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

Weekly

September 23, 2011 / 60(37);1279-1280

On July 8, 2011, 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). Originally, Boostrix was licensed in 2005 for persons aged 10 through 18 years, but in 2008, FDA approved an expanded age indication for Boostrix to include persons aged 19 through 64 years (*1*). FDA has now expanded the age indication to include persons aged 65 years and older. Boostrix is now licensed for use in persons aged 10 years and older as a single-dose booster vaccination (*2*). This notice summarizes the indications for use of Boostrix. Recommendations of the Advisory Committee on Immunization Practices (ACIP) for Tdap vaccines have been published previously (*3*--*6*). Publication of revised Tdap recommendations within the next year is anticipated.

On October 27, 2010, ACIP was presented data on the safety and immunogenicity of Boostrix in adults aged 65 years and older (*6*). Data were reviewed by ACIP from two clinical trials on the safety and immunogenicity of Boostrix in adults in this age group. The safety and reactogenicity profiles of Boostrix generally were similar to currently available tetanus and diphtheria toxoids (Td) vaccine. Immunogenicity of pertussis vaccine components was inferred using a serologic bridge to infants vaccinated with pediatric diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP), as defined by the Vaccines and Related Biological Products Advisory Committee (*7*).

For diphtheria and tetanus, immune responses to Boostrix were noninferior to the immune responses elicited by a comparator Td vaccine licensed in the United States (*2*). Immune responses to pertussis antigens (pertussis toxin [PT], filamentous haemagglutinin [FHA], and pertactin [PRN]) were noninferior to those observed following a 3-dose primary DTaP series with Infanrix (GlaxoSmithKline Biologicals) in a clinical trial in which clinical efficacy of DTaP also was demonstrated (*2,8,9*). Boostrix contains the same three pertussis antigens as Infanrix but in reduced quantities. The geometric mean concentrations for pertussis antibodies (PT, FHA, and PRN) after Boostrix administration increased 7.4 to 13.7-fold.* There are no contraindications to the co-administration of Tdap and influenza vaccine (*2*). No data on the administration of Tdap with other vaccines recommended for persons aged 65 years and older (e.g., zoster and pneumococcal polysaccharide vaccines) are available. However, Tdap can be administered with other indicated vaccines during the same visit.

Indications and Guidance for Use

For prevention of tetanus, diphtheria, and pertussis, ACIP recommends that adolescents and adults receive a one-time booster dose of Tdap. Adolescents aged 11 through 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 (*4*). For adults aged 19 through 64 years who previously have not received a dose of Tdap, a single dose of Tdap should replace a single decennial Td booster dose (*3*). Persons aged 65 years and older (e.g., grandparents, child-care providers, and health-care practitioners) who have or who anticipate having close contact with an infant aged less than 12 months and who previously have not received Tdap should receive a single dose of Tdap to protect against pertussis and reduce the likelihood of transmission (*6*). For other adults aged 65 years and older, a single dose of Tdap vaccine may be administered instead of Td vaccine in persons

who previously have not received Tdap (*6*). Tdap can be administered regardless of interval since the last tetanus or diphtheria toxoid--containing vaccine (*6*). After receipt of Tdap, persons should continue to receive Td for routine booster vaccination against tetanus and diphtheria, in accordance with previously published guidelines (*3*,*4*,*6*).

Currently, two Tdap products are licensed for use in the United States, Boostrix and Adacel (Sanofi Pasteur, Toronto, Canada). Adacel has been approved by FDA as a single dose in persons aged 11 through 64 years (*10*). With the recent FDA expanded licensure for use of Boostrix, ACIP will be reviewing the current recommendations on use of Tdap in persons aged 65 years and older. At this time, either Tdap product may be used in persons aged 65 years and older (*6*).

References

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