



State of California—Health and Human Services Agency
Department of Health Services



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TO: California Vaccines for Children (VFC) Program Providers

SUBJECT: Combined Tetanus, Diphtheria, and Pertussis (Tdap) Vaccines for Adolescents 10-18 Years of Age

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SUMMARY

Two Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap) products have been licensed by the Food and Drug Administration in 2005 as **single-dose (one-time use) booster** vaccines to provide protection against tetanus, diphtheria, and pertussis.

GlaxoSmithKline's BOOSTRIX® is indicated for persons aged 10–18 years, and Sanofi Pasteur's ADACEL® is indicated for persons aged 11–64 years.

In June 2005, the Advisory Committee on Immunization Practices (ACIP) voted to recommend the routine use of Tdap vaccines in adolescents aged 11–18 years to replace tetanus and diphtheria toxoids (Td) vaccines (http://www.cdc.gov/nip/vaccine/tdap/tdap_acip_recs.pdf), and incorporated Tdap into the VFC Program (http://www.cdc.gov/nip/vfc/acip_resolutions/605dtap.pdf). The California VFC program is following ACIP's provisional recommendations for the use of Tdap. We will provide you with any updated recommendations as soon as they become available.

BACKGROUND

Pertussis is a highly contagious respiratory tract infection. Immunity from childhood vaccination or illness wanes over time leaving adolescents susceptible. In 2003, U.S. adolescents aged 11–18 years made up 36% (4,144) of the total 11,647 reported cases; reported cases underestimate the true burden of pertussis. The clinical presentation of pertussis in adolescents ranges from mild cough to classic paroxysmal cough, post-tussive emesis, and inspiratory whoop. The morbidity of pertussis can be substantial and last for months. Hospitalization and complications (e.g., pneumonia and rib

fractures) occur in $\leq 2\%$ of reported adolescent cases. Pertussis outbreaks in schools with adolescents are disruptive and lead to significant public health control efforts. The primary objective of the adolescent pertussis booster vaccination program is to protect adolescents against pertussis. It is unknown, but suspected that the widespread use of Tdap in adolescents and adults may help to reduce transmission of pertussis to young infants, who are at highest risk of severe pertussis.

RECOMMENDATIONS FOR VACCINE USE

Who should receive Tdap?

Adolescents aged 10–18 years with no contraindication to the pertussis components who have:

- completed recommended childhood DTP/DTaP vaccinations and have not yet received Tdap;
→ If they have already received Td, intervals shorter than 5 years between Td and Tdap may be used, especially in settings with increased risk from pertussis (e.g., pertussis outbreaks and close contact with an infant aged < 6 months).
- never received pertussis vaccines but completed the recommended tetanus-diphtheria vaccination series with pediatric DT or Td.

The preferred age for Tdap vaccination is 11–12 years; routinely administering Tdap to young adolescents will reduce the morbidity associated with pertussis in adolescents.

Special circumstances

- No History of Primary Series of DTP/DTaP/Td/Tdap Vaccination: Adolescents who have never received tetanus-diphtheria-pertussis vaccination should receive a series of three vaccinations. The preferred schedule is a single Tdap dose, followed by a dose of Td ≥ 4 weeks after the Tdap dose and a second dose of Td ≥ 6 months after the first Td dose. Tdap may substitute for any one of the three Td doses in this series.
- History of Pertussis: Adolescents who have a history of pertussis generally should receive Tdap according to the routine recommendations.
- Pregnancy: Unless otherwise indicated, consider administering Tdap to adolescents who are in the second or third trimester of pregnancy. Pregnancy is not a contraindication for Tdap or Td.
- Pertussis Outbreaks and Other Settings with Increased Risk from Pertussis: The routine Tdap vaccination recommendations for adolescents should be used. Post-exposure chemoprophylaxis and other pertussis control guidelines are available by contacting Department of Health Services, Immunization Branch at (510) 620-3737.

Vaccination with Tdap and the new meningococcal conjugate vaccine (MCV4)

- Vaccine providers should administer Tdap (or Td) and tetravalent meningococcal polysaccharide-protein conjugate vaccine ([MCV4] Menactra™) (which contains diphtheria toxoid) during the same visit if both vaccines are indicated and available (MCV4 recommendations available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm).
- If Tdap and MCV4 are both indicated for adolescents but only one vaccine is available, generally the available vaccine should be administered.
- If simultaneous vaccination is not feasible, inactivated vaccines can be administered at any time before or after a different inactivated or live vaccine. Tdap (or Td) and MCV4 vaccines (which contain diphtheria toxoid) can be administered using any sequence. There is a theoretical risk of increased rates of local or systemic reactions when two diphtheria toxoid-containing vaccines are administered within a short interval (on different days).

