



Complete Summary

GUIDELINE TITLE

Prevention of pertussis among adolescents: recommendations for use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics, Committee on Infectious Diseases. Prevention of pertussis among adolescents: recommendations for use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine. *Pediatrics* 2006 Mar;117(3):965-78. [58 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [October 23, 2006 update, Menactra \(Meningococcal Conjugate Vaccine\)](#): Updated alert to consumers and health care providers regarding reports of Guillain Barre Syndrome (GBS) following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135.
- [October 3, 2005, Menactra \(Meningococcal Conjugate Vaccine\)](#): The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) notified consumers and health care providers of five reports of Guillain Barre Syndrome following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra).

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Pertussis

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide rationale and recommendations for adolescent use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccines

TARGET POPULATION

Adolescents 11 to 18 years of age

INTERVENTIONS AND PRACTICES CONSIDERED

1. Routine adolescent immunization with tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) (Boostrix and Adacel) (booster immunization)
2. Concurrent or sequential administration of tetravalent meningococcal conjugate vaccine (MCV4) with Tdap

3. Use of tetanus toxoid (TT) or tetanus and diphtheria toxoid (Td) when Tdap is unavailable or inadvisable

MAJOR OUTCOMES CONSIDERED

- Pertussis rates
- Vaccine coverage
- Cost-effectiveness of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccines
- Adverse effects of Tdap vaccine

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

US Preventive Services Task Force Rating System of Quality of Scientific Evidence

I: Evidence obtained from at least 1 properly designed, randomized, controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferentially from more than 1 center or group

II-3: Evidence obtained from multiple time series with or without the intervention or dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s)

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This American Academy of Pediatrics (AAP) policy statement was prepared in parallel with Centers for Disease Control and Prevention (CDC) recommendations and reports, "Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus and Diphtheria Toxoids and Acellular Pertussis Vaccines Formulated for Adolescents and Adults. Recommendations of the Advisory Committee on Immunization Practices (*Morbidity and Mortality Weekly Report*; in press)." Much of the background presented in this AAP report is based on the literature review, analyses of unpublished data, and deliberations of CDC staff in collaboration with the Advisory Committee on Immunization Practices (ACIP) Pertussis Working Group.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Two US economic studies have compared adolescent immunization with other pertussis immunization strategies. Both studies identified universal, single-dose tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) during adolescence as the most cost-effective strategy, considering a variety of assumptions regarding incidence of pertussis, waning immunity, vaccine efficacy, vaccine coverage, and infant transmission. One study compared 7 potential adolescent/adult pertussis immunization strategies during a 10-year interval, estimating the incidence of pertussis (from prospective studies) to be 450 to 507 cases per 100,000 population. Universal immunization of adolescents was cost-saving to society when the Tdap and program costs were \$37 or less (2002 dollars) per adolescent immunization. Another study compared 6 potential adolescent/adult Tdap immunization strategies over the course of a lifetime for the hypothetical cohort of 4 million US adolescents and estimated the incidence of pertussis (from Massachusetts surveillance data) to be 155 per 100,000 for adolescents and 11 per 100,000 for adults. The study assumed a Tdap immunization cost of \$25 per person immunized (i.e., an incremental cost of \$15 for Tdap over Td). In this model, immunizing all adolescents would cost \$1100 per pertussis case prevented or \$20,000 per quality-adjusted life-year saved (in 2004 dollars). In a sensitivity analysis, this study estimated that universal adolescent

Tdap would be cost-saving to society if the incidence of adolescent and adult pertussis was at least 4 times greater than their base case estimates (which would be similar to the first study's base case estimates).

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of the evidence (I-III) are given at the end of the "Major Recommendations" field.

Routine Adolescent Immunization with Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) Vaccine

1. Adolescents 11 to 18 years of age should receive a single dose of Tdap instead of tetanus and diphtheria toxoids (Td) vaccine for booster immunization against tetanus, diphtheria, and pertussis if they have completed the recommended childhood diphtheria, tetanus, and pertussis (DTP)/diphtheria and tetanus toxoids and acellular pertussis (DTaP) immunization series* and have not received Td; the preferred age for Tdap immunization is 11 to 12 years **(both evidence grade I)**.

*Note: Five doses of DTP/DTaP before the seventh birthday; if dose 4 was administered on or after the fourth birthday, dose 5 was not required. Children who begin the tetanus and diphtheria immunization series at 7 years of age or older required 3 doses of Td to complete the primary series.

