Revisions as of February 22, 2013<sup>1</sup> are based on ACIP recommendations from their 10/24/12 meeting.

- Tdap (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis) should be administered to pregnant women with every pregnancy irrespective of previous Tdap history (Section III-D. p 3 and Section IV-table C, p 6).
- Optimal timing for Tdap administration is at 27–36 weeks’ gestation.

<sup>1</sup>Available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm)

### I. Order:

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥11 years for contraindications.
3. Provide an Adolescent Well Visit Flyer to those 11—18 years of age.
4. Provide a current Vaccine Information Sheet (VIS) answering any questions.
5. Obtain a signed Vaccination Administration Record (VAR)
6. Give 0.5 ml of any tetanus, diphtheria, or pertussis-containing vaccine intramuscularly (IM).
   - a. The deltoid muscle of the upper arm should generally be used.
   - b. May be given simultaneously with all routine childhood and adult vaccines according to age and immunization status of recipient.

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**Immunizing Pharmacist Signature**

**Date**

For multiple signatures see: [http://1.usa.gov/PharmacyImmunizationProtocols](http://1.usa.gov/PharmacyImmunizationProtocols)

Revised: 02-22-2013
Reviewed: 12-2013
Original: 06-2005
### II. LICENSED SPECIFIC VACCINES

#### A. LICENSED COMBINATION Td VACCINE

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decavac™&lt;sup&gt;1&lt;/sup&gt; (sanofi pasteur)</td>
<td>Tetanus &amp; diphtheria toxoids</td>
<td>≥7 years</td>
<td>Trace in multi-dose vials &lt;0.3 µg/0.5 ml Not in Single-dose vials</td>
</tr>
<tr>
<td>Tenivac™&lt;sup&gt;1,2&lt;/sup&gt; (sanofi pasteur)</td>
<td>Tetanus &amp; diphtheria toxoids</td>
<td>≥7 years</td>
<td>No</td>
</tr>
</tbody>
</table>

#### B. LICENSED COMBINATION Tdap VACCINE<sup>3</sup>

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boostrix®&lt;sup&gt;4&lt;/sup&gt; (GSK)</td>
<td>Tetanus toxoid Diphtheria toxoid Acellular pertussis</td>
<td>≥10 years Off-label use</td>
<td>≥7 years&lt;sup&gt;5,6&lt;/sup&gt; No</td>
</tr>
<tr>
<td>Adacel™&lt;sup&gt;4&lt;/sup&gt; (sanofi Pasteur)</td>
<td>Tetanus toxoid Diphtheria toxoid Acellular pertussis</td>
<td>&gt;11–64 years</td>
<td>≥7 years&lt;sup&gt;5,6&lt;/sup&gt; No</td>
</tr>
</tbody>
</table>

<sup>1</sup>Available in a 0.5 ml single-dose syringe or vial.
<sup>2</sup>Td vaccines are interchangeable as long as age requirements are met as well as formulation specific intervals between doses.
<sup>3</sup>Tdap products are interchangeable as long as age requirements are met for each vaccine. Note that neither vaccine is licensed for use in children <10 years of age.
<sup>4</sup>Licensed only for a single dose at this time.
<sup>5</sup>Off-label age range. Currently Boostrix® is FDA-licensed for persons ≥10 years of age and Adacel® for persons 11–64 years of age; however, ACIP has endorsed the use of a single dose of these vaccines in all persons ≥7 years of age who have not been fully immunized against pertussis.
<sup>6</sup>ACIP recommends that Tdap should be administered to pregnant women with every pregnancy irrespective of previous Tdap history. (2012)
III. RECOMMENDATIONS FOR USE

A. To provide protection against pertussis, (especially in infants <12 months of age), persons ≥10 years of age who have not received Tdap should receive a single dose of Tdap at the first opportunity, regardless of whether and when they have received a Td booster.\(^1,2\)

B. Persons ≥7 years old without documentation of a childhood DTaP schedule or for whom vaccination status isn’t known should receive a series of 3 doses of an adult Td-containing vaccine. If the person is ≥7 years old and has not been fully immunized against pertussis, one (and only one) of these 3 doses should be Tdap - preferably the first dose.

C. If the person is ≥7 years old and has not been fully immunized against pertussis (i.e., did not complete a series of pertussis-containing vaccine before their seventh birthday), one (and only one) of the remaining Td-containing doses should be Tdap, which can be administered off-label for age. (See table IVC, p6.)

