vaccines.net). Scientific research studies and research reviews, however, have all concluded that vaccines do not cause diabetes.¹³⁻¹⁷
- Other people have been concerned that vaccines may be associated with Sudden Infant Death Syndrome (SIDS), which typically occurs in infants between 2 and 4 months of age (a period when many immunizations are given). All scientific studies and review papers have shown that vaccines do not cause SIDS.¹⁸⁻²¹ Since 1992, the rate of SIDS in the United States has been reduced by 40% as a result of an education campaign encouraging parents to put their babies to sleep on their backs.

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- Rates of childhood asthma have increased in recent years. This increase occurred during a period of time when the number of routine childhood immunizations also increased, so some have speculated that these may be related. As a result, medical researchers have studied whether vaccines might cause asthma. These studies found no increased risk of asthma after vaccination.²²⁻²³
- There has also been concern that multiple sclerosis (MS) might be associated with use of the hepatitis B vaccine.²⁴⁻²⁵ In 1994, the Institute of Medicine, an independent research organization that is part of the National Academy of Sciences, reviewed all available information and determined the evidence did not show that the vaccine causes nervous system diseases. More recently, in 1998, the Viral Hepatitis Prevention Board of the World Health Organization asked a panel of experts to review scientific data again. These experts also concluded that the hepatitis B vaccine does not cause multiple sclerosis.

Sources:

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Recommended books and Web sites on this topic:

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The Centers for Disease Control and Prevention (www.cdc.gov/nip/vacsafe/vaccinesafety/sideeffects/autism.htm)

National Alliance for Autism Research (NAAR) Web site (<http://babydoc.home.pipeline.com/naar/naar.htm>)

National Multiple Sclerosis Society Web site (www.nmss.org)