IMMUNIZATION PROTOCOL FOR PHARMACISTS

Tdap VACCINE
TETANUS TOXOID, REDUCED DIPHTHERIA TOXOID AND ACELLULAR PERTUSSIS ADSORBED

I. ORDER:

1. Screen for contraindications
2. Provide a current Vaccine Information Statement (VIS), answering questions.
3. Obtain a signed Vaccine Administration Record (VAR)
4. Give one single dose of Tdap vaccine (0.5 ml) intramuscularly (IM) to eligible persons 18 through 64 years of age.
   a. The deltoid muscle of the upper arm should generally be used.
   b. May be given simultaneously with all other vaccines, including travel vaccines.

_____ _____

Pharmacist signature Date

Electronic copy of this protocol available at
http://www.oregon.gov/DHS/ph/imm/provider/pharmpro.shtml
To request this material in an alternate format (e.g., Braille), please call (971) 673- 0300.

Original provided courtesy of the Oregon Department of Human Services, Health Services, January 2006

II. LICENSED Tdap VACCINES[1]

Product Name	Vaccine Components	Acceptable Age Range	Thimerosal
Boostrix®[2] (GSK)	Tetanus toxoid, Diphtheria toxoid, Acellular Pertussis	10 to 18 years	No
Adacel™[2] (Sanofi Pasteur)	Tetanus toxoid, Diphtheria Toxoid, Acellular Pertussis	11 to 64 years	No

[1] Tdap products are interchangeable as long as age requirements are met for each vaccine.

[2] **Licensed only for a single dose at this time**

III. RECOMMENDATIONS FOR USE

A. Adolescents aged 13-18 years who have not received Td 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 received Td.

B. Adolescents 11-18 years of age who received a prior Td are encouraged to receive a single dose of Tdap to provide protection against pertussis if they have completed the recommended childhood DTP or DTaP vaccination series. A 5-year minimum interval between the Td and Tdap is encouraged to reduce the chance of a local or systemic reaction. However, intervals shorter than 5 years between Td and Tdap can be used. The benefits of protection from pertussis generally outweigh the risks in settings with increased risk from pertussis (e.g., pertussis outbreaks and close contact with an infant <1 year of age).[1]

C. Vaccine providers should administer Tdap (or Td) and MCV4 (Menactra™) during the same adolescent or adult visit if both vaccines are indicated and available. If simultaneous administration of Tdap and MCV4 is not feasible these vaccines can be administered at any time before or after each other.

D. Adults 19-64 years of age should receive a single dose of Tdap if they have not received a Td booster within the past 10 years.[1,2]

E. Adults who have or will have close contact with infants <12 months of age (e.g., parents, childcare providers, health-care providers) should receive a single dose of Tdap.[3]

F. Postpartum women should receive a dose of Tdap if they haven't previously received Tdap vaccine.

[1] Tdap may be given at an interval shorter than 10 years. The safety of intervals as short as 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 Td booster.

[2] Tdap vaccine would replace the currently recommended tetanus-diphtheria vaccine that is used as the adult booster vaccine.

[3] Ideally, should try to be immunized one month before close contact with infants.

IV. VACCINE SCHEDULE FOR ADOLESCENTS AND ADULTS[1,2]

Dose and Route: 0.5 ml IM			
GROUP	**MINIMUM AGE**	**DOSE**	**RECOMMENDED AGE**
Adolescents	18 years for Boostrix®	1	13-18 years of age[3]
	18 years for Adacel™	1	
Adults[4,5,6]	19 years for Adacel™	1	19-64 years of age

[1] A 5-year interval between Td and Tdap is encouraged to reduce the chance of a local reaction.

[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 (but only one) of the 3 Td doses in the series.

[3] Should receive a single dose of Tdap as their catch-up-booster 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.

[4] Adacel™is the only Tdap vaccine currently licensed for adults ≥19 years of age.

[5] A single Tdap dose should replace the currently recommended Td vaccine that is used as the adult booster vaccine. 10 years later, when another tetanus and diphtheria booster is needed, go back to receiving Td again.

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

V. Tdap CONTRAINDICATIONS

A. An immediate anaphylactic reaction to any component of the vaccine or following a prior dose.[1]

B. Encephalopathy (e.g. coma, prolonged seizures) within 7 days of administration of a pertussis vaccine that is not attributable to another identifiable cause.[2]

VI. Tdap PRECAUTIONS[3]

A. History of an Arthus-type reaction following a previous dose of tetanus or diphtheria-containing vaccine.[4]

B. Progressive neurological disorder, uncontrolled epilepsy, or progressive encephalopathy.[5]

C. Severe latex allergy. (Boostrix®, prefilled needleless syringe).

D. History of Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine.

E. Moderate or severe acute illness.

[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] **Not True Precautions** for Tdap:

- -stable neurological disorder
- -Pregnancy
- -Breastfeeding
- -Immunosupression and HIV
- -Minor illness
- -Antibiotic use
- -Infection
- -History of extensive limb swelling reactions (ELS)
- -Temp ≥105° F after dose of DTaP or DTP
- -Convulsions with or without fever, occurring within 3 days after dose of DTaP or DTP
- -Persistent crying lasting ≥ 3 hours within 48 hours of DTaP or DTP.
- -Collapse or shock-like state within 48 hrs of DTaP or DTP

[4] If previous arthus reaction was likely, provider should consider deferring Tdap or Td vaccination until at least 10 years have elapsed.

