Td/Tdap Immunization Protocol

NAME, STRENGTH, DOSE, ROUTE, SITE

Name & Indication	Strength and Components	Dose	Route	Injection Site(s)
Td Tenivac® approved for age ≥7 years Tdvax™ approved for age ≥7 years	**Tenivac®** Diphtheria 2 Lf units and Tetanus 5 Lf units per 0.5 mL [tip caps of prefilled syringes may contain natural latex; vial contains no latex] **Tdvax™** Diphtheria 2 Lf units and Tetanus 2 Lf units per 0.5 mL [stopper of vial does not contain natural latex]	0.5 mL	IM	Administer in the deltoid muscle of the upper arm.
Tdap* Adacel® Approved for age 10 through 64 years Boostrix® Approved for age ≥10 years	**Adacel®** Tetanus 5 Lf units, Diphtheria 2 Lf units, and Acellular pertussis 2.5 mcg per 0.5 mL [vial stopper is latex free] **Boostrix®** Tetanus 5 Lf units, Diphtheria 2.5 Lf units, and Acellular pertussis 8 mcg per 0.5 mL	0.5 mL	IM	Administer in the deltoid muscle of upper arm.

*When feasible, administer Boostrix® to adults age 65 years and older; however, either vaccine product administered to a person age 65 years and older provides protection and is considered valid.

INTENDED AUDIENCE AND PATIENT POPULATION

- Persons 7 years of age and older in need of vaccination against tetanus, diphtheria and (if indicated) pertussis based on the following:
  - Lack of documentation of at least three doses of tetanus- and diphtheria-toxoid-containing vaccine
  - Lack of documentation of receiving a dose of pertussis-containing vaccine (i.e., Tdap) as an adolescent or adult, including
    - Persons aged 11 years of older who have not received Tdap vaccine or for whom vaccine status is unknown
    - Healthcare personnel of all ages
  - Children 7 years of age or older who did not complete the primary DTaP series, were never vaccinated against diphtheria, tetanus, or pertussis, or if vaccine status is unknown
  - Completion of a three-dose primary series of tetanus- and diphtheria-toxoid-containing vaccine with receipt of the last dose being 10 years ago or longer

- Recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous five years
- Pregnant adolescents/women should receive Tdap during each pregnancy, irrespective of their history of receiving the vaccine.

PRECAUTIONS

- History of Guillain-Barré syndrome within six weeks of previous dose of tetanus-toxoid-containing vaccine
- History of an Arthus reaction following a previous dose of tetanus-toxoid-containing and/or diphtheria-toxoid-containing vaccine, including meningococcal conjugate vaccine
- Moderate or severe acute illness with or without fever
- Tdap ONLY:
  - Progressive neurologic disorder

CONTRAINDICATIONS

- History of severe or life-threatening allergic reaction to any vaccine component or following a previous dose of any tetanus toxoid, diphtheria toxoid or pertussis containing vaccine
- History of severe allergy to latex if vaccine is not latex free
- Tdap ONLY:
  - History of encephalopathy within seven days of a previous dose of pertussis containing vaccine not attributable to another identifiable cause
    - Give Td instead

SIDE EFFECTS AND ADVERSE REACTIONS REPORTED

- Pain at injection site
- Redness or swelling at injection site
- Headache
- Tiredness
- Nausea, vomiting, diarrhea, stomachache
- Mild fever of at least 100.4°F or other systemic symptoms (chills body aches, sore joints, rash and swollen lymph glands)
- Severe allergic reactions are rare

ADMINISTRATION

1. **Schedule—General Recommendations**

   a. <u>Persons aged 11 through 18 years</u>:
      i. Administer 1 dose of Tdap vaccine to all adolescents age 11-12 years, even if they received Tdap vaccine at ages 7-9 years. Children who receive Tdap at age 10 years do not need to receive routine Tdap vaccine at age 11-12 years.
      ii. Booster doses of either Td or Tdap vaccine should be administered every 10 years throughout life.
      iii. Tdap may be administered regardless of the time interval since the last tetanus- and diphtheria-containing vaccine.

b. Persons aged 19 years and older:
   i. Persons ≥ 19 years who have never received a dose of Tdap should receive one dose, regardless of the interval since their last tetanus- or diphtheria-containing vaccine.
   ii. Booster doses of either Td or Tdap vaccine should be administered every 10 years throughout life.

c. Pregnant women/adolescents:
   i. Give one dose of Tdap during **each** pregnancy, at 27 to 36 weeks gestation, regardless of woman's history of receiving the vaccine.
   ii. If not administered during pregnancy, give Tdap immediately postpartum

2. Schedule--Catch-up Immunization Recommendations*

a. Persons aged 7 through 18 years:
   i. Persons who have never been vaccinated against pertussis, tetanus, or diphtheria should receive a 3-dose series of tetanus and diphtheria toxoid-containing vaccines. The preferred schedule is one dose of Tdap, followed by either Td or Tdap ≥4 weeks later, and one dose of either Td or Tdap 6 to 12 months later.
   ii. Persons aged 7-18 years who are not fully immunized against tetanus and diphtheria should receive one dose of Tdap, preferably as the first dose in the catch-up series. If additional tetanus toxoid-containing doses are required, either Td or Tdap may be used.

