OREGON HEALTH AUTHORITY

IMMUNIZATION PROGRAM

Diphtheria and Tetanus Toxoids*

DT[1, 2] (pediatric), Td[3, 4, 5] Tdap[6, 7] and TT[8]

Date: 03-29-2016

Updates to standing orders covering either new ACIP recommendations or new language. The revisions are as follows:

- Addition of Diphtheria and Tetanus Toxoid Adsorbed (DT) for use in children 6 weeks through 6 years of age. See page 5
- Addition of Tetanus Toxoid (TT) for booster use only in persons ≥7 years of age. See page 5
- Decavac®[3] is no longer available for purchase
- Tetanus Toxoid®[8] has been discontinued
- Table of all tetanus-containing vaccines, See Appendix, page 29,

I. OREGON IMMUNIZATION MODEL STANDING ORDER:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen for contraindications.
3. Provide a current Vaccine Information Statement (VIS), answering any questions.
4. Record all required data elements in the client's permanent health record.
5. Give **DT** vaccine 0.5 ml intramuscularly (IM) according to the age- appropriate schedule and situation of infants or children **<7** years of age.
   a. DT should be used if encephalopathy occurred within 7 days after administration of a previous dose of pertussis-containing vaccine.
6. Give **Td, Tdap, or TT** vaccine 0.5 ml intramuscularly (IM) according to the age-appropriate schedule and situation to persons **≥7** years of age.
   a. The deltoid muscle of the upper arm should generally be used.
7. May be given with all ACIP-recommended child and adult vaccinations.
8. Observe client for 15 minutes after vaccination to decrease the risk for injury should they faint.

_____

Signature Health Officer or Medical Provider Date

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Signature Health Officer or Medical Provider Date

* DTaP and combos' under separate order

II. A. LICENSED COMBINATION VACCINE (DT) [1, 2]

Product name	Vaccine components	Acceptable age range	Thimerosal
Diphtheria and Tetanus Toxoids Adsorbed (DT) For pediatric Use (Sanofi Pasteur) (2005)	Diphtheria & Tetanus toxoids	6 weeks–6 years up to the 7th birthday	None[1]
			Single-dose vial[2]: Trace (≤0.3 µg Hg/0.5 mL dose).

II. B. LICENSED COMBINATION VACCINE (Td) [3, 4, 5 ◊]

Product name	Vaccine components	Acceptable age range	Thimerosal
Decavac®[3*] (Sanofi Pasteur) No longer available for purchase 12-30-2014 Some may be on shelves	Tetanus & diphtheria toxoids	≥7 years	Trace in Single-dose vials and syringes <0.3 µg/0.5 ml
Tetanus & diphtheria toxoids[4] (Mass Biologicals)	Tetanus & diphtheria toxoids	≥7 years	<0.3 µg/0.5 ml Not as a preservative
Tenivac®[5*◊] (Sanofi Pasteur)	Tetanus & diphtheria toxoids	≥7 years	No

*Available in a 0.5 ml single−dose syringe or vial.[3, 5]

◊For persons 7 years of age and older, without contraindications, Tap is preferred. When pertussis is contraindicated, Tetanus and Diphtheria Toxoids Adsorbed for Adult Use (Td) is preferred to Tetanus T (TT) toxoid alone. [9, 10]

II. C. LICENSED COMBINATION VACCINE (Tdap) [6, 7] *

Product name	Vaccine components	Acceptable age range		Thimerosal
		FDA licensed	ACIP recommended off-label use	
Boostrix®[6◊] (GSK)	tetanus toxoid, diphtheria toxoid, acellular pertussis	≥10 years	≥7years[§]	No
Adacel®[7◊] (sanofi pasteur)	tetanus toxoid, diphtheria toxoid, acellular pertussis	10–64* Years	≥7 years[§]	No

II. B–C footnotes cont.

*Neither Boostrix®[6] nor Adacel®[7] is licensed for use in children <10 years of age.