2. Adolescents 11 to 18 years of age who received Td but not Tdap vaccine are encouraged to receive a single dose of Tdap to provide protection against pertussis if they completed the recommended childhood DTP/DTaP immunization series (see note above) **(evidence grade I)**. An interval of at least 5 years between Td and Tdap immunization is suggested to reduce the risk of local and systemic reactions after Tdap immunization. However, Tdap can be given at shorter intervals, particularly in settings of increased risk of pertussis (see "Adolescent Immunization With Tdap Vaccine in Special Situations" in this summary), because benefits of protection from pertussis outweigh possible increased local and systemic reactions **(evidence grade II-3)**. The safety of intervals as short as approximately 2 years between Td and Tdap is supported by a Canadian study of children and adolescents.
3. Health care professionals should administer Tdap and tetravalent meningococcal conjugate vaccine (MCV4) vaccines to adolescents 11 to 18 years of age during the same visit if both vaccines are indicated **(evidence grade I, Td and MCV4)** (Committee on Infectious Disease, American

Academy of Pediatrics Committee on Infectious Diseases, 2005). If simultaneous immunization is not feasible, MCV4 and Tdap vaccine can be administered using either sequence. The AAP suggests a minimum interval of 1 month between Tdap and MCV4 (**evidence grade III**).

Dosage and Administration

The dose of Tdap (Boostrix or Adacel) is 0.5 mL, administered intramuscularly. The deltoid muscle of the upper arm generally should be used.

Interchangeable Use of Tdap Products

A single dose of either Boostrix or Adacel may be administered to adolescents who have or have not completed the childhood DTP/DTaP immunization series regardless of the type or manufacturer of DTP/DTaP vaccines used to complete childhood immunization.

Simultaneous Immunization With Tdap and Other Vaccines

Administering all indicated vaccines during a single visit increases the likelihood that adolescents will receive each of the immunizations on schedule. Each vaccine should be administered by using a separate syringe at different anatomic sites. Some experts recommend administering no more than 2 injections per deltoid, separated by 1 inch during 1 visit.

Adolescent Immunization With Tdap Vaccine in Special Situations

Only 1 dose of Tdap should be administered to an adolescent. In most special situations, a single dose of Tdap is preferred to Td. Simultaneous administration of Tdap and MCV4, as well as a 5-year or greater interval between Td and Tdap, may limit the risk of increased local injection-site reactions. In certain settings, benefits of immunization to protect against disease outweigh risks of reactions.

Situations of Increased Risk of Acquiring Pertussis

4. Adolescents 11 to 18 years of age are encouraged to receive a single dose of Tdap, if they previously have not received Tdap, during situations of increased risk of acquiring pertussis even if they have received Td within 5 years. Situations of increased risk of acquiring pertussis include living in a community in which there is an increased rate of pertussis or an outbreak or having close direct contact with a case of pertussis, such as in a family, residential facility, a school, or school-related activity.

Situations of Increased Risk of Complications From Pertussis

5. Adolescents 11 to 18 years of age are encouraged to receive a single dose of Tdap, if they previously have not received Tdap, if they or their close contacts have increased risk of complications from pertussis even if they have received Td within 5 years. Situations of increased risk from pertussis include (1) having an underlying medical condition for which pertussis would have increased morbidity or possible mortality (e.g., neurologic, muscular, or

cardiac disorder; airway or pulmonary disorder) and (2) having close contact (e.g., household member or out-of-home caregiver) with an infant younger than 12 months of age.

Tetanus Prophylaxis in Wound Management

6. Adolescents 11 to 18 years of age who require tetanus toxoid vaccine as part of wound management (American Academy of Pediatrics (AAP), 2003) should receive a single dose of Tdap instead of Td if they have not previously received Tdap. A history of earlier MCV4 immunization should not be factored into management decisions for wound prophylaxis.
 - MCV4 should be given concurrently with Tdap vaccine, if feasible, if not given previously.
 - If Tdap is not available or if Tdap was administered more than 5 years previously, adolescents who need a tetanus toxoid vaccine as part of wound management should receive Td vaccine; tetanus toxoid (TT) can be administered if Td is not available or the adolescent has a contraindication or precaution to Td.
 - A thorough attempt must be made to determine if an adolescent has completed the 3-dose primary immunization series against tetanus. Persons with unknown or uncertain tetanus-immunization histories should be considered to have had no previous doses of a tetanus toxoid-containing vaccine (see "History of Incomplete DTP/DTaP/DT or Td Immunization" in this summary).
 - Persons who have not completed the primary series may require a tetanus toxoid-containing vaccine and passive immunization with tetanus immune globulin at the time of wound management. If tetanus immune globulin and a tetanus toxoid-containing vaccine are both indicated, each product should be administered using a separate syringe at different anatomic sites.

