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From *Medscape Medical News*

Rotavirus Vaccine Contraindicated in Infants With Severe Combined Immunodeficiency

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June 11, 2010—Rotavirus vaccine should not be administered to infants with severe combined immunodeficiency (SCID), according to the Centers for Disease Control and Prevention (CDC) and US Food and Drug Administration (FDA)-approved prescribing information and patient safety labeling.

Both monovalent (RV1) and pentavalent (RV5) rotavirus vaccines are contraindicated in infants diagnosed with SCID and can cause vaccine-acquired infection.

The CDC announced this new contraindication to rotavirus vaccine in the June 11 issue of *Morbidity and Mortality Weekly Report*.

SCID is a rare, life-threatening group of disorders caused by defects in several genes that is commonly diagnosed in infants after they have experienced a severe, potentially life-threatening infection from one or more pathogens. It occurs annually in about 40 to 100 new cases in the United States per year. Most infants commonly experience chronic diarrhea, failure to thrive, and early onset of infections.

In December 2009 and February 2010, Merck Co and GlaxoSmithKline Biologicals, the makers of the RV1 (RotaTeq) and RV5 (Rotarix) vaccines, respectively, updated their prescribing information and patient labeling with FDA approval to reflect this contraindication.

The CDC also has updated their list of contraindications to rotavirus vaccine after consulting with the Advisory Committee on Immunization Practices.

The addition of this contraindication was based on data from 8 reported cases of vaccine-acquired rotavirus infection in infants with SCID since 2006, when the rotavirus vaccine was first introduced in the United States. Five cases were reported in the literature — 4 in the United States and 1 in Australia. Two additional cases in the United States and another outside the United States were reported to the Vaccine Adverse Event Reporting System.

The 8 infants were between 3 and 9 months of age when diagnosed with SCID. All had received 1 to 3 doses of rotavirus vaccine before the diagnosis and presented with diarrhea. Most of the infants also had additional infections, such as *Pneumocystis jirovecii*, rhinovirus, adenovirus, *Salmonella*, *Escherichia coli*, and *Giardia*. The vaccine-acquired infection was confirmed using reverse transcription–polymerase chain reaction in all cases. In at least 6 cases, prolonged shedding of vaccine virus up to 11 months' duration was documented.

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The rotavirus vaccine is recommended by the Advisory Committee on Immunization Practices to be given to infants at ages 2 and 4 months for RV1 and ages 2, 4, and 6 months for RV5. This timeframe for rotavirus vaccination overlaps with the median age of 4 to 7 months when infants are usually diagnosed with SCID.

Rotavirus vaccine is indicated for the prevention of rotavirus gastroenteritis in infants.

The CDC advises parents to consult with an immunologist or infectious disease specialists before rotavirus vaccine is administered to infants with confirmed or suspected altered immunocompetence.

Morb Mortal Wkly Rep. 2010;59:687-688.

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