
Rotavirus: Questions and Answers

Information about the disease and vaccines

What causes rotavirus disease?

Rotavirus disease is caused by a virus, the rotavirus. The name rotavirus is derived from the Latin *rota*, meaning “wheel,” because the rotavirus has a wheel-like appearance when viewed by an electron microscope.

How does rotavirus spread?

The rotavirus enters the body through the mouth and then infects the lining of the intestines. Rotavirus is very contagious, spreading easily from children who are already infected to other children and sometimes adults. Large amounts of rotavirus are shed in the stool of infected persons and the virus can be easily spread via contaminated hands and objects, such as toys. Children can spread rotavirus both before and after they become sick with diarrhea.

Rotavirus is very stable and may remain viable in the environment for months if not disinfected.

How long does it take to show signs of rotavirus after being exposed?

The incubation period for rotavirus diarrhea is 1-3 days. Symptoms of infection vary and depend on whether it is the first infection or a repeat infection.

What are the symptoms of rotavirus?

In young children, rotavirus disease commonly begins with fever and vomiting, followed by diarrhea. Vomiting and diarrhea may last from three to seven days; the diarrhea may be watery. Children may lose interest in eating and drinking and become dehydrated from loss of fluids.

How serious is rotavirus?

All three symptoms of rotavirus disease (fever, vomiting, and diarrhea) cause children to lose fluids. Vomiting is especially dangerous because it's difficult to replace fluids in children who are vomiting persistently.

Prior to the availability of rotavirus vaccine, rotavirus infection was responsible for more than 400,000 doctor visits, more than 200,000 emergency room visits, 55,000-70,000 hospitalizations, and 20-60 deaths in the U.S. on an annual basis. In the first five years of life, four of five children in the United States were expected to develop rotavirus gastroenteritis, one in seven would require a clinic or emergency room visit, one in 70 would be hospitalized, and one in 200,000 would die from this disease.

Rotavirus infection is even more problematic in the developing world because children with rotavirus disease are less likely to receive the medical intervention necessary to prevent death from dehydration. In developing countries, rotavirus causes more than 500,000 deaths each year in children younger than age five years.

What are possible complications from rotavirus?

Rotavirus infection in infants and young children can lead to severe diarrhea, dehydration, electrolyte imbalance, and metabolic acidosis. Immunodeficient children may have more severe or persistent disease.

How do I know if my child has rotavirus?

Rotavirus disease is difficult to differentiate from illness caused by other pathogens. As a result, laboratory testing of the stool is needed to confirm a diarrheal illness as rotavirus disease.

Are children more likely to become infected at certain times of the year?

In the United States, rotavirus is a winter/spring disease (children are most likely to get infected between November and May). In tropical climates, the disease occurs year round.

Is there a treatment for rotavirus?

Children are typically treated by replacing lost body fluids through drinking liquids specifically made for rehydration; these liquids are called oral rehydration solutions. These products contain specific amounts of water, sugars, and salts. In severe cases, body fluids are replaced with fluids given directly through the veins by use of an intravenous line in the hospital.

How long is a person with rotavirus contagious?

Infected persons shed large quantities of virus in their stool beginning 2 days before the onset of diarrhea and for up to 10 days after onset of symptoms. Rotavirus may be detected in the stool of persons with immune deficiency for more than 30 days after infection.

Are any people at greater risk than others of being infected with rotavirus?

Groups at increased risk for rotavirus infection are usually those with increased exposure to virus. This includes children who attend childcare centers, chil-

dren in hospital wards, caretakers and parents of children in childcare or hospitals, and children and adults with immunodeficiency-related diseases.

Can you get rotavirus more than once?

A person may develop rotavirus disease more than once because there are many different rotavirus types, but second infections tend to be less severe than the first infections. After a single natural infection, 40% of children are protected against a subsequent rotavirus illness. Persons of all ages can get repeated rotavirus infections, but symptoms may be mild or not occur at all in repeat infections.

Wouldn't good hygiene be enough to prevent rotavirus disease?

Better hygiene and sanitation have not been very effective in reducing rotavirus disease. This is illustrated by the fact that virtually everyone in the world is infected by rotavirus disease by age five years, despite differences in sanitation between countries.

When did a rotavirus vaccine become available?

A vaccine to prevent rotavirus gastroenteritis was first licensed in August 1998 but was withdrawn in 1999 because of its association with an uncommon type of bowel obstruction called "intussusception."

In February 2006, the U.S. Food and Drug Administration (FDA) approved a new rotavirus vaccine, RotaTeq (by Merck). In April 2008, FDA approved a second rotavirus vaccine, Rotarix (by GlaxoSmithKline).

What kind of vaccine are they?

RotaTeq and Rotarix are both live attenuated (weakened) viral vaccines.

How is this vaccine given?

Both RotaTeq and Rotarix are given to babies orally (swallowed).

Who should get this vaccine?

National experts on immunization (such as the Centers for Disease Control and Prevention and the American Academy of Pediatrics) recommend routine vaccination of all infants with rotavirus vaccine.

What is the recommended schedule for getting this vaccine?

Both vaccines are given in a series: RotaTeq vaccine is given in a 3-dose series with doses given at ages 2, 4, and 6 months; Rotarix vaccine is given in a 2-dose series with doses given at ages 2 and 4 months.