D. A dose of Tdap vaccine should be administered during each pregnancy irrespective of the patient’s prior history of receiving Tdap.
   - Optimal timing for Tdap administration in pregnant women is at 27–36 weeks’ gestation.
   - If Tdap is not administered during pregnancy, Tdap should be administered immediately post-partum.

E. All health care personnel, regardless of age, should receive a single dose of Tdap regardless of the date since their last Td dose.

F. Use Tdap for routine tetanus and diphtheria booster or wound management if no prior Tdap dose.

G. Administer Tdap (or Td) simultaneously with other vaccines when indicated and available.

\(^1\) Except as part of a primary series for children not vaccinated with DTaP, there is no recommended interval to be observed before receipt of Tdap vaccine.

\(^2\) This recommendation applies to unvaccinated adults ≥65 years of age (FDA approved for BOOSTRIX®, but either Tdap vaccine product can be used).
### IV. A. SCHEDULES FOR TETANUS, DIPHTHERIA, AND PERTUSSIS-CONTAINING VACCINES

#### A. ROUTINE Td VACCINE SCHEDULE: Dose 0.5mL IM

<table>
<thead>
<tr>
<th>Dose&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>Minimum Age</th>
<th>Recommended Age</th>
<th>Recommended Interval&lt;sup&gt;3&lt;/sup&gt;</th>
<th>Decavac&lt;sup&gt;TM&lt;/sup&gt;</th>
<th>Tenivac&lt;sup&gt;TM&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7 years</td>
<td>≥7 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2&lt;sup&gt;3&lt;/sup&gt;</td>
<td>7 years</td>
<td>≥7 years</td>
<td>4 weeks after dose #1</td>
<td>8 weeks after dose #1</td>
<td></td>
</tr>
<tr>
<td>3&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>7 years</td>
<td>≥7 years</td>
<td>6 months after dose #2</td>
<td>6 months after dose #2</td>
<td></td>
</tr>
<tr>
<td><strong>Booster Doses</strong>&lt;sup&gt;6,7,8&lt;/sup&gt;</td>
<td>10 years</td>
<td>Every 10 years</td>
<td>≥5 years from last dose of a tetanus and diphtheria-containing vaccine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup>For unvaccinated persons ≥7 years of age (including persons who cannot document prior vaccinations), the primary series is three doses.

<sup>2</sup>For retrospective checking, doses that violate the minimum interval or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated, as age-appropriate.

<sup>3</sup>While the recommended interval between dose 1 and dose 2 is 4 weeks for Decavac<sup>TM</sup> and 8 weeks for Tenivac<sup>TM</sup>, the ALERT IIS will forecast for a recommended interval of 8 weeks and a minimum interval of 4 weeks for both Td products.

<sup>4</sup>Persons ≥7 years of age who have not completed the DTP/DT/DTaP series should have previous doses counted and should complete the series using Tdap or Td.

<sup>5</sup>If the 3<sup>rd</sup> dose of a tetanus and diphtheria-containing vaccine (includes previous doses of DTaP, DTP or DT) is administered on or after the 7<sup>th</sup> birthday and the 1<sup>st</sup> dose was given ≥1 year of age, a 4<sup>th</sup> dose is not required. There is a 6-month interval between dose 2 and dose 3. If the 1<sup>st</sup> dose was given at <1 year of age, a total of 4 doses are needed for the initial series. The minimum interval between doses 3 and 4 is 6 months.

<sup>6</sup>The first booster dose may be given at 11–18 years of age if at least 5 years have elapsed since the last dose of tetanus-containing vaccine. If Tdap was part of the initial series and was given to a person ≥10 years of age, the next booster dose is due ≥10 years after the last dose of tetanus-containing vaccine.

<sup>7</sup>If a booster dose is given at a time sooner than the minimum interval but to a person at least 10 years of age, as part of wound management, the next booster should be given 10 years later.

<sup>8</sup>If ≥6 doses of a diphtheria- or tetanus-containing vaccine is given before 7 years of age, a booster is due 5 years after the 6<sup>th</sup> or last dose.
IV. B. VACCINE SCHEDULE

<table>
<thead>
<tr>
<th>Group</th>
<th>Minimum Age</th>
<th>Dose</th>
<th>Recommended Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adolescents</td>
<td>10 years⁴</td>
<td>1</td>
<td>11-18 years of age⁴</td>
</tr>
<tr>
<td>Adults⁵,⁶</td>
<td>19 years</td>
<td>1</td>
<td>≥19 years of age</td>
</tr>
</tbody>
</table>

¹ Except as part of a primary series for children not vaccinated with DTaP, there is no recommended interval to be observed before receipt of Tdap vaccine.