◊Licensed only for a single dose at this time.[6, 7]

§Off-label age range. Currently Boostrix® is FDA-licensed for persons ≥10 years of age and Adacel ® for persons 10–64 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. There is no upper age limit.[11]

II.D. LICENSED TETANUS TOXID VACCINE (TT) [8]

Product name	Vaccine components	Acceptable age range	Thimerosal
Tetanus Toxoid for Booster Use Only*◊ (Sanofi Pasteur)	tetanus toxoid UCM166873 Discontinued: some may be on shelves	**FDA licensed** ≥7 years **NOT indicated for primary immunization**	25µ per dose

* Tetanus Toxoid is indicated for booster injection only for persons ≥7 years of age. NOT indicated for primary immunization.[8]

◊Tetanus Toxoid is interchangeable with Tetanus Toxoid Adsorbed (contains aluminum adjuvant) as a booster, and would only be preferred if aluminum was to be avoided. Adsorbed toxoids induce more persistent antitoxin titers. [8]

III. A. RECOMMENDATIONS FOR USE: DT

Only infants and children from 6 weeks – 6 years of age who have a valid contraindication to pertussis antigen (Section V, p 13) should receive DT (as opposed to DTaP) vaccine. See DTaP combo vaccine order.[1, 2, 12, 13]

NOTE: A special order for Pediatric DT vaccine can be placed with the State Immunization Program through your health educator. If there is a medical contraindication to pertussis antigen and no contraindications to past doses of a tetanus and diphtheria-containing vaccine, state supplied DT vaccine can then be sent to the public clinics for the specific patient(s) in question. Per Oregon Immunization Program (OIP) policy.

III. B. RECOMMENDATIONS FOR USE: Tdap and Td

A. 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. [14*◊]

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. One (and only one) of these 3 doses should be Tdap – preferably the first dose.[12]

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. [12]

D. It is preferred that pregnant women be vaccinated with Tdap between 27 and 36 weeks gestation, to prevent infant pertussis. [15]

- Pregnant women who never have been vaccinated against tetanus should receive three vaccinations containing tetanus and reduced diphtheria toxoids. The recommended schedule is 0, 4 weeks, and 6 – 12 months. Tdap should replace 1 dose of Td, preferably at 27 – 36 weeks' gestation. [15]

E. All health care personnel, regardless of age, should receive a single dose of Tdap regardless of the date since their last Td dose [16]

F. Use Tdap for routine tetanus and diphtheria booster or wound management if no prior Tdap dose.[17]

G. Administer Tdap (or Td) simultaneously with other vaccines when indicated and available.[18]

* 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.

◊ This recommendation also applies to unvaccinated adults ≥65 years of age (FDA approved for Boostrix®, but either Tdap vaccine product can be used).[19]

III. C. RECOMMENDATIONS FOR USE: Tetanus Toxoid (TT)

Tetanus Toxoid:

- Tetanus Toxoid is indicated for booster injection only for persons 7 years of age or older against tetanus.
- This vaccine is NOT indicated for primary immunization.
- In instances where the pertussis vaccine component is contraindicated, Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use) (DT) should be used for children 6 weeks–6 years of age. For persons 7 years of age and older, Tetanus and Diphtheria Toxoids Adsorbed For Adult Use (Td) is preferred to tetanus toxoid alone.[8]
- Tetanus Toxoid is interchangeable with Tetanus Toxoid Adsorbed (contains aluminum adjuvant) as a booster, and would only be preferred if aluminum was to be avoided.
- Although the rate of seroconversion is essentially equivalent with either form, adsorbed toxoids induce more persistent antitoxin titers.
- Tetanus Toxoid would be preferred over diphtheria-containing vaccines if there was a contraindication to the diphtheria component. [1, 2, 8]

IV. A. ROUTINE VACCINATION SCHEDULE FOR DT VACCINE (No trade name)

Dose*◊	Minimum Age §‡	Minimum Spacing §‡	Recommended Age
1	6 weeks		2 months
2	10 weeks	4 weeks after dose #1	4 months
3	14 weeks	4 weeks after dose #2	6 months
4**	12 months	6 months after dose #3	15 months◊◊
5§§	4 years	6 months after dose #4	4 years

*If 6 doses of DT or DTaP have been given before age 7 years, a Tdap booster is due at age 11-12 years. If a child less than 4 years of age has had 5 doses of DT or DTaP (valid and invalid doses), the 6th dose will be forecast at 4-5 years of age and 6 months after dose 5.[17]