History of Pertussis

7. Adolescents 11 to 18 years of age who have a history of pertussis generally should receive Tdap according to the routine recommendation. The duration of protection after *Bordetella pertussis* infection is unknown (waning may begin as early as 7 years after infection), and the diagnosis of pertussis can be difficult to confirm, particularly with test results other than a positive culture for *B pertussis* (Wendelboe et al., 2005). Administering pertussis vaccines to persons with a history of pertussis presents no theoretic safety concerns.

History of Receipt of DT or Td but Incomplete Pertussis Immunization

8. Adolescents 11 to 18 years of age who received DT or Td vaccine(s) instead of 1 or more doses of DTP/DTaP vaccine(s) generally should receive a single dose of Tdap vaccine to provide protection against pertussis if they completed the recommended childhood immunization series for tetanus and diphtheria toxoids* and have no contraindication to a pertussis vaccine. In routine situations, an interval of at least 5 years between the most recent Td dose and Tdap vaccine is suggested (see "Situations of Increased Risk of Acquiring

Pertussis" and "Situations of Increased Risk of Complications From Pertussis" in this summary).

*Note: Five doses of DTP/DTaP before the seventh birthday; if dose 4 was administered on or after the fourth birthday, dose 5 was not required. Children who begin the tetanus and diphtheria immunization series at 7 years of age or older required 3 doses of Td to complete the primary series.

History of Incomplete DTP/DTaP/DT or Td Immunization

9. Adolescents 11 to 18 years of age who have never been immunized against tetanus, diphtheria, or pertussis should receive a series of 3 tetanus and diphtheria toxoid-containing vaccines, 1 of which is Tdap. The preferred schedule is a single Tdap dose, followed by a dose of Td vaccine 4 weeks or more after the Tdap dose, and a second dose of Td vaccine 6 to 12 months after the Td dose. Tdap may substitute for any 1 of the 3 doses in the series. Adolescents who received other incomplete immunization schedules against tetanus and diphtheria should be immunized with Tdap and/or Td according to catch-up recommendations (AAP, 2003). A single dose of Tdap may be used to substitute for any 1 of the Td doses.

History of Receipt of DTP/DTaP/DT or Td Vaccine but Incomplete Records

10. In situations in which adolescents 11 to 18 years of age are likely to have received immunization against tetanus and diphtheria but cannot produce records, health care professionals can obtain serologic testing for antibodies to tetanus and diphtheria toxoids to avoid unnecessary immunizations. If antitetanus and antidiphtheria toxoid concentrations are each ≥ 0.1 IU/mL, previous immunization with tetanus and diphtheria toxoid-containing vaccines is presumed, and a single dose of Tdap vaccine is indicated; this Tdap dose is considered the adolescent booster dose.

Pregnancy

11. Pregnancy is not a contraindication to Tdap (or Td) immunization. The AAP recommends that pregnant adolescents be given the same considerations for immunization as nonpregnant adolescents. If Tdap or Td vaccine is indicated, administration in the second or third trimester (before 36 weeks of gestation) is preferred, when feasible, to minimize a perception of an association of immunization with adverse pregnancy outcomes, which are more common during the first trimester. No evidence exists of a risk of immunizing pregnant women with inactivated bacterial vaccines or toxoids or inactivated viral vaccines ("Use of diphtheria," 2000). Both Tdap and Td vaccines are categorized as pregnancy category C agents by the Food and Drug Administration (FDA). FDA-acceptable well-controlled human studies and animal reproduction studies have not been conducted for Tdap (FDA, "Product approval information: Boostrix™ licensing action," "Product approval information: Adacel™ licensing action", 2005). Because of lack of data on use of Tdap vaccine in pregnant women, both Tdap manufacturers have established pregnancy registries for women immunized with Tdap during pregnancy. Health care professionals are encouraged to report Tdap

immunization during pregnancy (Boostrix, GlaxoSmithKline Biologicals, 888-825-5249; or Adacel, Sanofi Pasteur, 800-822-2463).

