

Vaccines & Immunizations

Vaccines and Preventable Diseases:

Statement Regarding Rotarix® and RotaTeq® Rotavirus Vaccines and Intussusception

On October 28, 2010, summaries of post-licensure evaluations on rotavirus vaccines and intussusception were presented to the Advisory Committee on Immunization Practices. Some studies performed outside the United States have detected a low-level increased risk of intussusception following rotavirus vaccination, particularly shortly after the first dose. The level of risk observed in these post-marketing studies is substantially lower than the risk of intussusception after vaccination with RotaShield®, the previous rotavirus vaccine.

The Food and Drug Administration (FDA) licensed RotaTeq® (Merck & Co., Inc.) in February 2006 and Rotarix® (GSK Biologicals) in April 2008 for routine use in U.S. infants to prevent severe rotavirus disease in infants and children. Because a previous rotavirus vaccine, RotaShield® (Wyeth-Ayerst), was associated with intussusception, a form of bowel obstruction, the risk of this adverse event was specifically evaluated in a large pre-licensure trial for each vaccine. In these trials, each involving over 60,000 participants, conducted mainly in Finland and the United States for RotaTeq and in 11 Latin American countries for Rotarix, no increased risk for intussusception was observed. Post-marketing surveillance for intussusception is ongoing in many countries. On September 22, 2010, FDA approved a label change for Rotarix to advise practitioners of new data regarding intussusception from an evaluation in Mexico by GSK (see [Updated Vaccine Label for Rotarix® \(Vac-label-HCP.htm\)](#)).

Since 2007, the Pan American Health Organization has collaborated with ministries of health, the Centers for Disease Control and Prevention (CDC), and PATH, to evaluate, in Brazil and Mexico, the potential risk of intussusception after Rotarix immunization during routine use. Analyses of the data collected have identified a clustering of 18 hospitalizations for intussusception in the period 1–7 days after the first dose in Mexico, corresponding to a rate of intussusception that was about 4–5 times higher than in later periods after vaccination, after adjusting for age. No clustering was observed after the first dose in Brazil.

In a similar study sponsored by GSK Biologicals in a different population in Mexico, a possible increased risk of intussusception of about 1.8-fold was found in the 30-day period following the first dose of Rotarix, with a clustering of cases in the first week after vaccination.

In Australia, post-marketing surveillance studies found a possibility of an increase in intussusception cases in the first week after vaccination with both Rotarix and RotaTeq vaccines, although these findings are based on relatively few cases.

In the United States, more than 27 million doses of RotaTeq have been distributed. A study is being done through the Vaccine Safety Datalink (VSD) to see if RotaTeq, the vaccine primarily used in these practices, is associated with intussusception. This study, which includes data on more than 800,000 total doses of RotaTeq vaccine, has not found an increased risk of intussusception. However, the VSD study cannot rule out a risk of intussusception with RotaTeq as low as the risk currently reported with Rotarix in Mexico. An evaluation in the United States sponsored by Merck & Co., Inc. also did not show evidence of an increased risk of intussusception with RotaTeq; this study also could not rule out a low-level increased risk.

Rotarix has been available in the United States since 2008, and about 2.7 million doses of this vaccine have been distributed. There are not enough safety data on Rotarix from ongoing studies in the United States to allow detection of a level of risk as low as those reported in Mexico.

Some post-marketing studies from outside the United States have detected a low-level increased risk of intussusception following rotavirus vaccination, particularly shortly after the first dose. The level of intussusception risk observed in these post-marketing studies is substantially lower than the estimated risk following receipt of RotaShield (1 case/10,000 vaccinees). The documented benefits of rotavirus vaccine in U.S. children are substantial. The rotavirus vaccination program in the United States has reduced the number of infants and children needing hospitalization or emergency department care for rotavirus disease by about 85%. In the 2008 rotavirus season, 2 years after the introduction of RotaTeq, there were an estimated 40,000–60,000 fewer gastroenteritis-related hospitalizations than in the pre-vaccine seasons among children less than 5 years of age. While an increased risk of intussusception from rotavirus vaccine has not been documented in the United States, if a risk does exist of the magnitude seen in the data currently available from Mexico, 1 case of intussusception caused by rotavirus vaccine would occur per approximately 100,000 infants who are vaccinated following age recommendations. Considering that the data currently available suggest a small risk of intussusception caused by rotavirus vaccine is possible and considering that the benefits of rotavirus vaccination are great, CDC continues to recommend both Rotarix and RotaTeq to prevent severe rotavirus disease in U.S. infants and children. CDC will continue to monitor additional data on intussusception as they become available.


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Reference

World Health Organization, Global Advisory Committee on Vaccine Safety Statement on Rotarix and RotaTeq Vaccines and Intussusception.

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