

VACCINE ADVISORY

From the Texas Department of State Health Services Immunization Branch

The goal of the Vaccine Advisory is to disseminate, in a timely manner, practical information related to vaccines, vaccine-preventable diseases, and the vaccine programs managed by the Immunization Branch. The Immunization Branch welcomes readers' input to improve the contents of this document.

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<http://www.dshs.state.tx.us/immunize/vacadvise/default.shtm>

October 26, 2006

Advisory No. 3. The combined tetanus, diphtheria, and acellular pertussis (Tdap) vaccine

- ⇒ On June 30, 2005 the Advisory Committee on Immunization Practices (ACIP) voted to recommend the routine use of Tetanus and Diphtheria Toxoids and Acellular Pertussis (Tdap) vaccines in **adolescents aged 11–18 years** in place of tetanus and diphtheria toxoids (Td) vaccines. Complete recommendations were published on March 24, 2006.
- ⇒ On June 30, 2006 the ACIP voted to recommend that **pregnant women** who previously have not received a dose of Tdap – including women (adolescents 11-18 years and adults 19-64 years of age) who are breastfeeding – should receive Tdap after delivery, before discharge from the hospital or birthing center, if two years or more have elapsed since the last Td in most situations. If Tdap cannot be administered before discharge, it should be given as soon as feasible. Provisional recommendations were issued on June 20, 2006.
- ⇒ On October 26, 2005 the ACIP voted to recommend routine use of a single dose of Tdap for **adults 19–64 years of age** to replace the next booster dose of tetanus and diphtheria toxoids vaccine (Td). The ACIP also recommended Tdap for adults who have close contact with infants <12 months of age. Provisional recommendations were issued on March 2, 2006.

This advisory contains:

- ⇒ Background information
- ⇒ The link to the Centers for Disease Control (CDC) Morbidity and Mortality Weekly Report containing the complete Tdap recommendations for adolescents
- ⇒ Summary of ACIP's provisional recommendations for the Tdap vaccine for adults
- ⇒ Summary of ACIP's provisional recommendations for the Tdap vaccine for pregnant women
- ⇒ Texas Vaccines for Children Program

- ⇒ ImmTrac
- ⇒ Texas school and day care facilities requirements for the Tdap vaccine
- ⇒ Reporting vaccine adverse events
- ⇒ Surveillance and epidemiology
- ⇒ Additional resources

1) Background

Pertussis is a highly contagious respiratory tract infection. Although most children are protected against pertussis by vaccination during childhood, immunity wanes over time and leaves adolescents and adults unprotected. During spring 2005, two tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) products formulated for use in adolescents and, for one product, use in adults, were licensed in the United States: Boostrix® from GlaxoSmithKline Biologicals is licensed for use in persons aged 10–18 years, and Adacel™ from Sanofi Pasteur was licensed for use in persons aged 11–64 years. The ACIP subsequently recommended routine use of a single dose of Tdap for adolescents and adults.

2) Summary of ACIP Recommendations

Adolescents

The ACIP recommendations for adolescents are summarized as follows:

- Adolescents aged 11–18 years should receive a single dose of Tdap instead of Td for booster immunization against tetanus, diphtheria, and pertussis if they have completed the recommended childhood DTP/DTaP vaccination series and have not received Td or Tdap. The preferred age for Tdap vaccination is 11–12 years. If Tdap is not available, Td should be administered.
- Adolescents who received Td, but not Tdap, are encouraged to receive a single dose of Tdap to provide protection against pertussis if they have completed the recommended childhood DTP/DTaP vaccination series. An interval of at least 5 years between Td and Tdap is encouraged to reduce the risk for local and systemic reactions after Tdap vaccination. However, an interval less than 5 years between Td and Tdap can be used.
- 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, Td should be administered.
- Adolescents who have a history of pertussis generally should receive Tdap according to the routine recommendations.
- Adolescents who have no history of receiving tetanus-diphtheria-pertussis vaccination (DTP/DTaP, Td/ Tdap) 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 Td dose. Tdap may substitute for any **one** of the 3 Td doses in the series.