***** Tdap vaccines are not FDA-approved for children 7 to 9 years of age; however, a Tdap vaccine is recommended on the catch-up schedule for this age group per ACIP recommendations.

b. Persons aged 19 years of age and older:
   i. Persons who are unvaccinated or without documentation should complete the primary 3-dose series of tetanus and diphtheria toxoid-containing vaccine. The preferred schedule is one dose of Tdap, followed by one dose of either Td or Tdap at least 4 weeks afterward, and one dose of either Td or Tdap 6 to 12 months later.
   ii. Persons who are not fully immunized against tetanus and diphtheria should receive one dose of Tdap, preferably as the first dose in the catch-up series. If additional tetanus toxoid-containing doses are required, either Td or Tdap may be used.
   iii. For Tdap, there is no minimum interval following Td.

- Procedure
  - Prescription is required for patients who are seven years of age or older but not more than 13 years of age. (per Ohio Revised Code 4729.41)
  - Patient or legal guardian must first sign a consent form before the vaccination is administered.

- Provide patient/legal guardian with a copy of the most current federal Vaccine Information Statement (VIS) for the vaccine to be administered, i.e., Td (Tetanus and diphtheria) or Tdap (Tetanus, diphtheria, pertussis)

- Use appropriate product and dosage (from chart and schedule above) for intramuscular (IM) injection ONLY.

- Inject 0.5 mL of vaccine **intramuscularly** into the thickest point of a relaxed **deltoid** muscle. Most patients will receive 25 gauge, 1-inch needle. For patients weighing less than 130 lbs [60 kg], a 5/8-inch needle may be used for injection in the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle. For obese patients, a 1½ -inch needle will be used.

- Give with caution to persons on anticoagulant therapy or with bleeding tendencies after giving the injection, apply steady pressure to the injection area.

- Dispose of all supplies properly.

g. Record the date of administration, name/manufacturer/strength/dose of the immunization, lot number and expiration date of the immunization, route of administration, location of the injection site, and positive identification of the person administering the vaccine.

h. Monitor patients in the general vicinity of the administering pharmacist or pharmacy intern for at least **10 minutes** after giving the injection and treat accordingly.

i. Advise patient to report any adverse reaction to their pharmacist or primary care physician.

III. Monitoring parameters

(1) Patients who faint should be placed supine. Check their pulse and blood pressure immediately.

(2) Watch for rapidly falling blood pressure, difficulty breathing, sustained unconsciousness. Observe for adequate airway and pulse; administer CPR if needed. Have another member of the pharmacy staff call 911. Follow procedures in next section for treatment of severe allergic/anaphylactic reactions.

(3) Treat externally for shock. Keep patient warm, head low and feet elevated.

(4) Contact protocol physician as soon as possible to report the condition of the patient.

PROTOCOL FOR MANAGEMENT OF SEVERE ALLERGIC/ANAPHYLACTIC REACTIONS

(A) Pre-Vaccination Procedures
- (1) Be prepared to call 911.
- (2) Take a thorough history for allergies and prior adverse events before any immunization.
- (3) Allow adequate physical space for fainting or collapse without injury and to lay patient flat on a hard surface in the event CPR is needed.
- (4) Maintain current competency in vaccine administration and in cardiopulmonary resuscitation; observe all vaccinees for at least 10 minutes after immunization; remind vaccinees to report any adverse events to you.

(B) Supplies to Stock
- (1) Epinephrine USP, 1 mg/ml (1:1000). May be in vials of solution, *Ana-Guard* syringes, or in an *Epi-Pen* (0.15 mg & 0.3 mg). At least three adult and children's doses of epinephrine will be available wherever immunizations are given.
- (2) Diphenhydramine liquid and injection
- (3) Blood-pressure cuff, adult size, with stethoscope

(C) Recognition of Anaphylactic Reaction
- (1) Sudden onset of itching, redness, with or without hives, within several minutes of administering a medication. The symptoms may be localized or generalized.
- (2) Angioedema (swelling of the lips, face, throat)
- (3) Bronchospasm

(D) Emergency treatment
- (1) If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for a suitable period of time, watching for generalized symptoms. If none occur, go to paragraph D(8).
- (2) If symptoms are generalized, activate the emergency medical system (EMS). Call 911 **and** the protocol physician for instruction. This should be done by a second person, while the immunizer treats and observes the patient.
- (3) Administer epinephrine IM (refer to dosing chart). Standard dose is 0.01mg/kg up to 0.5 mg maximum in adults. Site of administration can be the anterolateral thigh if using auto-injector, or deltoid muscle above the vaccine injection site.
- (4) Administer diphenhydramine by IM injection (refer to dosing chart). DO NOT administer diphenhydramine or any other drug by mouth if the patient is not fully alert or if the patient has respiratory distress.
- (5) Monitor the patient closely until EMS arrives. Perform CPR and maintain airway, if necessary. Keep patient in supine position unless they are having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. Monitor vital signs frequently.
- (6) If EMS has not arrived and symptoms still persist, repeat dose of epinephrine every 10-20 minutes for up to 3 doses, depending on patient response.

