

RotaTeq Found Effective at Expiration Date

BY ALICIA AULT
Contributing Writer

WASHINGTON — Merck's experimental RotaTeq vaccine was effective against moderate and severe rotavirus at the end of its shelf life, which appears to be 18 months, lead investigator Umesh Parashar, M.D., reported at the National Immunization Conference sponsored by the Centers for Disease Control and Prevention.

A new vaccine is eagerly anticipated, because rotavirus causes 440,000 deaths and leads to 2.1 million inpatient visits in children under age 5 worldwide each year, said Dr. Parashar of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention (CDC). Rotavirus causes 5% of deaths in children under age 5 worldwide. In the United States, there are few deaths—only 20-60 per year—but there are 200,000-272,000 emergency department visits and 400,000 outpatient visits because of rotavirus annually.

Stan Block, M.D., a pediatrician in private practice in Bardstown, Ky., presented the RotaTeq data on behalf of trial sites in the United States and Finland.

RotaTeq is a pentavalent oral vaccine, aiming to provide protection against the G1, G2, G3, G4, and P1 strains.

From 2002 to 2004, 1,310 healthy infants aged 6-12 weeks were assigned to receive three doses of RotaTeq (at the end of shelf life) or placebo. The doses were given 4-10 weeks apart. Children with a gastrointestinal disorder, recent surgery, or acute fever or who had taken steroids within 2 weeks of the trial were excluded. RotaTeq could be given simultaneously with other vaccines, said Dr. Block.

Children were monitored for acute gastroenteritis through one rotavirus season.

There were 69 cases of rotavirus, for an overall efficacy of 72.5%. For severe acute gastroenteritis, the vaccine was 100% effective, and for both moderate and severe gastroenteritis, it was 76.3% effective.

The vaccine also appeared to be very safe. There were five potential cases of intussusception (all were in the placebo group), but all were negatively adjudicated by an independent safety monitoring board, Dr. Block said.

Children who received RotaTeq did have a statistically significant increase in temperature after the first dose, compared with placebo—13.4% of RotaTeq vaccinees, compared with 8.8% of placebo recipients. However, there was no increase in rates of fever after the second or third dose, he said. Only one child was documented to have a rotavirus vaccine strain a few days after the first dose of vaccine.

Merck is continuing a larger, 70,000-patient safety study. Preliminary results were presented at the CDC's Advisory Committee on Immunization Practices meeting in February, said Penny Heaton, director of clinical research at Merck.

So far, there have been 12 cases of intussusception in the RotaTeq group and 15 in the placebo group, she said. ■

How to Stop a Pertussis Outbreak

BY ALICIA AULT
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WASHINGTON — Wisconsin health authorities were able to put a stop to a spiraling outbreak of pertussis by advocating faster testing and use of antibiotics in all suspect cases, a state health department official reported at the National Immunization Conference sponsored by the Centers for Disease Control and Prevention.

Jeffrey Davis, M.D., of the Wisconsin

Division of Public Health, gave the details of the epidemic, which lasted from May 2003 until February 2004 and occurred primarily in Fond du Lac County. In the 5 years before the outbreak, there had only been five cases of pertussis in Wisconsin.

Cases were defined using the Centers for Disease Control and Prevention's (CDC) definition of pertussis: a cough illness lasting more than 2 weeks with paroxysms, whoop, or posttussive vomiting. Cases were confirmed through pa-

tient follow-up interviews and/or lab confirmation by isolating *Bordetella pertussis* in culture, or through a positive polymerase chain reaction (PCR) assay.

During the outbreak, there were 313 cases reported in the county (in a total population of 97,296); 193 were confirmed in the lab, and 120 were confirmed by epidemiology. Just over half the cases were in females, and the median age was 14 years. Of those with confirmed pertussis, 70% were aged 10-19

18,957 Cases

of Pertussis Reported in 2004—a 40-year high*¹⁻³

Prevent Them

Safety Information

There are risks associated with all vaccines. Local and systemic adverse reactions to DAPTACEL vaccine may include redness, swelling, pain or tenderness at the injection site, fever, irritability, prolonged crying, drowsiness, vomiting, and anorexia. Other local and systemic adverse reactions may occur.

DAPTACEL vaccine is contraindicated in persons with a hypersensitivity to any component of the vaccine. In addition, it is contraindicated in persons with any immediate anaphylactic reaction or encephalopathy not attributable to another identifiable cause.

Indications and Usage

DAPTACEL vaccine is indicated for the active immunization of infants and children 6 weeks through 6 years of age (prior to 7th birthday) for the prevention of diphtheria, tetanus, and pertussis (whooping cough). DAPTACEL vaccine is recommended for administration as a 4-dose series at 2, 4, 6, and 17 to 20 months of age. The interval between the 3rd and 4th dose should be at least 6 months. It is recommended that DAPTACEL vaccine be given for all doses in the series because no data on the interchangeability of DAPTACEL vaccine with other DTaP^t vaccines exist. As with any vaccine, vaccination with DAPTACEL vaccine may not protect 100% of individuals. Please see brief summary of Prescribing Information for DAPTACEL vaccine on adjacent page.

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