The first dose of either vaccine can be given as early as age 6 weeks or as late as age 14 weeks, 6 days. Vaccination should not be started for infants once

they reach their 15 week birthday. There must be at least 4 weeks between doses and all doses must be given by age 8 months. Rotavirus vaccine may be given at the same time as other childhood vaccines.

Should an infant who has already been infected with rotavirus still be vaccinated?

Yes. Infants who have recovered from a rotavirus infection may not be immune to all of the virus types present in the vaccine. Therefore, just like infants who have never had rotavirus disease, infants who have previously had rotavirus disease should still complete the vaccine series if they can do so by age 8 months.

How safe is this vaccine?

Clinical trials to determine the safety and effectiveness of the RotaTeq vaccine involved more than 70,000 infants in 11 countries. Because of the association of the earlier rotavirus vaccine with a type of intestinal blockage called intussusception, a study designed specifically to assess a risk of intussusception was conducted before licensure of RotaTeq. The vaccine was given to 35,000 children and another 35,000 were given a placebo (salt water). There was no difference in the incidence of intussusception between the two groups.

As with all vaccines, the safety of this vaccine is being monitored after licensure by the U.S. Food and Drug Administration (FDA) and by CDC through the Vaccine Adverse Event Reporting System. In addition, Merck and Co., Inc., has committed to monitoring the safety of the vaccine in a large number of U.S. infants. CDC will also conduct a large study in its Vaccine Safety Datalink Program, which evaluates vaccine safety among approximately 80,000 U.S. infants every year. Also, for the first three years of licensure, the manufacturer will report cases of intussusception to FDA within 15 days of receiving them, and all other serious side effects will be reported on a monthly basis.

As a result of this aggressive monitoring, on February 13, 2007, the FDA released a report on the number of intussusception cases reported since RotaTeq licensure. The number reported fell within what was expected and gives assurance that the vaccine does not pose an elevated risk for intussusception. To read the report, go to www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm142404.htm. To read a CDC Q&A about the report, go to www.cdc.gov/vaccinesafety/vaers/rotateq.htm.

In clinical trials, infants who received RotaTeq vaccine and those who didn't were monitored to deter-

mine if there were other possible side effects associated with the vaccine. Compared with infants who did not receive the vaccine, infants who did receive the vaccine had a slightly higher rate of diarrhea and vomiting within the first week and within the first 42 days after receiving the vaccine.

The FDA's approval of Rotarix in 2008 was based on clinical trials involving nearly 75,000 infants. These clinical trials were conducted in the Americas, Europe, Asia and Africa and reflect an ethnically diverse population.

In a controlled safety study conducted in Latin America and Finland, the risk of intussusception was evaluated in 63,225 infants. No increased risk of intussusception was detected among those infants who received the vaccine and those who did not.

As with all vaccines, the safety of this vaccine is being monitored after licensure by the U.S. Food and Drug Administration (FDA) and by CDC through the Vaccine Adverse Event Reporting System and other systems. In addition, GlaxoSmithKline has committed to monitoring the safety of the vaccine in a large number of U.S. infants. Also, for the first three years of licensure, the manufacturer will report any serious and unexpected adverse events to FDA within 15 days of receiving them, and all other initial adverse experience reports will be reported on a monthly basis.

In clinical trials, infants who received Rotarix vaccine and those who didn't were monitored to determine if there were other possible side effects associated with the vaccine. Compared with infants who did not receive the vaccine, infants who did receive the vaccine had a slightly higher rate of cough or runny nose within the first week after receiving the vaccine and a slightly higher rate of irritability within the first month after receiving the vaccine.

How effective is rotavirus vaccine?

Rotavirus vaccine is very effective against rotavirus disease. Studies show the vaccine to be highly effective (85%-98%) against severe rotavirus disease and

very effective against rotavirus disease of any severity (74%-87%) through approximately the first rotavirus season after vaccination. Chances that children will need to be hospitalized for rotavirus disease are also greatly decreased (96%) by the vaccine. Neither vaccine will prevent diarrhea or vomiting caused by other germs.

What side effects have been reported with rotavirus vaccine?

Vaccinated infants are slightly (1%-3%) more likely to be irritable or to have mild, temporary diarrhea or vomiting after getting a dose of vaccine than infants who did not get the vaccine. Moderate or severe reactions have not been associated with the vaccine.

Who should NOT receive rotavirus vaccine?

Any child who has had a severe (life-threatening) allergic reaction to a previous dose of rotavirus vaccine should not get another dose. A child with a severe (life-threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Because the oral applicator for Rotarix contains latex rubber, infants with a severe (anaphylactic) allergy to latex should not be given Rotarix; the RotaTeq dosing tube is latex-free. Rotavirus vaccine is contraindicated in infants diagnosed with the rare genetic disorder severe combined immune deficiency (SCID). Although this vaccine has not been associated with intussusception, as a precaution it is suggested that the risks for and the benefits of vaccination should be considered when vaccinating infants with a previous episode of intussusception.

Children who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover, including children who are experiencing diarrhea or vomiting. Healthcare providers will decide on a case-by-case basis whether to vaccinate a child with an ongoing digestive problem, an immune system weakened because of HIV/AIDS or another disease that affects the immune system, or a child who is receiving treatment with drugs such as long-term steroids or treatment for cancer.