Protocol for Tetanus Diphtheria Containing Vaccines (Adacel®, Boostrix®, TENIVAC®, and TDVAX™)

1. What's New

A. Updated recommendations to reflect that if Tdap is administered inadvertently to children 10 years of age that the Tdap dose may be counted as the adolescent dose recommended at age 11-12 years. This previously was considered to be an invalid dose.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of tetanus-containing vaccine, according to the age-appropriate schedule and vaccine history.

B. May be given with all ACIP-recommended child and adult vaccinations.

3. Vaccine Schedule

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM		
For unvaccinated persons ≥ 7 years of age[1]*		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 7 years	
2		4 weeks after dose 1
3		6 months after dose 2
The preferred schedule is 1 dose of Tdap, followed by either Td or Tdap for dose 2 & 3		
*See appendices for catch-up schedule for partially vaccinated children.		

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM		
Booster schedule for persons ≥ 10 years of age[2]		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
Adolescent booster	11 through18 years	These persons should receive a single dose of Tdap, preferably at age 11–12 years. For persons aged 7–9 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap dose should be administered at age 11–12 years. If a Tdap dose is administered at age ≥10 years, the Tdap dose may count as the adolescent Tdap dose.
Routine booster	≥19 years	Regardless of the interval since their last tetanus or diphtheria toxoid–containing vaccine, persons aged ≥19 years who have never received a dose of Tdap should receive 1 dose of Tdap.
Additional boosters		To ensure continued protection against tetanus and diphtheria, 1 booster dose of either Td or Tdap should be administered every 10 years throughout life.

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM
For Pregnant Persons[2]
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.

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM				
For Wound Management[2]				
History of absorbed 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 Tetanus Immune Globulin (TIG), regardless of immunization history or wound severity.				

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range***	**Thimerosal**
Adacel®[3]	Tetanus, diphtheria, and acellular pertussis	Single-dose vials and prefilled syringes containing a 0.5- mL suspension for injection	10-64 years	None
Boostrix®[4]			≥10 years	
TENIVAC®[5]	Tetanus and diphtheria		≥7 years	
TDVAX™[6]		Single-dose vials containing a 0.5- mL suspension for injection		≤0.3 mcg (not as a preservative)
*Off-label use is approved by ACIP				

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.[1]

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 and two doses of either Td or Tdap vaccine.

C. Pregnant persons: No change has been made to the recommendations for routine Tdap immunization during pregnancy. Pregnant persons should receive 1 dose of Tdap during each pregnancy, irrespective of their history of receiving the vaccine. Tdap should be

administered at 27–36 weeks' gestation, preferably during the earlier part of this period, although it may be administered at any time during pregnancy.

D. 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.[2]

6. Contraindications

A. Allergy: Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component, including latex (Adacel®, Boostrix®, Tenivac®)

Vaccine	Contains[7]
Adacel®	aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde, tip caps of prefilled syringes may contain latex
Boostrix®	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80, tip caps of prefilled syringes may contain latex
Tenivac®	aluminum phosphate, formaldehyde, sodium chloride, tip caps of prefilled syringes may contain latex
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.[1]

B. Guillain-Barré syndrome: Guillain-Barré syndrome <6 weeks after a previous dose of tetanus toxoid-containing vaccine.[1]

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.[1]

8. Other Considerations

A. Catch up schedules for 7 through 18 years of age:

i. If patients' vaccination status is unknown or incomplete, guidance for catch-up schedules can be found at https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html

1. For children 7-9 years of age: https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-1.pdf
2. For children and adolescents 10-18 years of age: https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-2.pdf

B. History of disease:

i. 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]

ii. 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.[1]

C. Inadvertent administration of the incorrect formulation:[1]

i. DTaP is not indicated for persons aged ≥7 years. If DTaP is administered inadvertently to a fully vaccinated child aged 7 through9 years, an adolescent Tdap dose should be administered at age 11 through 12 years.

ii. If DTaP is administered inadvertently to an under-vaccinated child aged 7 through 9 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 at age 11 through 12 years.

iii. If DTaP is administered inadvertently to a person aged ≥10 years, this dose should count as the adolescent Tdap dose Routinely administered at age 11 through 12 years.

iv. Children aged 7 through9 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 through12 years.

v. Children aged 10 years who are fully vaccinated. If Tdap is administered inadvertently, the Tdap dose may be counted as the adolescent dose recommended at age 11 through12 years.

9. Side Effects and Adverse Reactions

Tdap[3,4] Adverse Events	Frequency
Injection site pain	Very common, up to 78%
Other local reactions (redness, swelling)	Less Common, up to 21%
Fever >100. 4°F	Uncommon, up to 5%
Other systemic reactions (fatigue, headache, GI symptoms)	Common, up to 43%

Td[5,6] Adverse Events	Frequency
Injection site pain	Very common, up to 81%
Other local reactions (redness, swelling)	Less Common, up to 26%
Fever >100. 4°F	Uncommon, up to 2%
Other systemic reactions (fatigue, headache, GI symptoms)	Less Common, up to 25%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. 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®[3] Boostrix®[4] Tenivac®[5]	Store at 2°– 8°C (36°- 46°F)	Do not freeze. Do not use if vaccine has been frozen.	
TDAVAX™[6]			No latex.

11. References

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5. Tenivac®. [Package insert]. December 2022. https://www.fda.gov/media/76610/download. Accessed 23 July 2023.
6. TDVAX™. [Package insert]. November 2018. www.fda.gov/media/76430/download . Accessed 23 July 2023.
7. CDC. Vaccine Excipient Summary. November 2021. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 23 July 2023.
8. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). 20 June 2023. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed 23 July 2023.

12. Appendix

A. N/A