Investigational Tdap Booster Safe in Adolescents

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WASHINGTON — The safety profile of Aventis Pasteur's reduced-antigen tetanus-diphtheria acellular pertussis vaccine in adolescents is similar to that of the currently-licensed tetanus-diphtheria vaccine, Michael E. Pichichero, M.D., reported at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

Adacel (reduced-antigen tetanus-diphtheria acellular pertussis or Tdap) is licensed in Canada for booster immunization of adolescents and adults. It is under review by the Food and Drug Administration for use in individuals 11-64 years.

Two randomized multicenter U.S. trials included 2,990 adolescents aged 11-17 who received Tdap and 792 given tetanus-diphtheria toxoid (Td), said Dr. Pichichero, a pediatric infectious diseases specialist in Rochester, N.Y.

Immediate reactions (within 30 minutes) were reported at comparably low frequencies in both the Tdap and Td groups (0.5%-0.6%). Most reactions were mild and resolved within a day. Also comparable were the frequency, intensity, and mean duration of fever of 38° C or greater and injection site erythema and/or swelling.

Injection site pain was slightly but significantly more frequent in the Tdap group (79.2% vs. 71.0%), but this pain was usually of mild intensity and its mean duration did not differ significantly between the two groups, Dr. Pichichero said.

Postvaccination limb circumference measurements within 2 weeks of vaccination were similar between the two groups (increases of more than 3 cm occurred in roughly 5% of each group), and no study subjects had whole arm swelling. Headache, generalized body ache, and tiredness were the three most commonly reported solicited systemic events, all in less than 30% of each group. ■

New Rotavirus Vaccine Poses No GI Risk

WASHINGTON — GlaxoSmithKline's rotavirus vaccine is not associated with increased risk of intussusception, Miguel O'Ryan, M.D., reported at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy, sponsored by the American Society for Microbiology.

Unlike Wyeth's rhesus-human rotavirus reassortant-tetravalent RotaShield, which was withdrawn in 1999 due to an increased risk of intussusception, GlaxoSmithKline's Rotarix is a live attenuated monovalent human strain–derived vaccine. It is licensed in Mexico and in early 2005 it should be available in some Latin American countries. The company also will seek licensure in the United States, a spokesperson said.

Short-term safety and immunogenicity for Rotarix were established in phase II trials (Pediatr. Infect. Dis. J. 2004;23:S179-82 and Vaccine 2004;22:2836-42).

The current phase III data involve 63,225 healthy infants from 18 sites in 11 Latin American countries and in Finland (40% were from Mexico and Peru). They were randomized to receive a dose of vaccine or placebo at 2 and 4 months of age.

Active hospital surveillance for intussusception yielded six cases within 30 days of receiving the vaccine and seven cases within 30 days of placebo injection. Intussusception developed in an additional three vaccine and nine placebo recipients after more than 30 days. None of these differences were significant, said Dr. O'Ryan of the University of Chile, Santiago.

Unlike with RotaShield, in which most of the intussusception cases were clustered during the first week after dose 1, no such temporal clustering was seen with Rotarix. None of the 13 infants with intussusception in this study died. Surgery was required for four of the vaccine subjects and five in the placebo group, also not significantly different, he said.

The calculated risk for intussusception following Rotarix was –2.23/10,000, far lower than the 1/10,000 estimate for RotaShield (N. Engl. J. Med. 2001;344:564-72).

Dr. O'Ryan noted that although rotavirus is a far greater threat to infants in the developing world, the disease still results in high hospitalization rates in the developed world.

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