



VFC Resolution Update: Tetanus and Diphtheria Toxoid Containing Vaccines

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Background

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- CDC recommends a primary series of 5 DTaP vaccines for children <7 years
- For children aged <7 years who developed a contraindication to pertussis-containing vaccines, CDC previously recommended DT instead of DTaP
- The sole DT vaccine manufacturer in the United States discontinued DT production
- Last lot expired in April 2023
- No DT vaccine is available in the United States

Contraindication specific to pertussis vaccine component

- The only contraindication specific to the pertussis component in DTaP is encephalopathy within 7 days of vaccination, not attributed to another cause.
- Exact numbers are unknown, but occurrence of this adverse reaction is extremely rare.
- CDC issued updated vaccination guidance for young children with a contraindication to pertussis-containing vaccines.

Guidance

- CDC recommends young children receive DTaP as the first dose in the diphtheria, tetanus, and pertussis childhood vaccination series.
- CDC recommends continued use of DTaP unless a contraindication to pertussis-containing vaccines develops.
- For young children who develop a contraindication to pertussis-containing vaccines, vaccine providers may administer Td for all recommended remaining doses in place of DTaP.

Uncertain impact on diphtheria protection

- Td is licensed for ages ≥ 7 years
- Td contains a lower dose of diphtheria toxoid compared to DT
- Limited data suggest that low-dose diphtheria toxoid-containing vaccines may not reliably generate a protective diphtheria seroresponse.

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Key points

- CDC recommends a series of diphtheria, tetanus, and pertussis vaccine (DTaP) for children aged younger than 7 years.
- Use tetanus and diphtheria vaccine (Td) off-label for children aged <7 years who develop a contraindication to pertussis-containing vaccine.
- If Td is used, follow the same schedule that would be used for DTaP.
- Children who receive Td in place of DTaP may have sub-optimal protection against diphtheria.

<https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/td-offlabel.html>

VFC Resolution Updates

Td Vaccine Supply Update

- MassBiologics has discontinued production of their Td vaccine, TdVax.™ Grifols, who is the exclusive distributor for TdVax,™ expects to have product available through approximately June 2024.
- Sanofi, who manufactures Tenivac,® the only other US-licensed Td vaccine, is taking steps to augment their available supply of Td for the US. However, it is anticipated that the supply of Td vaccine in the US market will be constrained during 2024. Temporary ordering controls have been put into place in the public and private sectors to help manage the gap in supply.
- Tdap vaccine is available from both US-licensed manufacturers without supply constraints at this time.
- Based on the rarity of developing a contraindication to pertussis-containing vaccines, the temporarily constrained supply of Td vaccine is not anticipated to prevent providers from utilizing Td vaccine for these children in the VFC program.

Purpose of the Resolution

The purpose of this resolution is to (1) add Td vaccine for use in children < 7 years of age for whom receipt of the pertussis component is contraindicated and to (2) update the language regarding the Tdap booster to align with ACIP recommendations.

Eligible Groups

Children and adolescents aged 6 weeks through 18 years.

Recommended Schedule and Intervals (1)

Vaccines containing tetanus toxoid, diphtheria toxoid, and acellular pertussis antigens recommend for use in persons aged <7 years.

Vaccine Type	Vaccine	Brand (1)	Age for approved use in the routine schedule (2)				
			2 mos	4 mos	6 mos	15-18 mos	4-6 yrs (3)
DTaP	DTaP (4)	Daptacel	X	X	X	X	X
	DTaP (4)	Infanrix	X	X	X	X	X
Combination vaccines with DTaP	DTaP-HepB-IPV (4, 5)	Pediarix	X	X	X		
	DTaP-IPV/Hib (4, 6)	Pentacel	X	X	X	X	
	DTaP-IPV-Hib-HepB (4, 7)	Vaxelis	X	X	X		
	DTaP-IPV (8)	Kinrix					X
	DTaP-IPV (8)	Quadracel					X
Td	Td (9)	Tenivac		X	X	X	X
Td	Td (9)	TdVax		X	X	X	X

Recommended Schedule and Intervals (2)

- (1) The use of brand names is not meant to preclude the use of other comparable licensed vaccines.
- (2) Minimal intervals: Dose 1 to 2: 4 weeks. Dose 2 to 3: 4 weeks. Dose 3 to 4: 6 months. Dose 4 to 5: 6 months. For more information on age for use in catch-up immunization schedules please see: <https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html>
- (3) The fifth dose is not necessary if the fourth dose was given after the fourth birthday.
- (4) FDA-approved for use in infants as young as 6 weeks.
- (5) FDA-approved for use through age 6 years (prior to 7th birthday). The combined DTaP-HepB-IPV vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. Approved for the primary series only (Doses 1-3). For adequate immune response, the last dose of hepatitis B vaccine should be given at ≥ 24 weeks of age and therefore this combination vaccine should not be administered as a complete primary series on an accelerated schedule at 4-week intervals for prevention of pertussis.

