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
Contributing Writer

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 patient 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

years; 43% were aged 10-14 years. The incidence rate exceeded 1,000 per 100,000 in that younger cohort, said Dr. Davis.

After investigating, the health department determined that the outbreak probably started with two unvaccinated adolescents using a high school weight room. Of the initial 53 cases, 55% were linked to that weight room, said Dr. Davis.

During the epidemic's initial peak in mid-October, the health department alerted physicians to keep a close eye on potential cases. As the number of new cases continued to rise into November, the department issued another alert, suggesting more testing and use of antibiotics in any suspect cases.

That alert led to a sharp decline in cases, said Dr. Davis. During the first peak, it took a median of 10.5 days between the onset of cough and initiation of antibiotics. By the last peak, medication was generally started within 4 days of cough onset.

More than 5,000 courses of antibiotics were dispensed; 90% of the prescriptions were for azithromycin.

As physicians became more aware, they stepped up reporting, also, said Dr. Davis.

And PCR testing by the health department allowed for a rapid response—results were generally back to physicians within 24-48 hours. ■