

Immunization Pharmacy Protocol

Tetanus, diphtheria, and tetanus-containing Combination Vaccines (Adacel[®], Boostrix[®], TENIVAC[®], and TDVAX)

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1. What's new

Updated phrasing and formatting.

2. Oregon immunization pharmacy protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients for contraindications and precautions.

- C. Provide a current Vaccine Information Statement (VIS), answering any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Verify needle length for intramuscular (IM) injection into the deltoid muscle.
- F. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.
- G. Give a 0.5-mL dose of Td or Tdap IM, according to the age-appropriate schedule.
- H. May be given with all ACIP-recommended child and adult vaccinations.
- I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

I have read, understand, and I agree to participate by the terms of this protocol.

Pharmacist Signature

Date

3. Vaccine schedule for tetanus, diphtheria, and pertussis

For unvaccinated persons ≥7 years of age* ⁵			
Dose and Route - 0.5-mL, IM			
Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing
1	7 years	≥7 years	
2			4 weeks after dose 1
3			6 months after dose 2
Booster doses	11 years	10 years	≥5 years after last dose

*See Appendices for catch-up schedule for partially vaccinated children.

Booster schedule for persons ≥10 years of age⁶

Dose and Route: 0.5-mL, IM

Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing
First booster	11 years	10 years	≥5 years after last dose of DTaP
Additional boosters	≥21 years	N/A	Routine: every 10 years Wound management: ≥5 years

Pregnant Persons⁶

Dose and Route: 0.5-mL, IM

Tdap should be administered during **every** pregnancy, at 27–36 weeks' gestation, preferably during the earlier part of the third trimester. Vaccination during the third trimester provides the highest concentration of maternal antibodies to be transferred closer to birth.

Tdap can be given at any time during pregnancy if needed for catch-up or wound management.

4. Licensed Tdap / Td vaccine

Product Name	Vaccine Components	Acceptable Age Range	Preferred age	Thimerosal
Adacel ¹	Tetanus, diphtheria, and acellular pertussis	≥7 years*	11 years	None
Boostrix ²				
TENIVAC ³	Tetanus and diphtheria	≥7 years	N/A	≤0.3 mcg (not as a preservative)
TDVAX ⁴				

*Off-label use, approved by ACIP⁶

5. Recommendations for use

- A. **Routine use:** All persons ≥11 years of age who have not received a dose of Tdap should receive a single dose of Tdap at the first opportunity, regardless of when they last received a Td booster.⁵
- B. **Catch-up vaccination:** Persons who do not have documentation of receiving a series of diphtheria/tetanus-containing vaccine in childhood need a single-dose

of Tdap vaccine and two doses of Td vaccine given over 6 months. See appendix A for details.⁵

- C. **Wound management:** Either Td or Tdap can be used for wound management. Tdap is preferred for persons who haven't previously received Tdap or whose history is unknown.⁶

6. Contraindications:

- A. **Allergy:** Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Vaccine Excipient Summary ⁸
Adacel	aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde
Boostrix	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Tenivac	aluminum phosphate, formaldehyde, sodium chloride
TDVAX	aluminum phosphate, formaldehyde, thimerosal

- B. **Encephalopathy:** (Tdap) Encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap. These persons should receive Td in place of Tdap.⁵

7. Warnings and precautions:

- A. **Neurological disorders:** (Tdap) Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized; these precautions are for pertussis components.⁵
- B. **Guillain-Barré syndrome:** Guillain-Barré syndrome <6 weeks after a previous dose of tetanus toxoid-containing vaccine.⁵
- C. **Arthus-type hypersensitivity:** History of Arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccines; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine.⁵
- D. Moderate or severe acute illness with or without fever.⁷

8. Other considerations

A. History of disease:

- a. Persons who have a history of pertussis should receive a booster dose of Tdap according to the routine recommendation. While pertussis disease

likely confers some natural immunity, duration of protection is not long-term.⁵

- b. Tetanus or diphtheria disease does not confer immunity against re-infection. Persons who have a history of a primary series should receive a booster dose during convalescence. Persons without a history of vaccination should begin the 3-dose Tdap/Td series.⁵

B. Inadvertent administration of the incorrect formulation:⁵

- a. 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.
- b. 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.
- c. 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.
- d. 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.