◊Td should not be given before 7 years of age. If a child <7 years of age mistakenly receives Td instead of DT, the Td dose will count only if administered as the 4th or 5th dose. If received as dose 1, 2 or 3, the dose should be repeated with DT.[18]

§For retrospective checking, doses that violate the minimum spacing 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.[18]

‡When an invalid dose needs to be repeated, the repeat dose should be spaced after the invalid dose by a time equal to or greater than the minimum interval between doses.[18]

IV. A. Footnotes cont.

**For retrospective checking: DT4 administered ≥4 months after DT3 does not need to be repeated.[17]

◊◊If the interval between the 3rd and 4th dose is ≥6 months, and the child is not likely to return at the recommended age, the fourth dose of DT may be given as early as 12 months of age. [13]

§§Dose 5 is unnecessary if dose 4 was given on or after the 4th birthday.[13]

NOTE: If a child is older than 1 year at the time the first dose of DT is given, a third dose given 6-12 months after the second dose completes the primary series. The booster (4th dose) is to be given at a minimum of 4 years of age and at least 6 months after dose 3. [13]

IV. B. ROUTINE VACCINATION SCHEDULE FOR Td VACCINE (Decavac®[3] and Tenivac®[4])

Dose *◊	Minimum Age	Recommended Age	Recommended Interval	
			Decavac® not available for purchase	**Tenivac®**
1	7 years	≥7 years		
2§	7 years	≥7 years	4 weeks after dose #1	8 weeks after dose #1
3 ‡**	7 years	≥7 years	6 months after dose #2	6 months after dose #2
Booster Doses ◊◊§§‡‡	10 years	≥10 years	≥5 years from last dose of a tetanus and diphtheria-containing vaccine	

* For unvaccinated persons ≥7 years of age (including persons who cannot document prior vaccinations), the primary series is three doses.[12]

◊ 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.[18]

§While the recommended interval between dose 1 and dose 2 is 4 weeks for Decavac® and 8 weeks for Tenivac®, the ALERT IIS will forecast for a recommended interval of 8 weeks and a minimum interval of 4 weeks for both Td products.

‡ 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.[12]

IV. B. Footnotes cont.

** If the 3rd dose of a tetanus and diphtheria-containing vaccine (includes previous doses of DTaP, DTP or DT) is administered on or after the 7th birthday and the 1st dose was given ≥1 year of age, a 4th dose is not required. There is a 6-month interval between dose 2 and dose 3 If the 1st 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.[12]

◊◊ The first booster dose may be given at 10–18 years of age if ≥5 years have elapsed since the last dose of a 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.[12]

§§ 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.[12]

‡‡ 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 6th or last dose.[17]

IV. C. ACIP RECOMMENDED VACCINATION SCHEDULE FOR Tdap VACCINE (Boostrix®[6] and Adacel®[7])*

Age Group	Minimum Age	Dose‡	Recommended Age
Adolescents	7 years ◊§‡**	1	10–18 years‡
Adults◊◊§§	19 years	1	≥19 years
Pregnant Women ‡‡***◊◊◊	None	1	Tdap during each pregnancy is preferred at 27–36 weeks' gestation ‡‡***◊◊◊

* Tdap should be administered with other vaccines that are indicated during the same visit when feasible.[18]

◊ 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 4th dose was administered on or after the 4th birthday) and who have no contraindications.[13]

§ 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.[13]

‡Adolescents 10–18 years of age <u>who have completed the recommended childhood DTP or DTaP vaccination series ≥4 years ago</u> should receive a single dose of Tdap instead of Td. If a Tdap dose is given as part of wound management to a person ≥10 years of age, the next Td booster should not be administered for 10 years.[12]

IV. C. Footnotes cont.

** 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 to 8 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.[16]

◊◊ 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.[12, 16]

§§ Grandparents, child-care providers, health-care providers, and other unvaccinated adults in contact with infants <1 year of age should receive a Tdap booster. Either Boostrix® or Adacel® may be used for ≥65 years of age.[11]

‡‡"To ensure protection against maternal and neonatal tetanus, pregnant women who never have been vaccinated against tetanus should receive three vaccinations containing tetanus and reduced diphtheria toxoids. The recommended schedule is 0, 4 weeks, and 6 through 12 months. Tdap should replace 1 dose of Td, preferably between 27 and 36 weeks gestation to maximize the maternal antibody response and passive antibody transfer to the infant."[17]

*** If Tdap is not administered during pregnancy; it should be administered immediately postpartum. The postpartum dose is only recommended for women who have not previously received Tdap.[17]

◊◊◊" Tdap may be administered any time during pregnancy, but vaccination during the third trimester would provide the highest concentration of maternal antibodies to be transferred closer to birth. After receipt of Tdap, a minimum of 2 weeks is required to mount a maximal immune response to the vaccine antigens."[17]

V. A. DT CONTRAINDICATIONS

1. History of an anaphylactic reaction (hives, swelling of the mouth and throat, difficulty breathing, hypotension or shock) to any component of the vaccine (including thimerosal and natural latex rubber) or following any prior dose of a diphtheria and tetanus containing vaccine.[1, 2]

2. Any neurological reaction following a prior dose of DT vaccine. [1, 2]

3. Defer vaccination with DT to persons with moderate or severe illness with or without fever until the symptoms have resolved. Persons with mild illness (e.g. upper respiratory infection with or without low grade fever) may be vaccinated. [1, 2]

V. B. Tdap and Td CONTRAINDICATIONS[3, 5, 6, 7]

1. Severe allergic reaction to any vaccine component of Td or Tdap vaccine or following a prior dose.[*]

2. 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.[◊]

[*] 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.

[◊] Td vaccines should be administered for the remaining doses in the vaccination schedule to ensure protection against diphtheria and tetanus.

VI. A. DT PRECAUTIONS AND WARNINGS[1, 2]

1. In the case of infant or child with an underlying neurologic disorder, proven or suspected, DT should not be given until a physician has determined the infant's neurological status. Further doses of DTaP vaccine are considered contraindicated.[2]

2. Injection IM may cause hematoma in those with bleeding disorders e.g. hemophilia, thrombocytopenia or to persons on anticoagulant therapy. [1, 2]

3. Children with impaired immune responses, i.e., immuno-suppressive therapies (including irradiation, corticosteroids, antimetabolites, alkylating agents, and cytotoxic drugs), a genetic defect, or HIV infection may experience a reduced immune response to vaccines. Deferring DT may be considered in children receiving immunosuppressive therapy.[16]

4. For persons known to have developed Guillain-Barré syndrome (GBS) within 6 weeks of a previous tetanus toxoid containing vaccine the decision to give additional doses of DT should be based on consideration of the benefit of further vaccination versus the risk of recurrence of GBS. [1, 2]

5. Apnea flowing intramuscular vaccination has been observed in some infants born prematurely. Preterm infants should be vaccinated according to their chronological age from birth. [1]

VI. B. Tdap and Td PRECAUTIONS AND WARNINGS

1. Persons who experience an Arthus-type reaction following a previous dose of a tetanus toxoid–containing vaccine should not receive a tetanus-containing vaccine more frequently than every 10 years, even for tetanus prophylaxis as part of wound management.[3, 4, 5, 6, 7, 8]

2. History of an arthus-type hypersensitivity reaction following a previous dose of tetanus or diphtheria toxoid-containing vaccines, including MCV4 (Menactra®).[14]

3. Unstable neurological condition, uncontrolled epilepsy, or progressive encephalopathy. [6, 7]

4. Severe latex allergy. (The Boostrix®, pre-filled needleless syringes contain latex, as do tip caps of Decavac® and Tenivac®) [3, 5, 6]

5. History of Guillain-Barré syndrome within 6 weeks after a previous dose of tetanus toxoid-containing vaccine. [3, 4, 5, 6, 7, 8]

6. Moderate or severe acute illness. [3, 5, 6, 7]

7. If previous arthus reaction was likely, consider deferring Tdap or Td vaccination until at least 10 years have elapsed. [12]

8. ACIP does not consider a history of brachial neuritis to be a precaution or contraindication for administration of tetanus toxoid--containing vaccines.[10]

VII. A. SIDE EFFECTS AND ADVERSE REACTIONS FOR DT[2]

DT (no trade name) 2005

	Baltimore **UCM142732 Ref # 2**
	N=163
Age in Years	2—6 mo.*
Local Reaction, Injection site	%
Pain	0—2.8
Hardness ≥2.5 cm	1.3—3.6
Systemic Complaints	
Fever ≥38°C <39°C (≥100.4°F <102.2°F)	0.7—6.6
Irritability	13.0—15.2
Alteration in appetite	2.9—6.2
*DT package insert table 1 page 5[2]	