² A single dose of either BOOSTRIX® or ADACEL™ may be administered to adolescents who have completed the childhood DTP or DTaP vaccination series. Adolescents who have never been vaccinated against tetanus, diphtheria or pertussis should receive a series of 3 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. However, Tdap may substitute for any one (and only one) of the 3 Td doses in the series.

³ Boostrix® is labeled for use at ≥10 years of age, and its use is preferred for 10-year-olds. Although Adacel® is labeled for use at ≥11 years of age, this order authorizes its use, off label, for persons as young as 10 years of age (Medical Director, OHA Immunization Program).

⁴ Adolescents 10–18 years of age should receive a single dose of Tdap instead of Td if they have completed the recommended childhood DTP or DTaP vaccination series ≥5 years ago, and have not yet received a Td booster. If a Tdap dose is given sooner as part of wound management to a person ≥10 years of age, the next Td booster should not be administered for 10 years.

⁵ A single Tdap dose should replace the currently recommended Td vaccine that is used as the adult booster vaccine. When another tetanus and diphtheria booster is needed, Td should be administered.

⁶ Tdap should be administered with other vaccines that are indicated during the same visit when feasible.

IV. C. VACCINE SCHEDULE
## C. OFF–LABEL USE OF Tdap (recommended by ACIP)

<table>
<thead>
<tr>
<th>Group</th>
<th>Minimum Age</th>
<th>Dose</th>
<th>Booster due</th>
</tr>
</thead>
<tbody>
<tr>
<td>7–10 years of age&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>7 years</td>
<td>1</td>
<td>Td, 10 years from Tdap</td>
</tr>
<tr>
<td>≥19 years of age&lt;sup&gt;3,4&lt;/sup&gt;</td>
<td>19 years</td>
<td>1</td>
<td>Td, 10 years from Tdap</td>
</tr>
<tr>
<td>Pregnant Women&lt;sup&gt;5,6&lt;/sup&gt;</td>
<td>None</td>
<td>1</td>
<td>Tdap, during each pregnancy, at 27–36 weeks’ gestation</td>
</tr>
</tbody>
</table>

<sup>1</sup>A single dose of either Boostrix® or Adacel® may be administered to those who are not fully vaccinated against pertussis (5 doses of DTaP or 4 doses of DTaP if 4<sup>th</sup> dose was administered on or after the 4<sup>th</sup> birthday) and who have no contraindications.

<sup>2</sup>If additional doses of tetanus and diphtheria toxoid-containing vaccines are needed, then children should be vaccinated according to catch-up schedule, with Tdap preferred as the first dose.

<sup>3</sup>ACIP recommends that all adults’ age ≥19 years who have not yet received a dose of Tdap receive a single dose.

<sup>4</sup>Either Boostrix® (FDA licensed for this age group) or Adacel® (not FDA licensed) may be used for individuals over age≥ 65.

<sup>5</sup>If Tdap is not administered during pregnancy, it should be administered immediately postpartum.

<sup>6</sup>Off-label use approved by the ACIP, 24 Oct 2012.

Reference for Age Range:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm?s_cid=mm6001a4_w

Reference for Pregnant women:
B. Encephalopathy (e.g. coma, prolonged seizures) within 7 days of administration of a pertussis-containing vaccine that is not attributable to another identifiable cause is a contraindication to Tdap.²

| Tdap toxoid–containing vaccine.³ |
| B. Unstable neurological condition, uncontrolled epilepsy, or progressive encephalopathy.⁴ |
| C. Severe latex allergy. (the Boostrix®, pre-filled needleless syringes contain latex, as do tip caps of Decavac™ and Tenivac™). |
| D. History of Guillain-Barré syndrome within 6 weeks after a previous dose of tetanus toxoid-containing vaccine. |
| E. Previous history of brachial neuritis⁵ |
| F. Moderate or severe acute illness. |

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1. Because of the importance of tetanus vaccination, individuals with this history should be referred to an allergist to determine whether they can be desensitized to tetanus toxoid.
2. Td vaccine should be administered for the remaining doses in the vaccination schedule to ensure protection against diphtheria and tetanus.
3. If previous Arthus reaction was likely, consider deferring Tdap or Td vaccination until at least 10 years have elapsed.
4. Td may be used if decision made to withhold a pertussis-containing vaccine.
5. Institute of Medicine found evidence for a causal relation between tetanus toxoid vaccines and brachial neuritis. (pkg inserts for Decavac™ and Tenivac™).