C. Wound management recommendations:⁶

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	Administer if ≥10 years since last dose	No	Administer if ≥5 years since last dose	No

*Wounds contaminated with dirt, feces, soil or saliva; puncture wounds; avulsions; or wounds from missiles, crushing, burns or frostbite.

#Persons with HIV or severe immunodeficiency should receive TIG, regardless of immunization history or wound severity.

9. Side effects and adverse reactions

Tdap ^{1,2}	
Adverse Event	Frequency
Injection site pain	Up to 78%
Other local reactions (redness, swelling)	Up to 25%
Fever >100.4°F	Up to 5%
Other systemic reactions (fatigue, headache, GI symptoms)	Up to 43%

Td ^{3,4}	
Adverse Event	Frequency
Injection site pain	Up to 81%
Other local reactions (redness, swelling)	Up to 26%
Fever >100.4°F	Up to 2%
Other systemic reactions (malaise, headache, pain in joints)	Up to 25%

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	Temp	Storage Issues	Notes
Adacel ¹ Boostrix ² Tenivac ³	Store at 2°–8°C (36°–46°F)	Do not freeze. Do not use if vaccine has been frozen.	Tip caps of prefilled syringes may contain latex.
TDVAX ⁴			No latex.

11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at <https://vaers.hhs.gov/reportevent.html>.

VAERS Reporting Table:

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock (7 days)
B. (Tdap) Encephalopathy or encephalitis (7 days)
C. Brachial neuritis (28 days)
D. Shoulder Injury Related to Vaccine Administration (7 days)
E. Vasovagal syncope (7 days)
F. Any acute complications or sequelae (including death) of above events (interval — not applicable)
G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval — see package insert)

A pharmacist who administers any vaccine must report the following elements, available at the link below, 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](#).

12. References

1. Adacel® package insert, current as of 28 December 2020. Available at: www.fda.gov/vaccines-blood-biologics/vaccines/adacel. Accessed 7 October 2021.
2. Boostrix® package insert, current as of 10 September 2020. Available at: www.fda.gov/media/124002/download. Accessed 7 October 2021.
3. Tenvirac® package insert, current as of 9 December 2019. Available at: www.fda.gov/media/76610/download. Accessed 7 October 2021.
4. TDVAX™ package insert, current as of 16 November 2018. Available at: www.fda.gov/media/76430/download. Accessed 7 October 2021.
5. Liang, JL, Tiwari T, Moro P, et al. Prevention of pertussis, tetanus, and diphtheria with vaccines in the United States: Recommendations of the ACIP. MMWR 2018; 67(2):1–48. Available at: www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf. Accessed 7 October 2021.
6. Havers FP, Moro P, Hunter P, Hariri S, Bernstein H. Use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccines: Recommendations of the ACIP. MMWR 2020; 69(3): 77–83. Available at: www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6903a5-H.pdf. Accessed 7 October 2021.
7. 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/aciprecs/general-recs/downloads/general-recs.pdf. Accessed 28 September 2021.
8. CDC. Vaccine Excipient Summary. February 2020. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table2.pdf. Accessed 28 September 2021.

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: [standing orders](#)

Electronic copy of this pharmacy protocol is available at: [protocols](#)

13. Appendix A – Catch-up guidance 7 through 9 years

Available at: <https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-1.pdf>

Catch-Up Guidance for Children 7 through 9 Years of Age Tetanus-, Diphtheria-, and Pertussis-Containing Vaccines: Tdap/Td¹