- Adolescents who have not received pertussis vaccines but completed the recommended tetanus-diphtheria vaccination series with pediatric DT or Td generally should receive Tdap according to the routine recommendations if they do not have a contraindication to the pertussis components.

For the ACIP's final recommendations for adolescents, please visit http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e223a1.htm?s_cid=rr55e223a1_e

Adults

The ACIP has made provisional recommendations for adults 19-64 years of age who have not received Tdap previously and are summarized below:

- Adults should receive a single dose of Tdap to replace a single dose of Td for booster immunization against tetanus, diphtheria, and pertussis if they received the last dose of tetanus toxoid-containing vaccine ≥ 10 years earlier.
- Tdap may be given at an interval shorter than 10 years since receipt of the last dose of tetanus toxoid-containing vaccine to protect against pertussis. The safety of an interval as short as approximately 2 years between administration of Td and Tdap is supported by a Canadian study of children and adolescents. The dose of Tdap replaces the next scheduled booster dose of Td.
- Adults who have or who anticipate having close contact with an infant <12 months of age (e.g., parents, grandparents <65 years of age, childcare providers, healthcare workers) should receive a single dose of Tdap. An interval of 2 years or more since the last dose of tetanus toxoid-containing vaccine is suggested; a shorter interval can be used.

For ACIP's **provisional recommendations** for the Tdap vaccine for adults, please visit http://www.cdc.gov/nip/recs/provisional_rec/default.htm.

Pregnant women

The ACIP has made provisional recommendations for use of Td and Tdap in pregnant women (adolescents 11-18 years and adults 19-64 years of age), as follows:

- Pregnant women who previously have not received a dose of Tdap (including women who are breastfeeding) should receive Tdap after delivery, before discharge from the hospital or birthing center, if 2 years or more have elapsed since the last Td; shorter intervals can be used. If Tdap cannot be administered before discharge, it should be given as soon as feasible. The dose of Tdap replaces the next Td booster at ten years.
- To provide protection against pertussis in addition to tetanus and diphtheria, health-care providers can defer the Td vaccination if sufficient tetanus protection is likely, and vaccinate the postpartum woman with Tdap instead before discharge. Sufficient tetanus protection is likely if:
 1. The pregnant woman is younger than 30 years of age and has received a complete childhood immunization series* and at least one Td booster during adolescence or as an adult.

2. The pregnant woman is older than 30 years of age and has received a complete childhood immunization series* *and* at least two Td booster doses.
3. The pregnant woman has a protective level of serum tetanus antitoxin (0.1/ml or more by Elisa).

*The complete childhood immunization series consists of 4 or 5 doses of pediatric DTP, DTaP or DT. A primary series consisting of 3 doses of Td or tetanus toxoid (TT) administered during adolescence or as an adult substitutes for the childhood series of immunization.

The provisional recommendations address further considerations regarding the choice of Td and Tdap. Providers caring for pregnant women are advised to review the provisional recommendations in their entirety. These can be found at http://www.cdc.gov/nip/recs/provisional_rec/default.htm.

What is the difference between **provisional** and **final** recommendations? **Provisional** recommendations of the ACIP have yet to be officially approved by the Department of Health and Human Services (HHS) and CDC. The ACIP voted for these recommendations; however, these are under review by the Director of CDC and HHS. The recommendations will become official (thus called **final** or **complete**) when published in CDC's Morbidity and Mortality Weekly Report (MMWR). To view current provisional recommendations, go to: http://www.cdc.gov/nip/recs/provisional_rec/default.htm. And to view final recommendations, go to: <http://www.cdc.gov/nip/publications/acip-list.htm>.

ACIP recommendations are not updated annually, but as new data dictate.

3) Texas Vaccines for Children program

The Tdap vaccine has also been added to the Texas Vaccines for Children Program (TVFC). There are two Tdap products licensed for use: BOOSTRIX®, manufactured by GlaxoSmithKline Biologicals licensed for ages 10-18 years; and ADACEL™, manufactured by sanofi pasteur licensed for persons 11 through 64 years of age.

Regional and local health departments that provide safety net vaccinations for adults may order ADACEL™ for anyone 19 years of age or older.