Health care professionals should consider immunizing adolescents 11 to 18 years of age as soon as feasible in the immediate postpartum period, if the adolescent has not previously received Tdap, to reduce the risk of becoming infected and then transmitting pertussis to the infant (see "Situations of Increased Risk of Complications From Pertussis" in this summary). Protection of the adolescent mother against pertussis may develop 1 to 2 weeks after immunization. AAP recommendations for use of Tdap vaccines in pregnant adolescents may differ from those of the CDC.

Lack of Availability of Tdap or MCV4

12. If Tdap (or Td) vaccine and MCV4 are both indicated for adolescents but only 1 vaccine is available, the available vaccine generally should be administered and the other administered when the missed vaccine becomes available. If simultaneous immunization is not feasible, the AAP suggests a minimum interval of 1 month between administration of Tdap and MCV4.

Use of Td When Tdap Is Not Available

13. Health care professionals should administer a dose of Td when Tdap is indicated but not available if the last DTP/DTaP/DT/Td dose was administered 10 or more years earlier. After completion of childhood DTaP/DTP immunization, most adolescents are adequately protected against tetanus and diphtheria for at least 10 years. Immunization can be deferred temporarily when the last tetanus- and diphtheria-containing vaccine was administered less than 10 years earlier and the adolescent is likely to return for follow-up. If immunization is deferred, health care professionals should maintain a system to recall the adolescent when vaccine becomes available or should refer the adolescent to another facility for immunization.

Children 7 to 10 Years of Age With History of Incomplete Childhood DTP/DTaP Immunization

14. Neither Tdap vaccine is licensed for use in children younger than 10 years of age. Boostrix is licensed for children beginning at 10 years of age, (FDA, "Product approval information: Boostrix™ licensing action," 2005) and Adacel is licensed for children beginning at 11 years of age (FDA, "Product approval information: Adacel™ licensing action," 2005). Children 7 through 9 years of age who never received any pediatric DTP/DTaP/DT or Td dose generally should receive 3 doses of Td: dose 2 is administered 4 weeks or more after dose 1, and dose 3 is administered 6 to 12 months or longer after dose 2. A 10-year-old child could receive Boostrix for 1 of these doses. A single dose of Tdap is recommended for adolescents 11 to 18 years of age who have completed a 3-dose Td series if the series did not include Boostrix during the 10th year; an interval of at least 5 years between the most recent Td dose and Tdap is suggested (see "Situations of Increased Risk of Acquiring Pertussis" and "Situations of Increased Risk of Complications From Pertussis" in this summary). Children 7 to 10 years of age who received other incomplete immunization schedules against tetanus, diphtheria, and pertussis

should be immunized against tetanus and diphtheria according to catch-up recommendations (AAP, 2003) using an all-Td schedule (except children in their 10th year, who could receive a single dose of Boostrix substituted for 1 dose of Td).

Children with no history or an incomplete history of pediatric DTP/DTaP/DT or Td immunization could have received doses. Health care professionals can obtain serologic testing for antibodies against tetanus and diphtheria toxoids in these children. If tetanus and diphtheria toxoid antibody concentrations are each protective at ≥ 0.1 IU/mL, then the child can be presumed to have been immunized against tetanus, diphtheria, and possibly pertussis, and Td immunization may be deferred until the child is 11 to 12 years of age, when Tdap vaccine should be given.

Inadvertent Administration of Tdap or Pediatric DTaP Vaccine

15. Tdap vaccine is not indicated for children younger than 10 years of age. The family should be informed of any error in vaccine administration. If Tdap vaccine is administered inadvertently instead of DTaP to a child younger than 7 years of age as the first, second, or third dose of the immunization series, the Tdap dose should not be counted and DTaP should be given on the same day or as soon as possible, to keep the child on schedule for all vaccines. The remaining doses of the DTaP series should be administered on the usual schedule. If Tdap vaccine is administered inadvertently instead of DTaP to a child younger than 7 years of age as the fourth or fifth dose in the series, the dose should be counted as valid. If Tdap was administered as the fourth dose, the child should receive a fifth dose of the series using DTaP vaccine on the usual schedule. The routine recommendations for adolescent Tdap immunization would apply to children who inadvertently received Tdap instead of DTaP vaccine at an age younger than 7 years.

If Tdap is administered inadvertently instead of Td vaccine to a child 7 to 9 years of age, the Tdap dose should be counted as the adolescent Tdap booster. The child should receive a vaccine containing tetanus and diphtheria toxoids 10 years after the inadvertent Tdap dose.