Recommended Schedule and Intervals (3)

- (6) FDA-approved for use through age 4 years (prior to 5th birthday). The combined DTaP-IPV/Hib vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. Approved for the primary series and first booster dose (Doses 1-4). The combined DTaP-IPV/Hib vaccine is not indicated for children 5 years of age and older.
- (7) FDA-approved for use through age 4 years (prior to 5th birthday). The combined DTaP-IPV-Hib-HepB vaccine may be used when any component of the combination is indicated, and if other components are not contraindicated. Approved for the primary series only (Doses 1-3). For adequate immune response, the last dose of hepatitis B vaccine should be given ≥ 24 weeks of age and therefore this combination vaccine should not be administered as a complete primary series on an accelerated schedule at 4-week intervals for prevention of pertussis.
- (8) The combined DTaP-IPV vaccines may be used when any component of the combination is indicated, and if the other components are not contraindicated. Only approved for the booster dose at age 4 through 6 years. Earlier doses should use another vaccine.
- (9) Use tetanus toxoid- and diphtheria toxoid-containing vaccine if encephalopathy not attributable to another identifiable cause occurs within 7 days of administration of previous dose of pertussis-containing vaccine. For more information on the use of Td in children <7 please see: [About Young Children with a Contraindication to Pertussis-Containing Vaccines | CDC](#)

Recommended Schedule and Intervals (4)

Vaccines containing tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis antigens recommended for use in persons aged 7–18 years.

Vaccine Type	Brand
Tdap (1, 2, 3, 4)	Adacel
	Boostrix
Td (4, 5, 6)	Tenivac
	TdVax

Recommended Schedule and Intervals (5)

- (1) The use of brand names is not meant to preclude the use of other comparable licensed vaccines.
- (2) Persons aged 11-18 years should receive a single booster dose of Tdap, preferably at a preventive care visit at ages 11-12 years. The booster dose is not necessary if the Tdap dose was given after the ninth birthday.
- (3) Catch-up immunization: Persons aged 7-18 years who have never been vaccinated against pertussis, tetanus, or diphtheria should receive a series of three tetanus and diphtheria toxoid-containing vaccines, which includes at least 1 dose of Tdap. The preferred schedule is a dose of Tdap, followed by a dose of either Td or Tdap at least 4 weeks afterward and another dose of either Td or Tdap 6 to 12 months later. Persons aged 7-18 years who are not fully immunized against pertussis, tetanus, or diphtheria should receive one dose of Tdap (preferably the first) in the catch-up series; if additional tetanus toxoid-containing doses are required, either Td or Tdap vaccine can be used. The catch-up immunization schedule and minimum intervals between doses are available at: <https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>

Recommended Schedule and Intervals (6)

- (4) Adolescents who are pregnant should receive Tdap, irrespective of past history of Tdap receipt. Tdap should be administered from 27 through 36 weeks' gestation, preferably during the earlier part of this time period, although it may be administered at any time during pregnancy. If an adolescent did not receive Tdap during her current pregnancy and did not receive a prior dose of Tdap ever, then Tdap should be administered immediately postpartum. If an adolescent did not receive Tdap during her current pregnancy but did receive a prior dose of Tdap, then she should not receive a dose of Tdap postpartum.
- (5) Tetanus prophylaxis for wound management: A tetanus toxoid–containing vaccine is indicated as part of wound management if more than five years has passed since the last tetanus toxoid–containing vaccine dose. If a tetanus toxoid–containing vaccine is indicated for persons aged ≥ 11 years, Tdap is preferred for persons who have not previously received Tdap or whose Tdap history is unknown. If a tetanus toxoid–containing vaccine is indicated for a pregnant woman, Tdap should be used. For nonpregnant persons with documentation of previous vaccination with Tdap, either Td or Tdap can be used if a tetanus toxoid–containing vaccine is indicated.
- (6) Td should be used if encephalopathy not attributable to another identifiable cause occurs within 7 days of administration of a previous dose of pertussis-containing vaccine.

Dosage and Contraindications/Precautions

Recommended Dosage

Refer to product package inserts available at:

<https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states>

Contraindications/Precautions

Contraindications and precautions can be found at:

<https://www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm>

Statement Regarding Update Based on Published Documents

[If an ACIP recommendation regarding diphtheria, tetanus, and pertussis vaccination is published within 6 months following this resolution, the relevant language above (except in the eligible groups sections) will be replaced with the language in the recommendation and incorporated by reference to the publication URL.]