Boostrix Stacks Up to Current Pertussis Vaccines

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WASHINGTON — GlaxoSmithKline's candidate reduced–antigen content tetanus-diphtheria–acellular pertussis booster vaccine for adolescents compares favorably with other currently licensed vaccines, Leonard Friedland, M.D., reported at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

In a pivotal clinical study of 4,114 healthy 10-18 year olds, Boostrix (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine adsorbed [Tdap]) was comparable in both immunogenicity and safety with a currently licensed tetanus-diphtheria (Td) vaccine and produced antibody responses at least as high as those seen in infants who receive the current higher-antigen DTaP vaccine, said Dr. Friedland, director of clinical research and development and medical affairs for GlaxoSmithKline's Vaccines North America division.

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Pertussis is the only disease against which children are routinely immunized that is still increasing in the United States. That's because immunity from the vaccine wanes after about 10 years, and no pertussis vaccine is licensed for persons over age 7 years. In 2003, adolescents aged 10-19 made up 39% of all pertussis cases in the United States.

Boostrix is currently under review by the U.S. Food and Drug Adminstration for use as a single-dose booster in adolescents. If approved, it could replace the current Td booster, thereby protecting adolescents against pertussis without adding an extra injection, he noted at the conference, sponsored by the American Society for Microbiology.

All study subjects had previously received the routine childhood vaccinations against diphtheria, tetanus, and pertussis according to the recommended schedule. Most had received their first three doses as whole-cell pertussis vaccine. Some had received their fourth and/or fifth doses as acellular pertussis vaccine.

The proportion achieving a fourfold rise in titers of antidiphtheria antibody at 1 month postvaccination was 90.6% among the subjects who received Tdap, compared with 95.9% of those given Td. For antitetanus antibody, the proportions were 89.7% and 92.5%, respectively. Moreover, seroprotective levels of both antibodies were achieved in more than 99.9% of the subjects in both groups. These results met the pre-defined criteria for "noninferiority" of Tdap vs. Td, Dr. Friedland said.

Since there is no established serologic correlate of protection for pertussis, the antibody responses to each of the three pertussis antigens (PT, FHA, and PRN) of the subjects in this study were compared with those seen in infants following receipt of GlaxoSmithKline's DTaP vaccine (Infanrix). For each antigen, the geometric mean titers (enzyme-linked immunoabsorbent assay units/ml) were considerably higher in the adolescents following Tdap than among the infants who received DTaP (85.9 vs. 48.6 for PT, 617.3 vs. 89.1 for FHA, and 469.3 vs. 124.2 for PRN).

It is therefore "reasonable to assume that Tdap will be at least as effective as Infanrix for preventing pertussis in adolescents," he remarked.

Overall pain at the injection site did not differ between Tdap (75.3%) and Td (71.7%). The proportion reporting grade 2 or 3 pain was slightly greater in the Tdap group (51.2% vs. 42.5%), but the percentage with grade 3 pain—preventing normal activity—was less than 5% in both groups and not significantly different between them.

Large areas of swelling at the injection site is an adverse effect that has been observed in children receiving the DTaP booster. Only two subjects in this study—one from each vaccine group—reported diffuse swelling. The swelling did not involve adjacent joints and resolved completely in both subjects, Dr. Friedland said.

Headaches preventing normal activity were more frequent in the Tdap subjects (15.7% vs. 12.7%), with no differences in fever, fatigue, or GI symptoms. No serious events occurred in either group in the 31 days post vaccination, he reported. ■