DTaP is not indicated for people 7 years of age or older. If DTaP is administered inadvertently to a child 7 years of age or older or to an adolescent, the dose should be counted as the adolescent Tdap booster. The child or adolescent should receive a vaccine containing tetanus and diphtheria toxoids 10 years after the inadvertent DTaP dose.

Individuals Older Than 18 Years and Adults

16. To maintain protection against tetanus and diphtheria, the CDC has recommended decennial Td boosters for adults, beginning 10 years after the adolescent dose ("Immunization of adolescents," 1996). The safety and immunogenicity of 1 Tdap (Adacel) as a single booster immunization against tetanus, diphtheria, and pertussis have been demonstrated for people 19 to 64 years of age (FDA, "Product approval information: Adacel™ licensing action," 2005). CDC recommendations for the use of Tdap (Adacel) in persons older than 18 years will be published.

Contraindications and Precautions for Tdap and Td Vaccine Use

Contraindications to Administration of Tdap or Td

- Tdap or Td is contraindicated among people with a history of serious allergic reaction (i.e., anaphylaxis) to any component of the vaccines. Because of the importance of tetanus immunization, individuals with a history of anaphylaxis to components included in all Tdap and Td vaccines should be referred to an allergist to determine if they have a specific allergy to tetanus toxoid, can be desensitized to tetanus toxoid, and can safely receive tetanus toxoid vaccine.
- Tdap is contraindicated among people with a history of encephalopathy (e.g., coma, prolonged seizures) within 7 days of administration of a pertussis vaccine that is not attributable to another identifiable cause. These people should receive Td instead of Tdap.

Precautions to Administration of Tdap or Td or Both Vaccines

A precaution is a condition in a recipient that might increase the risk of a serious reaction. In these situations, health care professionals should evaluate the risks and benefits of administering Tdap or Td. Precautions include the following.

- Guillain-Barré syndrome 6 weeks or less after the previous dose of a tetanus toxoid vaccine. If a decision is made to continue tetanus toxoid immunization, Tdap is preferred if otherwise indicated.
- Progressive neurologic disorder, uncontrolled epilepsy, or progressive encephalopathy until the condition has stabilized. This precaution is for vaccines with pertussis components. If a decision is made to withhold pertussis immunization, Td may be used instead of Tdap.

Deferral of Administration of Tdap or Td or Both Vaccines

Reasons for deferral include the following.

- Moderate or severe acute illness with or without fever: immunization should be deferred until the acute illness resolves.
- History of a severe Arthus hypersensitivity reaction after a previous dose of a tetanus and diphtheria toxoid-containing vaccine or a diphtheria toxoid vaccine that does not contain tetanus toxoid, such as MCV4 (which contains diphtheria toxoid as a carrier protein); if a true Arthus reaction is likely, vaccine providers should defer Tdap or Td immunization for at least 10 years after the tetanus or diphtheria toxoid-containing vaccine. If the Arthus reaction was associated with a vaccine that contained diphtheria toxoid without tetanus toxoid, deferring Tdap or Td vaccine might leave the adolescent inadequately protected against tetanus. In this situation, if the last tetanus toxoid vaccine was administered 10 or more years earlier, providers may administer tetanus toxoid vaccine or consider measuring tetanus antibody concentrations to evaluate the need for tetanus immunization; tetanus antibody concentrations of ≥ 0.1 IU/mL are considered protective.

Conditions That Are Not Contraindications or Precautions to Administration of Tdap

The following conditions are not contraindications or precautions for Tdap. Adolescents with these conditions can receive a dose of Tdap if otherwise indicated. The first 4 conditions listed are precautions for pediatric DTaP/DTP but are not contraindications or precautions for Tdap immunization in adolescents.

