OREGON HEALTH AUTHORITY
IMMUNIZING PHARMACIST PROTOCOL

Diphtheria and Tetanus Toxoids* Td and Tdap	
Last Reviewed	22 April 2019
Last Revised	22 January 2019
This order expires	31 July 2021

Additional data from CDC. Prevention of pertussis, tetanus, and diphtheria with vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2018;67:1–48.

- For persons aged 7–10 years who receive a dose of Tdap as part of the catch-up series, an additional adolescent Tdap vaccine dose should be administered at age 11–12 years.[5]
- Persons with HIV infection or severe immunodeficiency who have contaminated wounds should also receive TIG, regardless of their history of tetanus immunization.
- Tetanus or diphtheria infection do not necessarily confer immunity against re-infection. Active vaccination should be initiated at the time of recovery from the illness, according to the schedule.
- Format change: All tables are numbered.
- VAERS reporting requirement changes.

*DT, DTaP and combination vaccines under separate order

I. OREGON IMMUNIZATION PHARMACY PROTOCOL:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥7 years of age 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. Verify needle length for IM injection into the vastus lateralis or deltoid muscles.
6. Avoid injecting in the upper third of the deltoid muscle.
7. Both client and vaccinator must be seated for vaccine administration.
8. Give **Td or Tdap** vaccine, 0.5 mL intramuscularly (IM), according to the age-appropriate schedule and situation to persons **≥7** years of age.
9. May be given with all ACIP-recommended child and adult vaccinations.
10. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk for injury should they faint.

Immunizing Pharmacist Date

II. A. Table 1. ROUTINE VACCINATION SCHEDULE FOR Td VACCINE (TDVAX™[1], Tenivac®[2])

Dose*	Minimum Acceptable Age◊	Preferred Age	Preferred Interval
1	7 years	≥7 years	
2	7 years	≥7 years	8 weeks after dose #1
3§	7 years	≥7 years	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.[8]

◊ 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.[7]

§ 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 a single dose of Tdap and additional doses of Td as needed.[8] If the first dose of DTaP was given at ≥1 year of age, the series may be completed with 3 doses of diphtheria-tetanus containing vaccine as long as the 3rd dose is given ≥7 years and at least 6 months after dose 2. [7,8]

II. B. Table 2: ACIP RECOMMENDED VACCINATION SCHEDULE FOR Tdap VACCINE (Boostrix®[3] and Adacel®[4]) *

Age Group	Minimum Acceptable Age	Dose‡	Preferred Age
Adolescents	7 years ◊	1	11–12 years◊
Adults§	19 years	1	≥19 years
Pregnant Women ‡		1	Tdap during each pregnancy at 27–36 weeks' gestation ‡

* Tdap should be administered with other vaccines that are indicated during the same visit when feasible.[4]

III. A. Table 3: LICENSED COMBINATION VACCINE (Td)[1,2] ◊

Product name	Vaccine components	Minimal Acceptable age range	Thimerosal
Tetanus & diphtheria toxoids[1] (Mass Biologicals)	tetanus & diphtheria toxoids	≥7 years	<0.3 µg/0.5 mL (Not as a preservative)
Tenivac®[2*◊] (sanofi pasteur)	tetanus & diphtheria toxoids	≥7 years	None

◊A single dose of Tdap may be indicated. See table 2. II.B. [5]

III. B. Table 4: LICENSED COMBINATION VACCINE (Tdap) [3,4]

Product name	Vaccine components	Minimal Acceptable age range		Thimerosal
Boostrix®[3] (GSK)	tetanus toxoid, diphtheria toxoid, acellular pertussis	**FDA licensed**[◊*]	**ACIP recommended off-label use**	No
		≥10 years	≥7years[§◊]	
Adacel®[4] (sanofi pasteur)	tetanus toxoid, diphtheria toxoid, acellular pertussis	10–64 years	≥7 years[§◊]	No

[*]Licensed only for a single dose at this time.[3,4]

[◊]Off-label age range. ACIP has endorsed the use of a single dose of either Tdap vaccine in children ≥7 years of age who have not been fully immunized against pertussis and as a single pertussis booster for adolescents and adults. There is no upper age limit.[5]

IV. A. RECOMMENDATIONS FOR USE: Td and Tdap: Tenivac®, Boostrix ®and Adacel®

1. **All persons ≥11 years** of age who have not received Tdap should receive a single dose of Tdap at the first opportunity, regardless of when they last received a Td booster. If a Tdap is given as part of wound management to a person ≥11 years of age, the next Td booster should not be administered for 10 years.* [5]

Tdap may be used in place of Td vaccine when Td is not immediately available.[5]

2. **Persons ≥7 years** old with◊, §:
   - No documentation of a childhood diphtheria tetanus or acellular pertussis schedule; or
   - Unknown vaccination status

   should receive one dose of Tdap. Any additional doses needed to complete a primary tetanus/diphtheria vaccination series should be Td vaccine.[5]

   * This recommendation also applies to unvaccinated adults ≥65 years of age (FDA approved for Boostrix®, but either Tdap vaccine product can be used).[5]

   ◊ 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. [5]

   §A 7–10 -year-old should have a TdaP as part of the catch-up schedule and then receive an additional adolescent dose at 11–12 years of age.[5]

3. **Pregnant women** should be vaccinated during each pregnancy with Tdap to prevent pertussis in the infant.[5]
   - Pregnant women who never have been vaccinated against tetanus should receive three doses of tetanus and diphtheria-containing vaccine. The recommended schedule is at times 0, 4 weeks, and 6–12 months.[5]
   - Tdap should replace 1 dose of Td, preferably at 27–36 weeks' gestation.[5]
   - For wound management, Tdap may be administered any time during pregnancy. Vaccination during the third trimester provides 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.[5]

- 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.[5]

4. **All health care personnel**, regardless of age, should receive a single dose of Tdap regardless of the date since their last Td dose[5]
5. **Wound Management**: Use Tdap in place of the Td booster or for wound management if there is no prior Tdap dose.[5]
6. **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 emergency doses of Td more frequently than every 10 years, even if they have a wound that is neither clean nor minor.[1] In all circumstances, the decision to administer TIG should be based on the primary vaccination history for tetanus (Table 6).[5]

V. A. Tdap and Td CONTRAINDICATIONS[1,2,3,4]

1. Severe allergic reaction to any vaccine component of Td or Tdap vaccine or following a prior dose. *[5]
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. Additional needed doses should be Td. ◊ [5]

* 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.[5]

VI. A. 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 toxoid-containing vaccine more frequently than every 10 years, even for tetanus prophylaxis as part of wound management.[5]
2. History of an Arthus-type hypersensitivity reaction following a previous dose of tetanus or diphtheria toxoid-containing vaccines, including MCV4 (Menactra®, Menveo®, or Prevnar 13®).[5]
3. Unstable neurological condition, uncontrolled epilepsy, or progressive encephalopathy.[5]
4. Severe latex allergy. (The Boostrix® pre-filled needleless syringes contain latex, as do tip caps of Tenivac®.)[2,3]
5. History of Guillain-Barré syndrome within 6 weeks after a previous dose of tetanus toxoid-containing vaccine.[5]
6. ACIP does not consider a history of brachial neuritis to be a precaution or contraindication for administration of tetanus toxoid--containing vaccines.[5]

VII. A. OTHER CONSIDERATIONS FOR Tdap and Td

1. **History of pertussis**:

   - Persons who have a history of pertussis should receive a pertussis-containing vaccine (i.e., Tdap) according to the routine recommendation.
   - Although pertussis disease is likely to confer natural immunity against pertussis, the immune response might be suboptimal against subsequent pertussis disease, and the duration of protection induced by an infection does not provide long-term immunity.[5]

2. **Booster: tetanus or diphtheria disease does not confer immunity**

   - Tetanus or diphtheria infection do not confer immunity against re-infection. Active vaccination should be initiated at the time of recovery from the illness according to the schedule.
   - Persons who have completed the primary tetanus vaccination series should receive a booster dose as soon as feasible during convalescence.
   - Persons with unknown or uncertain previous tetanus vaccination histories should be considered to have had no previous tetanus toxoid–containing vaccine and should begin the 3-dose tetanus and diphtheria toxoids vaccination series.[5]

3. **Inadvertent administration of Pediatric DTaP or Tdap to persons ≥7 years of age**:

   - DTaP is not indicated for persons aged ≥7 years. If **DTaP** is administered inadvertently to a **fully vaccinated** child aged 7–10 years, this dose should be counted as the adolescent Tdap dose.
   - If **DTaP** is administered inadvertently to an **under-vaccinated** child aged 7–10 years, this dose should count as the Tdap dose of the catch-up series and the child should receive an adolescent booster dose of Tdap.
   - If **DTaP** is administered inadvertently to a person aged ≥11 years, this dose should count as the Tdap dose, and the person should not receive an additional dose of Tdap.

   Children aged 7–10 years who are fully vaccinated**.** If **Tdap** is administered inadvertently, the Tdap dose should not be counted as valid. The adolescent

- Tdap dose should be administered as recommended when this child is aged 11–12 years.[5]

VII. B Table 5: TETANUS WOUND MANAGEMENT RECOMMENDATIONS [5]

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.

Persons aged ≥7 years who are not fully immunized against pertussis, tetanus or diphtheria should receive one dose of Tdap for wound management and as part of the catch-up series.
For nonpregnant persons with documentation of previous vaccination with Tdap, Td should be used if a tetanus toxoid–containing vaccine is indicated.[5]

§**Persons with HIV infection** or severe immunodeficiency who have contaminated wounds should also receive TIG, regardless of their history of tetanus immunization.

‡Yes, if it has been ≥10 years since the last dose.

**Yes, if it has been ≥5 years since the last dose of Tdap or Td. More frequent doses of Tdap or Td are not needed and can accentuate side effects.

VIII. A. Table 6: SIDE EFFECTS AND ADVERSE REACTIONS FOR Td: MassBiologics (no trade name)[1]

Number followed for safety:	N/A
Recipients: ≥7 years of age	Adverse Reaction %: N/A
Local Reaction, Injection site	
Pain	Yes
Redness	Yes
Swelling	Yes
Systemic Complaints	Yes
Fever	Yes
Chills	Yes
Convulsions	Yes
Nausea	Yes
Tiredness	Yes
Headache	Yes
Body ache	Yes
Sore and swollen joints	Yes
Rash	Yes
Package insert text on page 2	

VIII. B. Table 7: SIDE EFFECTS AND ADVERSE REACTIONS FOR Td[1]: Tenivac®[2]

VIII. C. 1. Table 8: SIDE EFFECTS AND ADVERSE REACTIONS FOR Boostrix®[3] and Adacel® [4] (Tdap)

Number followed for safety:	Adverse Reaction %	
	Boostrix®[3] N=3032*	Adacel®[4] N=1170–1175◊
Recipients age:	10–18 years	11–17 years
% Local Reaction, Injection site		
Pain	4.6–75.3	1.5–77.8
Redness	1.7–22.5	2.7–20.8
Swelling	2.5–21.1	2.8–6.5
Systemic Complaints		
Fever ≥99.5°F (37.5°C)	13.5	
Fever >100.4°F (38.0°C)	5.0	5.0
Fever >102.2°F (39.0°C)	1.4	0.9
Fever >103.1°F(39.5°C)		0.2
Chills		0.5–15.1
Alteration in appetite	3–26	6.6–13.3
Tiredness	3.7–37	1.2–30.2
Headache	3.7–43.1	2.0–43.7
Body ache		1.3–30.4
Sore and swollen joints		0.3–11.3
Rash		2.7
*Boostrix® package insert Table 1 page 7.		
◊Adacel® package insert Table 1 pages 7–8 and Table 2 page 9		

VIII. C. 2. Table 9: SIDE EFFECTS AND ADVERSE REACTIONS: Boostrix®[3]

Number followed for safety:	Adverse Reaction %		
	Boostrix®[3] N=1480*	Boostrix®[3] N=882*	Boostrix®[3] N=1697–1698◊
Recipient age:	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	
Fever ≥100.4°F (38°C)			1.4
Fever ≤103.0°F (38.8–≤39.4°C)	0.1	0.0	0.4
Fever ≥102.2°F (≥39.5°C)			0
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.			

IX. Table 10: Storage and Handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Notes	Temp	Storage Issues	Notes
Tenivac® [2] **Boostrix® [3]** **Adacel[4]**	Tip caps may contain latex	Store at 2°–8°C (36°–46°F)	Do not use if vaccine has been frozen. Report to health educator	Protect from light Use immediately after reconstitution
Td[1] **MassBiologics**	No latex			

X. ADVERSE EVENTS REPORTING

Private providers are to report events directly to VAERS and can read about options on how to do so at https://vaers.hhs.gov/reportevent.html

A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290-(2)(3).[9]

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

Table 11: VAERS Reporting Table:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Event and interval from vaccination	
Tetanus	A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Shoulder injury related to vaccine administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

Effective date: March 21, 2017. 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 manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET.

REFERENCES

1. Tetanus and Diphtheria Toxoids Adsorbed (Td). [Package insert]. 2009. Mass Biologics. Available at: www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM164127.pdf. Accessed 31 August 2018.
2. Tenivac® (Td). [Package insert]. 2013. Sanofi. Available at: www.fda.gov/downloads/BiologicsBloodVaccines/UCM152826.pdf. Accessed 04 September 2018.
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4. Adacel®. [Package insert]. 2017. Sanofi. Available at: www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142764.pdf. Accessed 04 September 2018.
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6. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Available at: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 31 August 2018.
7. Centers for Disease Control and Prevention. Immunization schedules. Catch-up schedule. Footnote 3 and 12. (2018, February). *Catch-up Immunization Schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind.* Retrieved from www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html Accessed 04 September 2018.
8. Centers for Disease Control and Prevention. Immunization Schedules. Catch-up Guidance for Children 7 through 18 years of age. Tetanus, Diphtheria, and Pertussis-Containing Vaccines: Tdap/Td. (2018). Available at www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap.pdf.
9. Oregon Secretary of the State. Board of Pharmacy, Chapter 855; Division 19; Licensing of Pharmacists. OAR 855-019-0270, 0280, and 0290. Available at: https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3967 Accessed 16 August 2018.

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.

APPENDIX*

Tetanus containing vaccines; total antigen
DT, DTaP, DTP, Td, Tdap. **Pertussis Components**

Antigens	P/A	Tetanus Toxoid	Diphtheria Toxoid	PT	FHA	Pertactin	Fimbriae types 2, 3
Daptacel Sanofi	P	5 Lf	15 Lf	10mcg	5mcg	3 mcg	5mcg
Pentacel Sanofi	P	5 Lf	15 Lf	20mcg	20mcg	3mcg	5mcg
Quadracel Sanofi	P	5 Lf	15 Lf	20 mcg	20 mcg	3mcg	5mcg
Infanrix GSK	P	10 Lf	25 Lf	25mcg	25mcg	8 mcg	
Pediarix GSK	P	10 Lf	25 Lf	25mcg	25mcg	8 mcg	
Kinrix GSK	P	10 Lf	25 Lf	25mcg	25mcg	8 mcg	
DT Sanofi	P	6.7 Lf	5 Lf				
Td Mass Bio	A	2 Lf	2Lf				
Tenavac Sanofi	A	5 Lf	2Lf				
Adacel Sanofi	A	5 Lf	2 Lf	2.5mcg	5mcg	3mcg	5 mcg
Boostrix GSK	A	5 Lf	2.5Lf	8mcg	8 mcg	2.5 mcg	

P = Pediatric **A = Adult**

*Adapted from CDC. Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) MMWR 2018;67; 1-48. Available at: https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf