



## Common Questions about **Vaccine Safety**

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### **Are vaccines safe?**

Vaccines are extremely safe and getting safer and more effective all the time as a result of medical research and ongoing review by doctors, researchers, and public health officials. Vaccines must meet the strict safety standards of the Food and Drug Administration (FDA) before they are approved. The FDA and Centers for Disease Control and Prevention (CDC) closely monitor each vaccine's safety as long as it is in use.<sup>1</sup>

- Serious adverse effects from vaccines are extremely rare. The chance of serious complications (including death) from the diseases that vaccines prevent is many times higher.
- As with all medicines, vaccines carry some degree of risk. Doctors and public health professionals consider benefits and risks before recommending any vaccine. This balance between benefits and risks is always subject to new information and can change when diseases are controlled and/or eradicated or when there is new evidence about a vaccine.
- For example, since smallpox has been and is no longer a realistic threat, the smallpox vaccine is no longer recommended.
- The polio vaccine recommendation was recently modified so that doctors in the United States now offer only IPV (inactivated polio vaccine). OPV (oral polio vaccine) is no longer used routinely in the United States because even the remote risk of it causing paralysis (vaccine-associated paralytic polio; 1 case in 2.4 million doses) is no longer acceptable.<sup>2</sup> Even this small risk was sufficient to lead to a change in the recommendation.
- In another example of the effectiveness of the monitoring system, in 1999, the rotavirus vaccine was withdrawn from the market after preliminary studies suggested a slightly increased risk of intestinal blockage (intussusception) in some very young infants. In the first 1.5 million doses of rotavirus vaccine, 15 cases of bowel obstruction were reported.<sup>3</sup>

### **What does the FDA do to ensure that vaccines are safe?**

The FDA regulates vaccines that are used in the United States, ensuring that they are shown to be safe and effective before they are approved for use. The vaccine first undergoes laboratory studies, then studies with animals, and then with humans. Vaccines are only tested in infants and children after they have been evaluated in adults. The results of the studies at every step in the process must show that the vaccine does what it is supposed to do, and that it does not harm people who receive it.

### **How are vaccines tested?**

Vaccine licensure is a lengthy process that may last up to 10 years. Vaccines must go through three phases of clinical trials in human beings before they are licensed for public use. To establish basic safety, Phase One trials are small, involving only 20-100 volunteers and lasting only a few months. To continue to gather information on efficacy and safety of each vaccine, Phase Two trials are larger (with several hundred volunteers), and last anywhere from a few months to a few years. Phase Three trials have several hundred to several thousand participants and typically last many years.

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Only after the FDA approves the vaccine for use in humans is the manufacturer allowed to market the vaccine. Each batch of vaccine made by the manufacturer is tested for safety, potency, and purity before being put on the market and a sample from each lot is routinely sent to the FDA. The FDA also regularly inspects the manufacturing facility and makes sure the vaccine is made in a safe and consistent manner.

**How is the safety of vaccines monitored?**

In 1990, the FDA and CDC established the Vaccine Adverse Events Reporting System (VAERS) so that reports of possible adverse reactions could be collected and analyzed. As many as 12,000 reports have been made in a single year, and about 2,000 of these reported serious illness or death. All reports are entered into a database; FDA and CDC use the data to monitor vaccine safety and conduct research studies. However, with further examination, most of these reported events have been found to be unrelated to vaccines. VAERS reports do not establish cause and effect. Only large epidemiological studies can show that the vaccine caused the adverse event.

To ensure that all relevant data are captured, the VAERS allows anyone to file a report if they suspect that their child or patient has a vaccine-related reaction. Because entries are not screened, the database contains events that are related and unrelated to vaccines. FDA and CDC monitor VAERS to determine whether any vaccine is associated with more adverse events than would be expected due to chance.

Recently, the rotavirus vaccine was withdrawn from the market after VAERS reports identified 15 cases of severe bowel obstruction in infants who received it. VAERS data were used as a “signal” that the vaccine might be causing the problem; however subsequent epidemiological studies were necessary to establish that the vaccine was likely responsible.

**Sources:**

- 1 Chen, RT, Hibbs B. Vaccine Safety: current and future challenges. *Pediatrics* Ann 1998 Jul;27(7): 445-55.
- 2 Zimmerman RK, Spann SJ. Poliovirus vaccine options. *Am Fam Physician* 1999;59:113-118.
- 3 Centers for Disease Control and Prevention. Intussusception among recipients of rotavirus vaccine—United States, 1998-1999. *MMWR Morb Mortal Wkly Rep* 48:577-581.

**Recommended books and Web sites on this topic:**

Humiston SG and Good C. *Vaccinating your child: Questions & answers for the concerned parent.* Atlanta: Peachtree Publishers; 2000.

Offit PA and Bell LM. *Vaccines: What every parent should know, revised edition.* New York: IDG Books; 1999.

American Academy of Pediatrics Web site ([www.aap.org](http://www.aap.org))

Centers for Disease Control and Prevention Web site ([www.cdc.gov/nip](http://www.cdc.gov/nip))

Food and Drug Administration Web site ([www.fda.gov/fdac/features/095\\_vacc.html](http://www.fda.gov/fdac/features/095_vacc.html))

Institute for Vaccine Safety ([www.vaccinesafety.edu](http://www.vaccinesafety.edu))

Centers for Disease Control and Prevention National Vaccine Program Office ([www.cdc.gov/od/nvpo](http://www.cdc.gov/od/nvpo))