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**VII. SIDE EFFECTS AND ADVERSE REACTIONS**

<table>
<thead>
<tr>
<th></th>
<th>Tdap</th>
<th>Td</th>
</tr>
</thead>
</table>
| **Local Reactions** | Pain, redness, swelling | Pain: 66%  
Redness: 25%  
Swelling: 21% | Common but self-limiting |
|---------------------|------------------------|------------------|--------------------------|
| **Severe Local Reactions** | Arthus-like  
Extensive painful swelling from shoulder to elbow$^{1}$ | Occasional | Occasional |
| **Systemic Reactions** | Fever  
Headache, fatigue, gastrointestinal symptoms | Temp $\geq 100.4^\circ$: 1.4%  
Occasional | Temp $\geq 100.4^\circ$: 1.1%  
Occasional |
| **Severe Systemic Reactions** | Guillian-Barré syndrome  
Brachial neuritis | Rare  
Rare | Rare  
Rare |

$^{1}$Generally begins 2–8 hrs after injection; most often in adults; particularly in those who have received frequent doses of diphtheria or tetanus toxoid.

VIII. OTHER CONSIDERATIONS

A. History of pertussis: Adolescents or adults with a history of pertussis disease generally should receive Tdap according to the routine recommendations. However, if the illness was <5 years ago and the diagnosis was culture confirmed, it is reasonable to wait 3–5 years before administration of Tdap, unless tetanus and diphtheria toxoids are needed.

B. Incomplete or unknown vaccination history: Adults who have never received tetanus and diphtheria toxoid-containing vaccine should receive a series of three vaccinations. The preferred schedule is a single dose of Tdap, followed by Td ≥4 weeks later, and a 2nd dose of Td 6–12 months later. Tdap should be used for one and only one dose in the series. The other two doses should be Td.

C. Wound management for pregnant women: As part of standard wound care to prevent tetanus, Tdap may be given to a pregnant woman (at any gestational age) if ≥5 years have elapsed since she last received a dose of tetanus-containing vaccine. CDC reference: http://wwwemergency.cdc.gov/disasters/disease/tetanus.asp.

D. Tetanus disease does not confer immunity because of the very small amount of toxin required to produce illness. Persons recovering from tetanus disease should begin or complete active immunization with tetanus toxoid (Td) during convalescence.

E. Inadvertent administration of Tdap or Pediatric DTaP: Guidance on the best approach to vaccination following misadministration of Tdap to infants or DTaP to adolescents can be found at: www.cdc.gov/mmwr/pdf/rr/rr5503.pdf p. 27.

F. For someone with a history of fainting with injections, a 15-minute observational period is recommended after immunization.

IX. ADVERSE EVENTS REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.hhs.gov. In addition, a copy of the reporting form should be reported to the patient’s primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4).
X. Events Reportable to VAERS

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Illness, disability, injury or Condition covered</th>
<th>Time period for the onset of a significant reaction following vaccine administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines containing tetanus toxoids</td>
<td>Anaphylaxis or anaphylactic shock</td>
<td>4 hours</td>
</tr>
<tr>
<td></td>
<td>Brachial Neuritis</td>
<td>2—28 days</td>
</tr>
<tr>
<td></td>
<td>Any acute complication or Sequel</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>(including death)</td>
<td></td>
</tr>
</tbody>
</table>

**REFERENCES**

1. CDC. Updated recommendations on use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) in pregnant women; Advisory Committee on Immunization Practices (ACIP). 2012. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm)

2. CDC. Updated recommendations for use of tetanus toxoid reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine in adults aged 65 years and older — Advisory Committee on Immunization Practices (ACIP), 2012. MMWR 2012; 61:468–70. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/mm6125a4.htm.

3. CDC. Updated recommendation for use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine from The Advisory Committee on Immunization Practices (ACIP), 2010. MMWR 2011;60:13–5. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm?s_cid=mm6001a4_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm?s_cid=mm6001a4_w)


5. CDC. Preventing tetanus, diphtheria, and pertussis among adolescents: Use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine; MMWR 2006; 55 (RR-3). Available at: [www.cdc.gov/mmwr/PDF/rr/rr5503.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5503.pdf).

7. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and post partum women and their infants. MMWR 2008; 57 Available at: www.cdc.gov/mmwr/PDF/rr/rr57e0514.pdf


To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

Electronic copy of this protocol available at: http://1.usa.gov/PharmacyImmunizationProtocols