NOTE: Other: Persons experiencing an Arthus-type hypersensitivity reaction or a fever higher than 103°F (39.4°C) following a prior dose of tetanus toxoid usually have high serum tetanus antitoxin levels. Because these persons are at increased risk of hypersensitive reaction to immunization, do not give them DT or emergency doses of Td more frequently than every 10 years, even if they have a wound that is neither clean nor minor.[2, 8, 12, 13]

VII. B. 1. SIDE EFFECTS AND ADVERSE REACTIONS FOR Boostrix[6] and Adacel[7] (Tdap) 8—18 years of age

Number followed for Safety	Boostrix[6] N =3032* § Adverse Reaction %	Adacel[7] N=1170—1175◊ § Adverse Reaction %
Age in Years	10—18 years	11—17 years
Local Reaction, Injection site		
Pain	75.3	77.8
Redness	22.5	20.8
Swelling	21.1	20.9
Systemic Complaints		
Fever ≥99.5°F (37.5°C)	13.5	5.0
Fever >102.2°F (39.0°C)	1.4	0.9
Chills		15.1
Alteration in appetite	26.0	13.3
Tiredness	37.0	30.2
Headache	43.1	43.7
Body ache		30.4
Sore and swollen joints		11.3
Rash		2.7
*Boostrix package insert Table 1 page 7.		
◊Adacel package insert Table 1 page 7—8 and Table 2 page 9		
§ Generally begins 2–8 hrs after injection; most often in adults; particularly in those who have received frequent doses of diphtheria or tetanus toxoid.[10, 15]		

VII. B.2. SIDE EFFECTS AND ADVERSE REACTIONS FOR Boostrix[6] and Adacel[7] (Tdap) 18—65 years of age

Number followed for Safety	Boostrix[6] N =1480[* §] Adverse Reaction %	Boostrix[6] N - 882[**] Adverse Reaction %	Adacel[7] N=1697—1698[◊ ‡] Adverse Reaction %
Age in Years	19—64 years	≥65 years	18—64 years
Local Reaction, Injection site			
Pain	61.0	21.5	65.7
Redness	21.1	10.8	24.7
Swelling	17.6	7.5	21.0
Systemic Complaints			
Fever ≥99.5°F (37.5°C)	5.5	2.0	1.4
Fever >102.2°F (39.0°C)	0.1	0.0	0.4
Chills			8.1
Alteration in appetite	15.9	7.6	9.2
Tiredness	28.1	12.5	24.3
Headache	30.1	11.5	33.9
Body ache			21.9
Sore and swollen joints			9.1
Rash			2.0
*, §Boostrix package insert Table 4 page 10.			
◊, ‡Adacel package insert Table 1 page 7—8 and Table 2 page 9.			
**Boostrix pacage insert Table 4 page 10.			
◊◊Generally begins 2–8 hrs after injection; most often in adults; particularly in those who have received frequent doses of diphtheria or tetanus toxoid.[10, 15]			

VII. C.1. SIDE EFFECTS AND ADVERSE REACTIONS FOR Td [3, 4]

	No Trade Name MassBiologics[4]	Decavac[3*] ≥7 years of age Sanofi	Decavac[3*] ≥7 years of age Sanofi
	≥7 years of age	N=783—787	N =551—561
		%	%
Age in Years	None stated	11—17	18—64
Local Reaction, Injection site			
Pain	Yes	71.0	62.9
Redness	Yes	19.7	21.6
Swelling	Yes	18.3	17.3
Systemic Complaints	Yes	**N=787**	**N=560—561**
Fever ≥100.4°F (38°C)	Yes	2.7	1.1
Fever >102.2°F (39.0°C)		0.6	0.2
Chills	Yes	12.6	6.6
Convulsions	Yes		
Nausea	Yes	12.3	7.9
Vomiting		2.8	1.8
Tiredness	Yes	27.3	20.7
Headache	Yes	40.4	34.1
Body ache	Yes	29.9	18.8
Sore and swollen joints	Yes	11.7	7.0
Rash	Yes	2.0	2.3