(7) Record all vital signs, medications administered to the patient, including the time, dosage, response, and other relevant clinical information.

(8) Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may recur after epinephrine and diphenhydramine wear off, as much as 24 hours later. After the event is concluded, complete a VAERS form. Report forms may be obtained online at www.vaers.hhs.gov or by calling 1-800-822-7967.

Suggested Dosing of Epinephrine and Diphenhydramine				
Age Group Dose	**Weight * in kg**	**Weight * in lbs**	**Epinephrine Dose**** 1 mg/mL injectable (1:1000 dilution) intramuscular	**Diphenhydramine (Benadryl)** 12.5 mg/5 mL liquid 25 and 50 mg capsules or tablets 50 mg/mL injectable
1-6 mos	4-7 kg	9-15 lbs	0.05 mg (0.05 ml)	5 mg
7- 18 mos	7-11 kg	15-24 lbs	0.1 mg (0.1 ml)	10 mg
19-36 mos	11-14 kg	24-31 lbs	0.15 mg (0.15 ml)	15 mg
37-48 mos	14-17 kg	31-37 lbs	0.15 mg (0.15 ml)	20 mg
49-59 mos	17-19 kg	37-42 lbs	0.2 mg (0.2 ml)	
5-7 yrs	19-23 kg	42-51 lbs	0.2 mg (0.2 ml)	30 mg
8-10 yrs	23-35 kg	51-77 lbs	0.3 mg (0.3 ml)	
11-12 yrs	35-45 kg	77-99 lbs	0.4 mg (0.4 ml)	40 mg
13 yrs & older	45+ kg	99+ lbs	0.5 mg (0.5 ml)	50-100 mg

*Dosing by body weight is preferred

**Epinephrine can also be administered using an autoinjector available in 0.15 mg and 0.3 mg doses. Children weighing 15 to 30 kg should receive 0.15 mg if given by autoinjector.

ACCIDENTAL NEEDLE STICK

(A) Procedures

(1) Wash needle stick site with soap and water.

(2) Report the exposure to the physician on the protocol. Prompt reporting is essential because, in some cases, post-exposure treatment may be recommended and it should be started as soon as possible. **The National Clinicians' Post Exposure Prophylaxis Hotline (PEPline) has current recommendations (888.448.4911).**

(3) Discuss risks of acquiring HBV, HCV, HIV and the need for post-exposure treatment with the provider managing your exposure.

(4) Person giving the vaccination should already have received the Hepatitis B vaccine (extremely safe and effective).

(5) Follow-up testing should be available to all workers concerned about possible infection through occupational exposure.

(B) Treatment of Exposure

HCV - no treatment available

HBV - Post-exposure treatment of HBV is highly effective in preventing infection. Treat exposure as soon as possible after exposure, preferably within 24 hours and no later than 7 days after exposure. Hepatitis B vaccine and hepatitis B immune globulin (HBIG) are both approved for treatment use. If any symptoms suggesting HBV infection develop, patient should contact a physician.

HIV - Start as soon as possible, ideally within 72 hours of exposure. Benefit of treatment delayed beyond 72 hours is not defined. No medications are FDA-approved for prevention. Pharmacist will follow current HIV prevention guidelines recommended by CDC. Truvada® (emtricitabine and tenofovir disoproxil fumarate) plus Isentress® (raltegravir) OR Truvada® plus Tivicay® (dolutegravir) are recommended for 28 days with repeated testing to confirm HIV negative status.

(C) Precautions During Follow-Up

HBV – no precaution recommended

HCV – low risk, so no precautions are recommended

HIV - 6-12 weeks is when most of the signs and symptoms of infection show. Do not donate blood, semen, or organs during this time. Do not have sexual intercourse during this time, or else use a condom consistently and correctly. Women should not breast feed. HIV is transmitted through breast milk.

See page 8 for Physician Authorization

Administration of the Td and Tdap vaccines, under the direction of the physician who signed below, may be performed by the following individuals:

_____ _____ _____

_____ _____ _____

Administration of the Td and Tdap vaccines, under the direction of the physician who signed below, may be performed at the following location(s) including street address(es):

_____

_____

As the authorizing physician, I will review, on a biennial basis, the activities of the health care providers administering the vaccine under this protocol.

Date: _____

*MUST BE RENEWED WITH PHYSICIAN ON A BIENNIAL BASIS

Physician Signature: _____

Physician Name: _____

Address: _____

City: _____ State: _____ Zip:_____

Medical License #: _____

Pharmacist in Charge Name_____

Pharmacist in Charge Signature_____

Date_____ Pharmacist in Charge License #_____

Pharmacy Name_____

Pharmacy Address_____

City_____ State_____ Zip_____

PHYSICIAN/BOARD OF HEALTH NOTIFICATION

Notify the individual's primary care physician, or if the individual has no family physician, the County Board of Health of the district in which the individual lives, within 30 days after administering the immunization; document accordingly.