- Temperature ≥ 105 degrees F (≥ 40.5 degrees C) within 48 hours after DTP/DTaP immunization not attributable to another cause
- Collapse or shock-like state (hypotonic hyporesponsive episode) within 48 hours after DTP/DTaP immunization
- Persistent crying lasting 3 hours or longer occurring within 48 hours after DTP/DTaP immunization
- Convulsions with or without fever, occurring within 3 days after DTP/DTaP immunization
- History of entire or extensive limb swelling (ELS) reaction after pediatric DTP/DTaP or Td immunization that was not an Arthus hypersensitivity reaction
- Stable neurologic disorder, including well-controlled seizures, history of seizure disorder, and cerebral palsy
- Brachial neuritis
- Latex allergy other than anaphylactic allergies (e.g., a history of contact to latex gloves) (The tip and rubber plunger of the Boostrix needleless syringe contain latex; this Boostrix product should not be administered to adolescents with a history of a severe [anaphylactic] allergy to latex but may be administered to people with less severe allergies [e.g., contact allergy to latex gloves]. The Boostrix single-dose vial and Adacel preparations do not contain latex.)
- Pregnancy
- Breastfeeding
- Immunosuppression, including people with human immunodeficiency virus infection (Tdap poses no known safety concern for immunosuppressed people; the immunogenicity of Tdap in people with immunosuppression has not been studied and could be suboptimal)
- Intercurrent minor illness
- Antibiotic use

Reporting of Adverse Events After Immunization

As with any newly licensed vaccine, surveillance for rare adverse events associated with administration of Tdap vaccine is important for assessing safety in large-scale use. The National Childhood Vaccine Injury Act of 1986 requires health care professionals to report specific adverse events that follow tetanus, diphtheria, or pertussis immunization. All clinically significant adverse events should be reported to Vaccine Adverse Event Reporting System (VAERS) (National Vaccine Advisory Committee, 2003) even if a causal relationship to immunization is uncertain. VAERS reporting forms and information are available on the Internet at <http://vaers.hhs.gov> or by calling 800-822-7967. Web-based reporting is available, and health care professionals are encouraged to report electronically to promote better timeliness and quality of safety data.

Vaccine Injury Compensation

Refer to the original guideline document for details.

Definitions:

US Preventive Services Task Force Rating System of Quality of Scientific Evidence

I: Evidence obtained from at least 1 properly designed, randomized, controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferentially from more than 1 center or group

II-3: Evidence obtained from multiple time series with or without the intervention or dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s)

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (See the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Prevention of pertussis among adolescents
- Indirect benefit also is likely to extend to unimmunized peers and other age groups.

POTENTIAL HARMS

Three types of local adverse events can follow tetanus-diphtheria-pertussis immunization: (1) typical reactions (local pain, redness, and induration, sometimes associated with fever, headache, and other systemic symptoms); (2)

entire or extensive limb swelling (ELS); and (3) Arthus type III hypersensitivity reactions.

See the "Major Recommendations" field for additional precautions.

CONTRAINDICATIONS

CONTRAINDICATIONS

See the "Major Recommendations" field for contraindications.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics, Committee on Infectious Diseases. Prevention of pertussis among adolescents: recommendations for use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine. Pediatrics 2006 Mar;117(3):965-78. [58 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Mar

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee on Infectious Diseases, 2005-2006: Keith R. Powell, MD, *Chairperson*; Robert S. Baltimore, MD; Henry H. Bernstein, DO; Joseph A. Bocchini, Jr, MD; John S. Bradley, MD; Michael T. Brady, MD; Penelope H. Dennehy, MD; Robert W. Frenck, Jr, MD; David W. Kimberlin, MD; *Sarah S. Long, MD; Julia A. McMillan, MD; Lorry G. Rubin, MD

Liaisons: Richard D. Clover, MD, American Academy of Family Physicians; Stephen L. Cochi, MD, Centers for Disease Control and Prevention; Joanne Embree, MD, Canadian Paediatric Society; Marc A. Fischer, MD, Centers for Disease Control and Prevention; Mamodikoe Makhene, MD, National Institutes of Health; Douglas R. Pratt, MD, Food and Drug Administration; Benjamin Schwartz, MD, National Vaccine Program Office; Jeffrey R. Starke, MD, American Thoracic Society; Jack Swanson, MD, Practice Action Group

Ex Officio: Larry K. Pickering, MD, Red Book Editor

Consultant: Edgar O. Ledbetter, MD

Staff: Alison Siwek, MPH

* Lead author

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Academy of Pediatrics \(AAP\) Policy Web site](#).

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 3, 2006. This summary was verified by the guideline developer on April 11, 2006. This summary was updated by ECRI on October 25, 2006 following the U.S. Food and Drug Administration (FDA) advisory on Menactra (Meningococcal Conjugate Vaccine).

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions. Please contact the Permissions Editor, American Academy of Pediatrics (AAP), 141 Northwest Point Blvd, Elk Grove Village, IL 60007.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 11/3/2008

