INFORMATION PAPER

Military Vaccine Agency
16 April 2012

SUBJECT: Rotavirus and Rotavirus Vaccine

1. Purpose. To describe rotavirus disease and the rotavirus vaccines.

2. Facts.

a. Microbiology. Rotaviruses have a characteristic wheel-like appearance when viewed by electron microscopy. The name rotavirus is derived from the Latin word “rota” meaning wheel. Rotaviruses are non-enveloped, double-shelled viruses that are about 70 nm in diameter and replicate in the cytoplasm after entering the cell by endocytosis. Five predominant strains of virus (G1-G4, G9) account for 90% of isolates in the US. Rotaviruses are very stable and are able to survive in the environment without disinfection for weeks or months. Disinfectants with 95% ethanol are the most effective in killing the virus.

b. Disease. Rotavirus disease is characterized by vomiting, watery diarrhea for 3–8 days, and dehydration, often accompanied by fever and abdominal pain. Once infected, the incubation period is relatively short at 1 to 3 days. Symptoms are more severe during the first infection than subsequent infections, and immunity after infection is incomplete. Some infected individuals may be asymptomatic with self-limiting watery diarrhea. In infants and young children dehydration and electrolyte imbalance are often the cause of hospitalization and/or death.

c. Epidemiology. Rotavirus is the most common cause of severe diarrhea in infants and children, resulting in 55,000–70,000 hospitalizations and 20–60 deaths in the United States and over 600,000 deaths worldwide each year. The virus is highly communicable, as evidence by the nearly universal infection of children by age 5 years. Transmission is primarily fecal-oral, but can occur by contact with respiratory tract secretions and other body fluids. Because the virus is stable in the environment, transmission can occur through ingestion of contaminated water or food and contact with contaminated surfaces. In the United States and other temperate climate countries, rotavirus infections have a seasonal pattern with outbreaks occurring from November to May.

d. Vaccine.

1) RotaTeq® (RV5), manufactured by Merck & Co., has been approved for use since 2006. RotaTeq is a live, oral, pentavalent vaccine. The vaccine is suspended in a buffer solution and does not contain any preservatives or thimerosal. The vaccine is supplied in a container consisting of a squeezable plastic, latex-free dosing tube with a twist-off cap, allowing for direct oral administration.

2) Rotarix® (RV1), manufactured by GlaxoSmithKline, was approved in April 2008. Rotarix is a live, oral, monovalent vaccine. They vaccine is provided as a lyophilized powder and it does not contain any preservatives or thimerosal. The vaccine should be reconstituted with the diluent in the prefilled oral syringe and must be administered within 24 hours of reconstitution.

e. Caution. Contraindications for both vaccines include a demonstrated history of hypersensitivity to the vaccine or any component of the vaccine, severe combined immunodeficiency disease, and history of intussusception. Rotarix is contraindicated in infants with a history of uncorrected congenital malformation of the gastrointestinal tract. Precautions for the use of both rotavirus vaccines include infants who are immunocompromised or who have a history of gastrointestinal disease, chronic diarrhea, failure to thrive, a history of congenital abdominal disorders, abdominal surgery, and intussusception. Administration of the rotavirus vaccines should be delayed in infants suffering from acute vomiting or diarrhea. The Rotarix oral applicator contains natural latex rubber in the tip cap and rubber plunger which may cause a reaction in latex sensitive individuals

f. Immunization.

1) RotaTeq®is a three dose series with each dose administered 4 to 10 weeks apart. Each 2 mL dose is administered orally into the infant's inner cheek by squeezing the dosing tube until empty. The series may be started as early as 6 weeks of age and the third dose should be administered before 32 weeks of age.

2) Rotarix® is a two dose series with an interval of at least 4 weeks between the first and second dose. Each 1 mL dose is administered orally into the infant's inner cheek utilizing the oral applicator. The series may be started as early as 6 weeks of age and the second dose should be administered before 24 weeks of age.

g. Adverse Events. Common adverse events noted after vaccination included diarrhea, vomiting, irritability, fever, and loss of appetite. If any symptoms of intussusception to include severe vomiting or diarrhea, bloody bowel movements, high fever or severe stomach pain occur infant should immediately be assessed by their pediatrician or emergency room.

h. DoD Policy. Administer the rotavirus vaccines consistent with FDA approved product label and Advisory Committee on Immunization Practices recommendations.

i. Special Precaution. None.

3. References.

a. Centers for Disease Control and Prevention. Prevention of Rotavirus Gastroenteritis Among Infants and Children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2009;58(RR-02):1-25

b. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by Military Vaccine Agency: www.vaccines.mil/rotavirus

Ms. Jateya Jones/(703) 325-6579

Approved by: LTC Patrick Garman