Understanding the Vaccine Adverse Event Reporting System (VAERS)

For more information on vaccines, vaccine-preventable diseases, and vaccine safety:
http://www.cdc.gov/vaccines/conversations

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- The Vaccine Adverse Event Reporting System (VAERS) is one component of the United States' comprehensive vaccine safety monitoring system.
- VAERS reports are monitored carefully by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).
- Reports of adverse events (possible side effects) after vaccination do not mean that the reported problem was caused by a vaccine. Reports are signals that alert scientists of possible cause-and-effect relationships that need to be investigated.
- Anyone can submit a report to VAERS including health care professionals, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine.

questions and answers

What is VAERS?

VAERS is a national vaccine safety surveillance program overseen by CDC and FDA. VAERS collects and analyzes reports of adverse events that happen after vaccination. Each year, VAERS receives around 30,000 reports. Most of these reports describe known, mild side effects such as fever. Scientists at CDC and FDA monitor VAERS reports closely to identify reported adverse events that need to be studied further. Sometimes, it is only after a vaccine has been approved and used broadly that rare side effects can be detected by monitoring systems such as VAERS.

How are the VAERS data used?

VAERS scientists look for unusually high numbers of reports of an adverse event after a particular vaccine or a new pattern of adverse events. If scientists see either of these situations, focused studies in other systems are done to determine if the adverse event is or is not a side effect of the vaccine. Information from VAERS and vaccine safety studies is shared with the public. Throughout the process of monitoring VAERS, conducting studies, and sharing findings, appropriate actions are taken to protect the public's health.

For example, if VAERS identifies a mild adverse event that is verified as a side effect in a focused study, this information is reviewed by CDC, FDA, and vaccine policy makers. In this situation, the vaccine may continue to be recommended if the disease-prevention benefits from vaccination outweigh the risks of a newly found side effect.

Information about newly found side effects is added to the vaccine's package insert that lists safety information. Newly found side effects also are added to the Vaccine Information Statement (VIS) for that vaccine. If serious side effects are found, and if the risks of the vaccine side effect outweigh the benefits, the recommendation to use the vaccine is withdrawn.

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal law requires that VISs be handed out whenever (before each dose) certain vaccinations are given.

Adverse events reported to VAERS are not necessarily side effects caused by vaccination. An ***adverse event*** is a health problem that happens after vaccination that may or may not be caused by a vaccine. These events may require further investigation. By definition, a ***side effect*** has been shown to be linked to a vaccine by scientific studies.

Before the FDA licenses (approves) a vaccine for use, the vaccine must be tested with volunteers during clinical trials to make sure it is safe and effective. Sometimes side effects show up in clinical trials. Most often side effects found in clinical trials are minor, such as possible pain at the injection site, and the vaccine is licensed because the disease-prevention benefits outweigh the risk of getting the side effect.

As part of the United States' comprehensive vaccine safety monitoring system, VAERS detects rare vaccine adverse events, signaling to scientists that focused studies are needed to determine whether the adverse event is a side effect or if there is no medical link.

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Vaccines are tested before they are used, so why are there possible unknown side effects?

When vaccines are ready for tests in humans, they are tested on thousands to tens of thousands of volunteers. However, even this large number is not always enough to find rare side effects, such as a one-in-a-million side effect. So, VAERS is needed to constantly look for possible side effects that might not have been detected previously.

Are all events reported to VAERS caused by vaccinations?

VAERS data alone usually cannot be used to answer the question, "Does a certain vaccine cause a certain side effect?" This is mainly because adverse events reported to VAERS may or may not be caused by vaccines. There are reports in VAERS of common conditions that are found shortly after vaccination, often related by chance alone, and investigations find no medical link between vaccination and the condition.

To know if a vaccine causes a side effect, scientists must know whether the adverse event is occurring after vaccination with a particular vaccine more often than would be expected without vaccination. They also need to consider whether the association between the vaccine and the adverse event is consistent with existing medical knowledge about how vaccines work in the body.

Who can report to VAERS?

Anyone can submit a report to VAERS including parents, patients, and health care professionals. Vaccine manufacturers who receive reports of adverse events also report the information to VAERS. FDA and CDC encourage anybody who experiences any adverse event after vaccination to report to VAERS. Individuals completing a report can work with a health care professional to make sure they fill out the report form completely. By working together, health care professionals and patients/parents can provide FDA and CDC with data that will be most useful and accurate for examining possible trends.

Why should I report to VAERS?

Reporting to VAERS gives valuable information that helps CDC and FDA ensure that vaccines are very safe. If a previously unknown adverse event does come up, timely reports will help scientists find it and determine how to best address the issue.

How do I report to VAERS?

Reports can be submitted online, by fax, or by mail. To report to VAERS online, go to *https://vaers.hhs.gov/esub/step1* and follow the 5 steps. Or, to print out the form to return it by fax or mail, go to *https://vaers.hhs.gov/resources/vaers_form.pdf*. To request a form by phone, call 1-800-822-7967. Forms may be returned by fax to 1-877-721-0366 or mailed to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. VAERS staff may call for more information.

What events should I report to VAERS?

VAERS encourages the reporting of all adverse events that occur after administration of any vaccine licensed in the United States.

How do I find out if a vaccine adverse event has been reported to VAERS?

Request information about adverse events reported to VAERS by sending a fax to 301-443-1726, by calling 301-827-6500, or by writing to: Food and Drug Administration, Freedom of Information Staff (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. Public data sets that include all adverse events reported to VAERS also are available online at *http://vaers.hhs.gov/data/index*.

Remember, just because an adverse event or condition has been reported does not prove that the adverse event is caused by vaccination. Parents who are concerned about vaccine side effects should talk to their child's health care professional.

| the science |

These articles tell more about VAERS and provide examples of the important role it serves as part of the U.S. vaccine safety monitoring system.

An Overview of the Vaccine Adverse Event Reporting System (VAERS) as a Surveillance System by J.A. Singleton et al. *Vaccine*. July 1999. Vol 17: pages 2908-2917. *http://www.sciencedirect.com/science?_ob=MImg&_imagekey=B6TD4-3WRB2MG-R-9&_cdi=5188&_user=856389&_pii=S0264410X99001322&_origin=search&_coverDate=07%2F16%2F1999&_sk=999829977&view=c&wchp=dGLzVlz-zSkzV&md5=a46c65b0b00e73287cf51d7ed0ec2aa9&ie=/sdarticle.pdf*

Intussusception among Recipients of Rotavirus Vaccine—United States, 1998–1999 in CDC's *MMWR*. July 1999. Vol 48: pages 577-581. *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4827a1.htm*

Intussusception among Infants Given an Oral Rotavirus Vaccine by T.V. Murphy et al. *New England Journal of Medicine*. February 2001. Vol 344: pages 564-572. *http://content.nejm.org/cgi/reprint/344/8/564.pdf*

The Role of the Vaccine Adverse Event Reporting System (VAERS) in Monitoring Vaccine Safety by John Iskander et al. *Pediatric Annals*. September 2004. Vol 33: pages 599-606. *http://www.ncbi.nlm.nih.gov/pubmed/15462575* (abstract only)

Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine by Barbara Slade et al. *Journal of the American Medical Association*. August 2009. Vol 302: pages 750-757. *http://jama.ama-assn.org/cgi/content/full/302/7/750*

For more information on vaccines call 800-CDC-INFO (800-232-4636) or visit *http://www.cdc.gov/vaccines*.