When to use Td instead of Tdap

- When Tdap is indicated, but not available, vaccine providers should administer Td if the last DTP/DTaP/DT/Td vaccine was > 10 years earlier to provide protection against tetanus and diphtheria. Td can be deferred temporarily when the last DTP/DTaP/DT/Td was administered within 10 years and the adolescent is likely to return for follow-up. Vaccine providers should maintain a system to recall adolescents when Tdap/Td vaccination is deferred.
- Tetanus Prophylaxis in Wound Management: Adolescents who require a tetanus toxoid-containing vaccine as part of wound management should receive a single dose of Tdap instead of Td if they have not previously received Tdap; if Tdap is not available or was previously administered, adolescents who need a tetanus toxoid-containing vaccine should receive Td (www.cdc.gov/mmwr/preview/mmwrhtml/00041645.htm).

POTENTIAL VACCINE REACTIONS

For both vaccine brands, approximately 75% of adolescents reported pain at injection site and approximately 20% of adolescents reported redness and swelling. As with DTaP immunization earlier in childhood, local inflammation may be moderate or severe on occasion. The most common systemic reaction was headache which was reported by approximately 40% of adolescents. Temperatures $\geq 38.0^{\circ}\text{C}$ occurred in 5% of adolescents. Report suspected reactions to the Vaccine Adverse Events Reporting System (VAERS) at 800-822-7967 (toll-free) or <http://vaers.hhs.gov>.

CONTRAINDICATIONS AND PRECAUTIONS TO Tdap

Setting	Contraindication or Precaution	Recommendation
History of anaphylactic reaction to any of the components of Tdap or its constituents, such as diphtheria toxoid	Contraindication	Consider referral to an allergist for evaluation and desensitization
History of encephalopathy (e.g., coma, prolonged seizures) occurring within 7 days of a pertussis vaccination that was not attributable to another identifiable cause	Contraindication	Use Td
History of arthus-type hypersensitivity reaction following a dose of tetanus toxoid	Precaution	Td or Tdap should not be given more frequently than every 10 years, even in the case of a dirty wound
History of Guillain-Barre syndrome (GBS) within 6 weeks after previous dose of tetanus toxoid containing vaccines	Precaution	Decision to use Tdap or any vaccine containing tetanus toxoid must be made after consideration of risks and benefits
History of temperature $\geq 105^{\circ}\text{F}$ (40.5°C) within 48 hours of DTaP vaccination, not attributable to another identifiable cause	Precaution	Decision to use Tdap or any pertussis-containing vaccine must be made after consideration of risks and benefits
History of collapse or shock-like state (hypotensive hyporesponsive episode) within 48 hours of DTaP vaccination	Precaution	Decision to use Tdap or any pertussis-containing vaccine must be made after consideration of risks and benefits
History of persistent crying ≥ 3 hours within 48 hours of DTaP vaccination	Precaution	Decision to use Tdap or any pertussis-containing vaccine must be made after consideration of risks and benefits
Progressive neurological disorder, uncontrolled epilepsy, or progressive encephalopathy	Precaution	Td may be used instead of Tdap until a treatment regimen has been established and condition has stabilized
Severe latex allergy	Precaution	Use single dose vials of any Tdap vaccine. Do not use pre-filled syringes of BOOSTRIX Tdap vaccine.
Moderate or severe illness	Precaution	Immunize after recovery from acute phase of illness

Minor illnesses such as colds or allergic rhinitis are not contraindications for administration of Tdap.

ORDERING AND BILLING

How to order Tdap for VFC-eligible children

VFC Providers may order Tdap using the attached order form (DHS 8501(9/05)). Remember to complete all the boxes in the four columns of the order form, even if you are ordering only Tdap. Maintain a copy of your order forms for your office files. Please be aware that your orders of Tdap may be adjusted, especially during this introductory phase.

How supplied

Both Tdap vaccines:

- are supplied as single-dose (0.5 mL) vials. Boostrix is also available in pre-filled syringes.
- should be refrigerated at 2°-8°C. DO NOT FREEZE.
- do not contain thimerosal or other preservatives.

