

Rotavirus

Questions and Answers

What is rotavirus?

Rotavirus is the most common cause of severe diarrhea in young children worldwide. It can result in acute dehydration, vomiting, and fever and is responsible for nearly 600,000 deaths each year, mostly in developing countries.¹ This accounts for more than one-third of deaths from diarrhea worldwide and about 5 percent of all deaths among children less than five years of age.

How is rotavirus spread?

Rotavirus is highly contagious and is typically transmitted by the fecal-oral route. Contaminated water, hands, or objects pass the virus. The virus can survive well on toys or other surfaces. It may also be spread through droplets in the air.

What are the symptoms of rotavirus infection?

After an incubation period of 18 to 36 hours, a child may develop diarrhea that lasts for three to seven days. The illness often begins with explosive vomiting and may be accompanied by fever. With severe diarrhea and vomiting, a child can become dehydrated from acute loss of fluid and electrolytes, which can lead to shock, cardiac arrhythmia, and death.

Where does rotavirus infection occur?

Rotavirus is found in every country. Regardless of where they live, virtually all children become infected in the first three to five years of life. Because of greater access to medical care, children in developed countries are at lower risk of death. However, in the United States alone, rotavirus causes an estimated 50,000 hospitalizations each year.²

Why haven't we heard of rotavirus before?

Rotavirus is a relatively "new" disease, as it was only clinically discovered in 1973. Since then it has taken many years to get a sound estimate of the disease burden, and complete, accurate data from Asia and Africa are still needed.

What can be done to prevent rotavirus and diarrheal disease in general?

In the past 20 years diarrhea mortality has decreased significantly due to improvements in sanitation and nutrition and the availability of oral rehydration solution (ORS).

Mortality due to rotavirus remains a stubborn exception. Improvements in water, sanitation, and hygiene do not significantly reduce its spread. Vaccination is the only way to prevent severe episodes of rotavirus infection, and rotavirus vaccines will be an important new addition to a portfolio of interventions to prevent and manage diarrheal disease. This portfolio should include rotavirus vaccines, as well as ORS, zinc, breastfeeding, and improvements in nutrition, hygiene, and water quality.

Why does cleaning the water reduce diarrhea but not rotavirus?

Rotavirus is so contagious and resilient that providing safe water and promoting good hygiene does not significantly impact incidence. Incidence is nearly the same around the world, regardless of water quality and hygiene practices.

What is the treatment for rotavirus?

ORS is a common intervention for managing diarrhea, and it can be effective in treating mild rotavirus infections. In severe cases when rapid dehydration occurs, however, ORS is not sufficient, and urgent medical care is required. Tragically, such care is out of reach for many children in developing countries. Due to the persistent vomiting sometimes associated with rotavirus infection, parents or caregivers will often stop administering ORS because the child can't keep it down, further limiting its effect.³

New research indicates that zinc supplementation can significantly reduce the burden of dehydration caused by diarrheal disease,⁴ but no studies have specifically evaluated its effect on rotavirus infections. Additionally, as with ORS, the profuse vomiting associated with rotavirus may discourage caregivers from administering zinc.

Is there a vaccine against rotavirus?

Currently, two rotavirus vaccines are in late stages of development. In early 2006, results from clinical trials conducted in South America, North America, and Europe, showed these vaccines to be highly safe and efficacious.⁵ Both of these vaccines are under consideration for approval by the US Food and Drug Administration and the European Medicines Evaluation Agency. In addition, a number of countries have licensed these vaccines for use.

The vaccines are orally administered and given in two and three doses, respectively. So far, they have been primarily studied in middle- and high-income countries. But historically, oral vaccines have been shown to perform differently in different regions of the world. The global health community recognizes the need to carry out additional studies of the safety and efficacy of these vaccines in developing countries of Africa and Asia, where the burden of disease is very high.⁶ PATH is designing and conducting such clinical trials in collaboration with the vaccine manufacturers.