[5] Td may be used if decision made to withhold a pertussis containing vaccine.

VII. SIDE EFFECTS AND ADVERSE EVENTS

Adverse Event	**Boostrix® 10-18 yrs.[1] (0-15 days post vaccine)**	**Adacel™ 11-17 yrs.[2] (0-14 days post vaccine)**	**Adacel ™ 18-64 yrs.[2]**
	%	**%**	**%**
Any injection site pain	75.3	77.8	65.7
Any swelling at injection site	21.1	20.9	21.0
Any injection site redness	22.5	20.8	24.7
Fever >100.4° F (38° C) > 102° F (38.8° C) > 103.1° F (39.5°C)	5.0 1.4 Not available	5.0 0.9 0.2	1.4 0.4 0.0
GI symptoms – Any Nausea Vomiting Diarrhea	26.0 Not available Not available Not available	Not available 13.3 4.6 10.3	 9.2 3.0 10.3
Any headache	43.1	43.7	33.9
Any fatigue	37.0	30.2	24.3
Sore & swollen joints	Not available	11.3	9.1

[1] Adapted from Boostrix® package insert. Pg.11 Available at: http://www.fda.gov/cber/label/tdapgla050305LB.pdf. In the US-safety study, no serious adverse events were reported to occur within 31 days of vaccination.

[2] Adapted from Adacel™ package insert. Pg.19-21. Available at: http://www.fda.gov/cber/label/tdapave061005LB.pdf. Serious adverse events were reported in 1.5% of Adacel™ vaccine recipients.

VIII. OTHER CONSIDERATIONS:

A. **History of Pertussis**: Adults with a history of pertussis generally should receive Tdap according to the routine recommendations.

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. **Pregnancy and breastfeeding are not contraindications** to vaccination with Tdap. Pregnant women who are unimmunized or only partially immunized against tetanus should complete the primary series. Previously vaccinated pregnant women who have not received a Td immunization within the last 10 years should receive a booster dose.

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

IX. TETANUS WOUND MANAGEMENT AMONG PERSONS 18- 64 YRS.

Vaccination History of tetanus toxoid doses	Clean, minor wound Administer:		All other wounds[1] Administer:	
	Tdap or Td[2]	**TIG**	**Tdap or Td[2]**	**TIG**
Unknown or < 3 doses	Yes	No	Yes	Yes
≥ 3 doses	No[3]	No	No[4]	No

[1] Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns and frostbite.

[2] Tdap is preferred over Td for adolescents and adults who have never received Tdap. Td is preferred over TT for adolescents and adults who received Tdap or if Tdap is not available; however, TT is acceptable.

[3] **Yes, if > 10 years since the last tetanus toxoid vaccine dose**

[4] **Yes, if > 5 years since the last tetanus toxoid vaccine dose**

TIG=tetanus immune globulin.

TT=tetanus toxoid

X. ADVERSE EVENT 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.org. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510.

Table 1. Events Reportable to VAERS for Tetanus toxiod-containing vaccines

Illness, disability, injury or condition covered	**Time period until first symptom or the onset of significant reactions following vaccine administration**
A. Anaphylaxis or anaphylactic shock	4 hours
B. Brachial Neuritis	2-28 days
Any acute complication sequela (including death)	Not applicable

XI. REFERENCES:

1. Advisory Committee on Immunization Practice (ACIP) Votes to Recommend Routine Use of Combined Tetanus, Diphtheria and Pertussis (Tdap) Vaccines for Adolescents; 6/2005. Available at: http://www.cdc.gov/nip/vaccine/tdap/tdap_ACIP_recs.pdf.
2. ACIP Provisional Recommendations for Tdap in Adults. 12/15/05. Available at: www.cdc.gov/nip/vaccine/tdap/tdap_adult_recs.pdf.
3. Advisory Committee on immunization Practice Recommends Adult Vaccination with Tdap; 11/9/05 Press Release. Available at: www.cdc.gov/od/oc/media/pressrel/r051109.htm.
4. Adacel™ package insert. Available at: http://www.fda.gov/cber/label/tdapave061005LB.pdf.
5. Boostrix® package insert. Available at: http://www.fda.gov/cber/label/tdapgla050305LB.pdf.

For more information or to clarify any part of the above order, consult with the vaccine recipient's primary health care provider or call Health Services, Immunization Program, (971) 673-0300.