Centers for Disease Control and Prevention

Vaccine Safety

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Rotavirus Vaccines

Safety Information

Rotavirus and How to Protect Against It

Rotavirus is a contagious virus that can cause gastroenteritis (inflammation of the stomach and intestines). Symptoms include severe watery diarrhea, often with vomiting, fever, and abdominal pain. Infants and young children are most likely to get rotavirus disease. They can become severely dehydrated and need to be hospitalized and can even die. You can protect against rotavirus disease with safe, effective vaccination.

Child and Adult Immunization Schedules
Get CDC's official recommended immunization schedules for children, adolescents, and adults.

Rotavirus Vaccine Side Effects

The rotavirus vaccine is very safe, and it is effective at preventing rotavirus disease. Vaccines, like any medicine, can have side effects. Most babies who get rotavirus vaccine do not have any problems with it.

Common Side Effects of Rotavirus Vaccine

- Irritability
- Mild, temporary diarrhea or vomiting

Some studies suggest that rotavirus vaccination possibly causes a small increase in the risk of intussusception, a type of bowel blockage. This side effect is very rare.

Available Rotavirus Vaccines

There are two rotavirus vaccines approved for use in the United States:

- Rotarix [PDF – 22 pages] : The Food and Drug Administration (FDA) approved this vaccine in 2008 for use in infants 6 to 24 weeks of age.
- RotaTeq [PDF – 13 pages] : FDA approved this vaccine in 2006 for use in infants 6 to 32 weeks of age

Many studies were done before the vaccines were licensed and found that they are safe.

How CDC Monitors Vaccine Safety

CDC and FDA monitor the safety of vaccines after they are approved or authorized. If a problem is found with a vaccine, CDC and FDA will inform health officials, health care providers, and the public.

CDC uses 3 systems to monitor vaccine safety:

- The Vaccine Adverse Event Reporting System (VAERS): an early warning system, co-managed by CDC and FDA, to monitor for potential vaccine safety problems. Anyone can report possible vaccine side effects to VAERS.
- The Vaccine Safety Datalink (VSD): a collaboration between CDC and 13 healthcare organizations that conducts vaccine safety monitoring and research.
- The Clinical Immunization Safety Assessment (CISA) Project: a partnership between CDC and several medical research centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

A Closer Look at the Safety Data

- Studies from the United States and other countries show a small increased risk of intussusception following rotavirus vaccination. About 1 in 20,000 US infants to 1 in 100,000 US infants who get rotavirus vaccine might develop intussusception within a week of getting the vaccine. This means that between 40 and 120 U.S. infants might develop intussusception related to rotavirus vaccine each year.

More Resources

- Rotavirus Vaccine Information Statement
- Rotavirus Vaccine: Who Should Not Get Vaccinated
- Information on Rotavirus Vaccination
- CDC Feature: Protect Your Child against Severe Rotavirus
- Questions and Answers about Intussusception

Related Scientific Articles

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