Billing information

Child Health and Disability Prevention (CHDP) Program: Claims may be submitted for doses of Tdap given to children covered by CHDP on or after August 31, 2005. However, providers should wait until notified by CHDP to submit claims.

- For patients aged 10-18 years, the CHDP administration fee is \$9.00 using CHDP code **72**.

Other codes for the use of Tdap that are not supplied by VFC:

- The CPT code for Tdap is **90715**
- The CPT codes for administration of Tdap are:
 - **90471** when Tdap is the only vaccine has been given during the visit, and
 - **90472** when Tdap and another vaccine(s) have been given.

REFERENCES

Vaccine Information Statement (VIS): An interim Tdap VIS has been published by the Centers for Disease Control and Prevention and is posted on the National Immunization Program VIS page (<http://www.cdc.gov/nip/publications/VIS/default.htm>). This interim form may be used until a final VIS is published in 2006.

Product Insert: Refer to the product package inserts for Tdap vaccines for additional information. These may be found at <http://www.fda.gov/cber/label/tdapgla050305LB.pdf> and <http://www.fda.gov/cber/label/tdapave061005LB.pdf>.

ACIP and American Academy of Pediatrics (AAP) recommendations: Provisional ACIP recommendations for Tdap are available at http://www.cdc.gov/nip/vaccine/tdap/tdap_acip_recs.pdf. AAP recommendations and other information about Tdap are available to AAP members at <http://www.cispimmunize.org/>.

Vaccine Injury Compensation Program (VICP): Tdap will eventually be included in the federal VICP, but is not included at present (<http://www.hrsa.gov/osp/vicp/INDEX.HTM>).

TABLES

Table 1. Recommended Schedule for Diphtheria, Tetanus, and Pertussis Vaccines

Dose	Age
DTaP 1	2 months (as early as 6 weeks)
DTaP 2	4 months
DTaP 3	6 months
First DTaP Booster	15-18 months
Second DTaP Booster *	4-6 years
Tdap Booster †	11-12 years

* The second booster is not necessary if the fourth dose is administered on or after the fourth birthday.

† Tdap is preferred over Td as adolescents are susceptible to pertussis due to waning immunity. A Tdap or Td booster is recommended at any age from 11 through 18 years if they have completed the recommended childhood DTP/DTaP vaccination series and have not received a Td dose. In unusual situations, Td, rather than Tdap may be indicated (please see above).

Table 2. Intervals for Vaccination for Diphtheria, Tetanus, and Pertussis Containing Vaccines

Vaccine	Min. Age (Dose 1)	Minimum interval between doses			
		Dose 1 to 2	Dose 2 to 3	Dose 3 to 4	Dose 4 to 5
DTaP	6 week	4 weeks	4 weeks	6 months	6 months*
DTaP-HepB-IPV†	6 week	4 weeks	8 weeks		
DT	6 week	4 weeks	4 weeks	6 months	6 months*
DTaP-Hib‡	15-18 mos			6 months	
Tdap§	10-11 yrs				
Td (catch-up schedule) 	7 years	4 weeks	6 months	5 years	-----

Note: DT containing vaccines are not indicated for children > 6 years of age.

* The fifth dose is not necessary if the fourth dose was given after the fourth birthday.

† The combined DTaP-HepB-IPV vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. The combined DTaP-HepB-IPV vaccine is approved for the primary series only (Doses 1-3). For adequate immune response, the last dose of hepatitis B vaccine should be given at ≥ 24 weeks of age and therefore this combination vaccine should not be administered as a complete primary series on an accelerated schedule at 4 week intervals for prevention of pertussis.

‡ The combined DTaP/*Haemophilus influenzae* type b (Hib) vaccine is only indicated for the fourth dose at age 15-18 months.

§ Recommended at age 10-11 years or older as a booster dose. Tdap is preferred over Td as adolescents are susceptible to pertussis due to waning immunity. Tdap is indicated for a single booster dose if the childhood DTP/DTaP vaccination series has been completed. A five-year interval is encouraged if Tdap is administered after Td. Please see ACIP recommendations for further information.

|| Recommendation at age 10-11 years or older as a booster rather than Tdap may be indicated in some special situations (please see ACIP recommendations).

Enclosures