Private TVFC providers may not immunize adults 19 years and older. However, private TVFC providers should use Tdap to vaccinate adolescents 11-18 years of age.

Tdap vaccine may be ordered using the TVFC Biological Order Form (C-68). The number of doses requested should be consistent with prior orders for the Td booster. Inventory and usage should be submitted monthly along with other vaccines using the Monthly Biological Report (C-33). Both of these forms have been revised to include Tdap.

Although Tdap is replacing the use of Td in TVFC offices, a few doses of Td should be retained for adolescents who have no history of receiving tetanus-diphtheria-pertussis vaccination, patients that have a contraindication to pertussis vaccine, and children between seven and 10 years of age not indicated for the Diphtheria, Tetanus, and Pertussis (DTaP) or Tdap vaccines.

For Medicaid billing purposes, the CPT code for Tdap is 90715.

4) ImmTrac

ImmTrac users can report Tdap vaccines administered using the ImmTrac code: "Tdap." Although ImmTrac can record Tdap vaccine doses administered, and doses will be reflected on the client immunization history, the ImmTrac immunization scheduler will not generate recommendations for Tdap at this time. Providers should consult ACIP recommendations to determine when administration of Tdap is recommended. For more information about ImmTrac, please refer to: www.ImmTrac.com.

5) Texas school requirements for the Tdap vaccine

Tdap can be given in lieu of Td vaccination. However, pertussis vaccine is not currently required for adolescents.

6) Epidemiology and Surveillance

In 2005, the US incidence of pertussis was 8.7 cases per 100,000 population (total of 25,616 cases were reported); the Texas incidence was 9.89 cases per 100,000 population (total of 2,224 cases were reported). A total of 35 infants younger than four months of age died from pertussis in the US, eight of these were from Texas. In the US, fifty percent of the pertussis cases occurred among persons 10 years and older. In TX, forty-eight percent of pertussis cases occurred among persons 10 years of age and older.

7) Reporting adverse vaccine events

Clinically significant adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Adverse events from privately purchased vaccine may be reported directly to VAERS at <http://vaers.hhs.gov/>. Secure web-based reporting is available on the VAERS website. Contact 800-VAC-RXNS for forms and information.

A copy of the VAERS form is also available in the Texas Vaccines for Children toolkit. To request a VAERS form or additional information, call the VAERS contact in your area:

- **In Texas:** 800.252.9152
- **For Bexar County:** 210.207.2087
- **For City of Houston:** 713.558.3518

8) Resources (Vaccines)

American Academy of Pediatrics' Policy Statement: *Prevention of Pertussis Among Adolescents: Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) Vaccine.* <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;117/3/965>

Boostrix® package insert (pdf file)

<http://www.boostrix.com/dtc/resources.html>

ADACEL™ package insert (pdf file)

www.fda.gov/cber/label/tdapave061005LB.pdf

Tdap Vaccine Information Statement:

<http://www.cdc.gov/nip/publications/VIS/default.htm#tdap>

The DSHS Addendum to Tdap VIS is available at:

<http://www.dshs.state.tx.us/immunize/vischart.shtm> (Scroll down to number 21)

The National Immunization Program: <http://www.cdc.gov/nip/vaccine/tdap/default.htm>

9) Resources (Diseases)

The National Immunization Program:

Diphtheria: <http://www.cdc.gov/nip/menus/diseases.htm#dip>

Pertussis: <http://www.cdc.gov/nip/menus/diseases.htm#pertussis>

Tetanus: <http://www.cdc.gov/nip/menus/diseases.htm#tetanus>

DSHS Infectious Disease Control Unit pertussis webpage (includes reporting information):

<http://www.dshs.state.tx.us/idcu/disease/pertussis/>

DSHS Infectious Disease Control Unit diphtheria webpage (includes reporting information):

<http://www.dshs.state.tx.us/idcu/disease/diphtheria/>

DSHS Infectious Disease Control Unit webpage (includes reporting information):

<http://www.dshs.state.tx.us/idcu/disease/tetanus/>

We hope you generously forward this advisory to others who may benefit from this information.

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