

FDA Approval of Expanded Age Indication for a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine



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On December 4, 2008, the Food and Drug Administration (FDA) approved an expanded age indication for the tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) Boostrix (GlaxoSmithKline Biologicals, Rixensart, Belgium). Boostrix is now licensed for use in persons aged 10--64 years as a single-dose booster immunization; the vaccine initially was licensed for persons aged 10--18 years. This announcement summarizes the indications for use of Boostrix. Complete recommendations of the Advisory Committee on Immunization Practices (ACIP) for Tdap vaccines have been described previously (1--3).

On October 23, 2008, ACIP was presented data on the safety and immunogenicity of Boostrix in adults aged 19--64 years and notified of the impending expanded age indication for Boostrix. Guidance for the use of Boostrix is the same as for Adacel (Sanofi Pasteur, Toronto, Canada), another Tdap vaccine licensed for use in adults.

Data were reviewed by ACIP from two clinical trials conducted among U.S. adults aged 19--64 years. In both trials, the safety and reactogenicity profiles of Boostrix generally were similar to those of Adacel. For diphtheria and tetanus, immune responses to Boostrix were noninferior. Pertussis antibody concentrations for pertussis toxoid (PT), filamentous hemagglutinin (FHA), and pertactin in the first clinical trial were noninferior to those of infants after a primary diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccination series with Infanrix (GlaxoSmithKline Biologicals, Rixensart, Belgium) in a clinical trial in which efficacy of DTaP also was demonstrated (4--6). Boostrix contains the same three pertussis antigens as Infanrix but in reduced quantities.

Coadministration with influenza vaccine was evaluated in the second trial. In this trial, seroresponse to concomitantly or separately administered Boostrix and influenza vaccine Fluarix (GlaxoSmithKline Biologicals, Rixensart, Belgium) were noninferior for diphtheria, tetanus, PT, and influenza. Noninferiority criteria were marginally exceeded for FHA and pertactin responses; however, serologic correlates of protection for pertussis have not been established. Antibody levels in both groups exceeded those observed in infants after primary DTaP vaccination, in trials in which efficacy of DTaP against pertussis disease was subsequently demonstrated. Decreased immune response to Tdap pertussis antigens when coadministered with influenza vaccine has been reported previously for other U.S.-licensed Tdap vaccines (7).

Indications and Guidance for Use

For prevention of tetanus, diphtheria, and pertussis, adolescents and adults are recommended to receive a one-time booster dose of Tdap. Adolescents aged 11--18 years who have completed the recommended

childhood diphtheria and tetanus toxoids and pertussis vaccine (DTP)/DTaP vaccination series should receive a single dose of Tdap instead of tetanus and diphtheria toxoids (Td) vaccine, preferably at a preventive care visit at age 11 or 12 years (1). For adults aged 19--64 years who previously have not received a dose of Tdap, a single dose of Tdap should replace a single decennial Td booster dose (2).

Boostrix is now indicated for use as a single-dose booster immunization in persons aged 10--64 years. The recommended interval between 2 doses of Td-containing vaccines in adolescents and adults is at least 5 years because of concern over increased reactogenicity (1,2); however, data are available suggesting that intervals as short as approximately 2 years are safe (8). An interval <5 years between Td and Tdap may be used if increased risk for acquiring pertussis (e.g., during outbreaks or periods of increased pertussis activity in the community, or among health-care workers) exists (1,2). The safety and effectiveness of Tdap have not been established in pregnant women, nursing mothers, and children aged <10 years. Current doses in stock can be used for persons aged 10--64 years.

References

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