*Decavac package insert Table 2 page 10 and table 3 page 11

VII. C.2. SIDE EFFECTS AND ADVERSE REACTIONS FOR Td[5]

	Tenivac* ≥7 years of age Sanofi	Tenivac* ≥7 years of age Sanofi	Tenivac* ≥7 years of age Sanofi
	N=491—492	N=247	N=688—695
	%	%	%
Age in Years	11—18	19—59	≥60
Local Reaction, Injection site			
Pain	80.1	74.9	35.3
Redness	25.6	15.8	18.1
Swelling	15.0	17.0	12.1
Systemic Complaints			
Fever ≥99°F (37.5°C)	4.3	5.7	2.5
Tiredness	14.5	17.0	8.9
Headache	23.0	25.1	11.7
Muscle weakness	32.3	17.4	4.9
Sore and swollen joints	15.7	10.9	8.5
*Tenivac package insert Table 2 pages 8—9			

VII. C. SIDE EFFECTS AND ADVERSE REACTIONS FOR TT Adsorbed[8]

Adverse reactions may be local and include redness, warmth, and edema, induration with or without tenderness as well as urticaria, and rash. Malaise, transient fever, pain, hypotension, nausea and arthralgia may develop in some patients after the injection.

Arthus-type hypersensitivity reactions, characterized by severe local reactions (generally starting 2 to 8 hours after an injection) may occur, particularly in persons who have received multiple prior boosters. On rare occasions, anaphylaxis has been reported following administration of products containing tetanus toxoid. Upon review, a report by the Institute of Medicine (IOM) [National Academy of Science], concluded the evidence established a causal relationship between tetanus toxoid and anaphylaxis. Deaths have been reported in temporal association with the administration of tetanus toxoid-containing vaccines.

Trials contained thimerosal.

VIII. A. OTHER CONSIDERATIONS FOR DT

A. Epinephrine Injection (1:1000) and other appropriate agents and equipment must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.[18]

B. Normally no more than 6 doses of a diphtheria/tetanus-containing vaccine are recommended by 7 years of age. However, in some situations, the benefits of a pertussis containing vaccine being added to a DT series needs to be weighed against the risk of a local reaction occurring after receiving 7 or 8 doses of a DT-containing vaccine.[17]

C. Infants under 12 months of age: Should additional doses of pertussis-containing vaccine become contraindicated after a DTP/DTaP series has been initiated, DT should be substituted for each of the remaining scheduled DTP/DTaP doses.[18]

D. **Do not restart a series**. Give the next dose in the series as close as possible to the spacing guide listed on the schedule. Complete series according to the schedule as close as possible.[18]

E. **Children who are foreign-born** and who do not have documentation of vaccinations received previously should be considered susceptible and started on the age-appropriate vaccination schedule.[18]

F. **Children who have had pertussis**. Although well-documented pertussis may confer short-term protection against reinfection in children, the duration of such protection is unknown, and completing the DTaP series is recommended regardless of a patient's history of pertussis. [20]

G. **For someone with a history of fainting** with injections, a 15-minute observational period is recommended post immunization.[18]

H. **Wound Management**; see section IX. Page [22].

VIII. B. OTHER CONSIDERATIONS FOR Tdap and Td

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. [10, 21]

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.[17]

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).[15]

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.[12]

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[9]

IX. TETANUS WOUND MANAGEMENT RECOMMENDATIONS [22]

History of adsorbed tetanus toxoid doses	Clean, minor wounds		All other wounds*	
	TdaP or Td◊	TIG§	TdaP or Td◊	TIG§
Unknown or <3 doses	Yes	No	Yes	Yes
>3 doses‡	No**	No	No◊◊	No

* 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.

◊ **For children younger than 7 years** of age, DTaP is recommended; if pertussis vaccine is contraindicated, DT is given.

For persons 7-9 years of age Td is recommended.

For persons >10 years, Tdap is preferred to Td if the patient has never received Tdap and has no contraindication to pertussis vaccine.

For persons 7 years of age or older, if Tdap is not available or not indicated because of age, Td is preferred to TT.

§ TIG is human tetanus immune globulin. Equine tetanus antitoxin should be used when TIG is not available.

‡ If only three doses of fluid toxoid have been received, a fourth dose of toxoid, preferably an adsorbed toxoid, should be given. Although licensed, fluid tetanus toxoid is rarely used.

** Yes, if it has been 10 years or longer since the last dose.

◊◊ Yes, if it has been 5 years or longer since the last dose. More frequent boosters are not needed and can accentuate side effects.

TIG=tetanus immune globulin.

TT=tetanus toxoid

X. Storage and Handling

All clinics and pharmacies enrolled with the VFC program must immediately report any storage and handling deviations to their Oregon Immunization Program health educator. The health educator assignment map is located at: http://bit.ly/HE_Map

Vaccine	Temp	Storage Issues	Notes
DT[1, 2] **No trade name**	Store at 2°–8°C (36˚F–46˚F)	Do not use if vaccine has been frozen. Report to health educator.	Latex in vial stopper[2]
Decavax® [3]	Store at 2°–8°C (36˚F–46˚F)	Do not use if vaccine has been frozen. Report to health educator. Do not use after expiration date.	Tip caps may contain latex
Td[4] **MassBiologics**	Store at 2°–8°C (36˚F–46˚F)	Do not use if vaccine has been frozen. Report to health educator.	No latex
Tenivac[5]	Store at 2°–8°C (36˚F–46˚F)	Do not use if vaccine has been frozen. Report to health educator. Do not use after expiration date.	Tip caps may contain latex
Boostrix[6]	Store at 2°–8°C (36˚F–46˚F)	Do not use if vaccine has been frozen. Report to health educator.	Tip caps may contain latex
Adacel[7]	Store at 2°–8°C (36˚F–46˚F)	Do not use if vaccine has been frozen. Report to health educator. Do not use after expiration date.	Tip caps may contain latex
Tetanus Toxoid[8]	Store at 2°–8°C (36˚F–46˚F)	Do not use if vaccine has been frozen. Report to health educator.	Discontinued

XI. A. VAERS Table of Reportable Events Following Vaccination*

Vaccine/Toxoid	Event and interval from vaccination
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaPHepB- IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval- see package insert)
Pertussis in any combination; DTaP, DTP, DTPHib, Tdap, P, DTaP-IPV, DTaP- IPV/Hib, DTaPHepB- IPV	Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval- see package insert)

*** Effective date: November 10, 2008.** The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturers package insert. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.
vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

XII.ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/esub/step1. Save a copy of the report number for your records, and send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278). Private providers are to report events directly to VAERS and can read about options on how to do so at http://vaers.hhs.gov/index.

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 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this standing order is available at:
http://1.usa.gov/OregonStandingOrders

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APPENDIX:

Tetanus containing vaccines; total antigen
DT, DTaP, DTP, Td, Tdap or TT.

Antigens	P/A	Tetanus Toxoid	Diphtheria Toxoid	Pertussis Components: PT	FHA	Pertactin	Fimbriae types 2, 3
Daptacel[1] Sanofi	P	5 Lf	15 Lf	10mcg	5mcg	3 mcg	5mcg
Pentacel[2] Sanofi	P	5 Lf	15 Lf	20mcg	20mcg	3mcg	5mcg
Quadracel[3] Sanofi	P	5 Lf	15 Lf	20 mcg	20 mcg	3mcg	5mcg
TT (DT)[4] Sanofi	P	5 Lf	25 LF				
Infanrix[5] GSK	P	10 Lf	25 Lf	25mcg	25mcg	8 mcg	
Pediarix[6] GSK	P	10 Lf	25 Lf	25mcg	25mcg	8 mcg	
Kinrix[7] GSK	P	10 Lf	25 Lf	25mcg	25mcg	8 mcg	
DT[8] Sanofi	P	6.7 Lf	5 Lf				
TT[9] Sanofi	A	4Lf		Discontinued			
Td[10] Mass Bio	A	2 Lf	2Lf				
Decavac[11] Sanofi	A	5 Lf	2Lf	Discontinued			
Tenavac[12] Sanofi	A	5 Lf	2Lf				
Adacel[13] Sanofi	A	5 Lf	2 Lf	2.5mcg	5mcg	3mcg	5 mcg
Boostrix[14] GSK	A	5 Lf	2.5Lf	8mcg	8 mcg	2.5 mcg	

P = Pediatric **A = Adult**

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