Sufficient evidence of a vaccine's safety, efficacy, and affordability is necessary for national governments to make informed decisions on the introduction of rotavirus vaccines in the public sector. Through its support of clinical trials and dissemination of key materials, PATH is generating and distributing this critical information.

How much will a vaccine cost?

To ensure broad use of a rotavirus vaccine in developing countries, cost is an important issue. Presently, rotavirus vaccines are offered in the private sectors of several middle-income countries for as much as \$50 per dose and for roughly \$7 per dose in the public sectors. But both prices are well out of acceptable range for the poorest countries.

Efforts are underway to develop sustainable financing options so that the poorest countries can access the vaccines. And as more manufacturers develop rotavirus vaccines and introduce them to the market, the price will be further reduced.

Wasn't there a vaccine in the past?

In August 1998, a rotavirus vaccine, Rotashield[®], was licensed in the United States, and approximately one million children were vaccinated within nine months. About 100 (0.01%) of these children developed a type of bowel obstruction called intussusception.

Intussusception occurs for unknown reasons in about 1 child per 10,000, most often in infants four to ten months of age, regardless of whether or not they have received a vaccine. Because of the uncertainty about the relationship between Rotashield and intussusception, the manufacturer voluntarily pulled the product off the market.

The current rotavirus vaccine candidates were tested extensively to determine any risk for adverse events, including intussusception. Researchers found that the risk of intussusception was similar among children who received the vaccine and those who received a placebo, indicating that the vaccines are safe for use.⁵

What does PATH's rotavirus vaccine program do?

PATH's rotavirus vaccine program works to accelerate the availability of a rotavirus vaccine in the developing world by providing resources on disease burden and vaccine impact to support informed, evidence-based decision-making and by working with partners to conduct clinical trials of rotavirus vaccine candidates in poor countries.

The program was established in 2003 and is supported by a grant from the GAVI Alliance. Activities are conducted in partnership with WHO and the US Centers for Disease Control and Prevention.

For more information about rotavirus visit
www.rotavirusvaccine.org or email rvinfos@path.org

¹ Parashar U, Gibson C, Bresee J, Glass R. Rotavirus and severe childhood diarrhea. *Emerging Infectious Diseases*. 2006;12(2). Available online: <http://www.cdc.gov/ncidod/EID/vol12no02/05-0006.htm>.

² Parashar U, Holman R, Clarke M, Bresee J, Glass R. Hospitalizations associated with rotavirus diarrhea in the United States, 1993 through 1995: Surveillance based on the new ICD-9-CM rotavirus-specific diagnostic code. *Journal of Infectious Diseases*. 1998;177(1). Available online: http://www.journals.uchicago.edu/JID/journal/issues/v177n1/ja07_13/ja07_13.web.pdf.

³ Ahmed F. Children at risk of developing dehydration from diarrhea: A case-control study. *Journal of Tropical Pediatrics*. 2002;48: 259–263.

⁴ Zinc Investigators' Collaborative Group: Bhutta Z, Black R, Brown K, et al. Prevention of diarrhea and pneumonia by zinc supplementation in children in developing countries: Pooled analysis of randomized controlled trials. *Journal of Pediatrics*. 1999;135:689–697.

⁵ Ruiz-Palacios G, Pérez-Schael I, Velázquez, F, et al. Safety and efficacy of an attenuated vaccine against severe rotavirus gastroenteritis. *New England Journal of Medicine*. 2006;354(1):11–22. Available online: <http://content.nejm.org/cgi/content/full/354/1/11>.

Vesikari, T, Matson D, Dennehy P, et al. Safety and efficacy of a pentavalent human-bovine (wc3) reassortant rotavirus vaccine. *New England Journal of Medicine*. 2006;354(1):23–33. Available online: <http://content.nejm.org/cgi/content/full/354/1/23>.

⁶ World Health Organization. Rotavirus vaccines. *Weekly Epidemiological Record*. 2006; 81(1):8. Available online: <http://www.who.int/wer/2006/wer8101/en/index.html>.