IF current age is	AND # of previous doses of DTaP, DT, Td, or Tdap is	AND	AND	AND	THEN	Next dose due
7 through 9 years ¹	3	Dose 1 was given before 12 months of age	It has been at least 6 calendar months since Dose 3	Any dose was Tdap ¹	Give Dose 4 (Td or Tdap) today	Give Tdap at 11–12 years of age ^{1,2}
				No dose was Tdap	Give Dose 4 (Tdap) today	
		It has not been 6 calendar months since Dose 3	Any dose was Tdap ¹	No dose today	Give Dose 4 (Td or Tdap) at least 6 calendar months after Dose 3 ¹	
			No dose was Tdap		Give Dose 4 (Tdap) at least 6 calendar months after Dose 3 ¹	
	Dose 1 was given at 12 months of age or older	No dose was Tdap	→	Give Dose 4 (Tdap ²) today	Give Tdap at 11–12 years of age ^{1,2}	
		Any dose was Tdap	→	No dose today		
	4	→	Dose of DTaP or Tdap given after 4 th birthday	→	No dose today	Give Tdap at 11–12 years of age ^{1,2}
			No DTaP or Tdap given after 4 th birthday	→	Give a dose of Tdap today	Give Tdap at 11–12 years of age ^{1,2}

¹For persons 7–9 years of age who receive a dose of Tdap, the routine adolescent Tdap dose should be administered at age 11–12.

²Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Reference: Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger—United States, 2021. www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

Catch-Up Guidance for Children 7 through 9 Years of Age

Tetanus-, Diphtheria-, and Pertussis-Containing Vaccines: Tdap/Td¹

IF current age is	AND # of previous doses of DTaP, DT, Td, or Tdap is	AND	AND	AND	THEN	Next dose due
7 through 9 years ¹	3	Dose 1 was given before 12 months of age	It has been at least 6 calendar months since Dose 3	Any dose was Tdap ¹	Give Dose 4 (Td or Tdap) today	Give Tdap at 11–12 years of age ¹²
				No dose was Tdap	Give Dose 4 (Tdap) today	
		Dose 1 was given at 12 months of age or older	It has not been 6 calendar months since Dose 3	Any dose was Tdap ¹	No dose today	Give Dose 4 (Td or Tdap) at least 6 calendar months after Dose 3 ¹
				No dose was Tdap		Give Dose 4 (Tdap) at least 6 calendar months after Dose 3 ¹
	4	→	Dose of DTaP or Tdap given after 4 th birthday	→	No dose today	Give Tdap at 11–12 years of age ¹²
			No DTaP or Tdap given after 4 th birthday	→	Give a dose of Tdap today	Give Tdap at 11–12 years of age ¹²
		→	No dose was Tdap	→	Give Dose 4 (Tdap ²) today	Give Tdap at 11–12 years of age ¹²
			Any dose was Tdap	→	No dose today	

¹For persons 7–9 years of age who receive a dose of Tdap, the routine adolescent Tdap dose should be administered at age 11–12.

²Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Reference: Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger—United States, 2021. www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

14. Appendix B – Catch-up guidance 10 through 18 years

Available at: <https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-2.pdf>

Catch-Up Guidance for Children 10 through 18 Years of Age Tetanus-, Diphtheria-, and Pertussis-Containing Vaccines: Tdap/Td

The table below provides guidance for children whose vaccinations have been delayed. Start with the child's age and information on previous doses (previous doses must be documented and must meet minimum age requirements and minimum intervals between doses). Use this table in conjunction with table 2 of the Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, found at www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html.

IF current age is	AND # of previous doses of DTaP, DT, Td, or Tdap is	AND	AND	AND	THEN	Next dose due
10 through 18 years	Unknown or 0	→	→	→	Give Dose 1 (Tdap) today	Give Dose 2 (Td or Tdap) at least 4 weeks after Dose 1
	1	Dose 1 was given before 12 months of age	→	→	Give Dose 2 (Tdap) today	Give Dose 3 (Td or Tdap) at least 4 weeks after Dose 2
		Dose 1 was given at 12 months of age or older	It has been at least 4 weeks since Dose 1	Dose 1 was Tdap	Give Dose 2 (Td or Tdap) today	Give Dose 3 (Td or Tdap) at least 6 calendar months after Dose 2
			It has not been 4 weeks since Dose 1	Dose 1 was not Tdap	Give Dose 2 (Tdap) today	
		Dose 1 was given at 12 months of age or older	It has not been 4 weeks since Dose 1	Dose 1 was Tdap	No dose today	Give Dose 2 (Td or Tdap) at least 4 weeks after Dose 1
	Dose 1 was not Tdap			No dose today	Give Dose 2 (Tdap) at least 4 weeks after Dose 1	
	2	Dose 1 was given before 12 months of age	It has been at least 4 weeks since Dose 2	Any dose was Tdap ¹	Give Dose 3 (Td or Tdap) today ²	Give Dose 4 (Td or Tdap) at least 6 calendar months after Dose 3
				No dose was Tdap ²	Give Dose 3 (Tdap) today	
			It has not been 4 weeks since Dose 2	Any dose was Tdap ¹	No dose today	Give Dose 3 (Td or Tdap) at least 4 weeks after Dose 2 ²
				No dose was Tdap ²	No dose today	Give Dose 3 (Tdap) at least 4 weeks after Dose 2
		Dose 1 was given at 12 months of age or older	It has been at least 6 calendar months since Dose 2	Any dose was Tdap ¹	Give Dose 3 (Td or Tdap) today ²	Give Td or Tdap 10 years after Dose 3
				No dose was Tdap ²	Give Dose 3 (Tdap) today	
It has not been 6 calendar months since Dose 2			Any dose was Tdap ¹	No dose today	Give Dose 3 (Td or Tdap) at least 6 calendar months after Dose 2 ²	
			No dose was Tdap ²	No dose today	Give Dose 3 (Tdap) at least 6 calendar months after Dose 2	

¹Given at 10 years of age or older.

²If the previous Tdap dose(s) was administered before the 10th birthday, then a dose of Tdap is recommended now.

³Or Tdap administered at 9 years of age or younger.

Reference: Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger—United States, 2021. www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Catch-Up Guidance for Children 10 through 18 Years of Age

Tetanus-, Diphtheria-, and Pertussis-Containing Vaccines: Tdap/Td

IF current age is	AND # of previous doses of DTaP, DT, Td, or Tdap is	AND	AND	AND	THEN	Next dose due
10 through 18 years	3	Dose 1 was given before 12 months of age	It has been at least 6 calendar months since Dose 3	Any dose was Tdap ¹	Give Dose 4 (Td or Tdap) today ²	Give Td or Tdap 10 years after Dose 4
				No dose was Tdap ²	Give Dose 4 (Tdap) today	
			It has not been 6 calendar months since Dose 3	Any dose was Tdap ¹	No dose today	Give Dose 4 (Td or Tdap) at least 6 calendar months after Dose 3 ²
				No dose was Tdap ²	No dose today	Give Dose 4 (Tdap) at least 6 calendar months after Dose 3
		Dose 1 was given at 12 months of age or older	No dose was Tdap ¹	→	Give Dose 4 (Tdap) today	Give Td or Tdap 10 years after Dose 4
			Any dose was Tdap ²	→	No dose today	Give Td or Tdap 10 years after Dose 3
	4	→	No Tdap was given after 7 th birthday	→	Give a dose of Tdap today ⁴	Give Td or Tdap 10 years after Tdap dose
				No Tdap was given after 10 th birthday		
			Any dose of Tdap was given at age 7 years or older ¹	No Tdap was given after 10 th birthday	No dose today	Give Td or Tdap 10 years after Dose 4
				Tdap was given after 10 th birthday		

¹Given at 10 years of age or older.

²If the previous Tdap dose(s) was administered before the 10th birthday, then a dose of Tdap is recommended now.

³Or Tdap administered at 9 years of age or younger.

⁴The preferred age at administration for this dose is 11–12 years. However, if Tdap is administered at age 10 years, the Tdap dose may count as the adolescent Tdap dose.

Reference: Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger—United States, 2021. www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf