OREGON HEALTH AUTHORITY
IMMUNIZATION PROGRAM

DT and DTaP-containing combination vaccines	
Last Reviewed	14 January 2019
Last Revised	14 January 2019
This order expires	31 July 2020

Addition of DT.

I. OREGON IMMUNIZATION MODEL STANDING ORDER:

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen for contraindications.
3. Provide a current Vaccine Information Statement (VIS) and answer 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 DT or DTaP-containing vaccine 0.5 mL **IM.** Schedules in section II.
9. May be given with routine childhood vaccines. See section II A for exceptions.
10. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

_____

Signature Health Officer or Medical Provider Date

_____

Signature Health Officer or Medical Provider Date

II. VACCINE SCHEDULE

II. A. Table 1: ROUTINE VACCINATION SCHEDULE FOR DT VACCINE (No trade name)[1]

Dose*	Minimum Acceptable Age◊§	Minimum Acceptable Spacing§	Preferred Age
1	6 weeks		2 months
2	10 weeks	4 weeks after dose #1	4 months
3	14 weeks	4 weeks after dose #2	6 months
4**	12 months	6 months after dose #3	15–18 months
5◊◊	4 years	6 months after dose #4	4–6 years

*If 6 doses of DT or DTaP have been given before age 7 years, a one-time dose of Tdap is due at age 11–12 years. If a child <4 years of age has had 5 doses (whether valid or invalid) of DT or DTaP, the 6th dose will be forecast at 4–5 years of age and 6 months after dose 5.[7]

◊Td should not be given before 7 years of age. If a child <7 years of age mistakenly receives Td instead of DT, the Td dose will count only if administered as the 4th or 5th dose. If received as dose 1, 2 or 3, the dose should be repeated with DT.[7]

§For retrospective checking, doses that violate the minimum spacing 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. When an invalid dose needs to be repeated, the repeat dose should be spaced after the invalid dose by a time equal to or greater than the minimum interval between doses.[8]

Previously unvaccinated children who receive their first DT dose at age <12 months should receive a total of 4 doses of DT, the first 3 doses at 4- to 8-week intervals and the fourth dose 6 to 12 months later (similar to the recommended DTaP schedule).[7]

**For retrospective checking: DT4 administered ≥4 months after DT3 does not need to be repeated.[9]

◊◊Dose 5 is unnecessary if dose 4 was given on or after the 4th birthday.[7]

NOTE: If a child is older than 1 year of age at the time the first dose of DT is given, a third dose given 6–12 months after the second dose completes the primary series. The DT booster (4th dose) is to be given at a minimum of 4 years of age and at least 6 months after dose 3.[7]

II. B. Infanrix®[2], Daptacel ®[5], Preferred Vaccine Schedule

(DTaP) Ages 6 weeks to 6 years

DOSE 0.5 mL	PREFERRED AGE	MINIMUM ACCEPTABLE AGE	MINIMUM ACCEPTABLE INTERVAL TO NEXT DOSE
1	2 months	6 weeks	4 weeks
2	4 months	10 weeks	4 weeks dose 1 to 2
3	6 months	14 weeks	4 weeks dose 2 to 3
4	15–20 months	12 months	6 months doses 3 to 4
5	4–6 years	4 years	6 months doses 4 to 5

1. If Menactra® is to be administered to a child at increased risk for meningo-coccal disease, including one who is HIV-infected, it is recommended that Menactra® be given either before or concomitantly with Daptacel.[9]

Co-administration of Menveo® and Daptacel® was not associated with reduced responses to meningococcal serogroups.[9]

2. Because of concern about adverse reactions, the total number of doses of vaccines containing diphtheria and tetanus toxoids (e.g., DTaP, DT, and DTP) received should not exceed 6 doses before the seventh birthday. Only documented doses count toward the maximum of 6 doses.[8]

3. **Minimum interval between third and fourth DTaP doses.** The recommended minimal interval between the third and fourth doses of DTaP is 6 months, and the minimum age for receipt of the fourth dose of DTaP is 12 months. However, a fourth DTaP dose is considered valid if administered at least 4 months after the third dose of DTaP and the child is aged ≥12 months.[8]

II. C. Combination PEDIARIX®[3] Preferred Vaccine Schedule*◊

(DTaP, IPV, and HepB) Ages 6 weeks to 6 years

DOSE 0.5 mL	PREFERRED AGE	MINIMUM ACCEPTABLE AGE	MINIMUM ACCEPTABLE INTERVAL TO NEXT DOSE
1	2 months	6 weeks	4 weeks
2	4 months	10 weeks	4 weeks dose 1 to 2
3	6 months	6 months	4 weeks dose 2 to 3

*Pediarix® is licensed for the first three doses of the DTaP series. It is not approved for the 4th dose of the DTaP or IPV series. However, if this combination vaccine is misadministered as the 4th or 5th dose of the DTaP or IPV series, the dose need not be repeated and can be counted as valid.[3]

◊Pediarix® can be used interchangeably before or after any individual DTaP, HepB, or IPV dose in the primary series.[3]

II. D. COMBINATION PENTACEL®[4] Preferred Vaccine Schedule * ◊ §

(DTaP, IPV, and Hib) Ages 6 weeks to 4 years

DOSE 0.5 mL	PREFERRED AGE	MINIMUM ACCEPTABLE AGE	MINIMUM ACCEPTABLE SPACING
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to 2
3	6 months	14 weeks	4 weeks dose 2 to 3
4	15–18 months	12 months	6 months dose 3 to 4

*If Pentacel® is inadvertently administered to children ≥5 years of age, the DTaP, IPV and Hib doses should be counted as valid doses.[11]

◊Pentacel® may be used to complete the vaccination series in children previously vaccinated with one or more doses of any single or combination DTaP or Hib vaccine when other antigens of Pentacel® are also needed.[11]

§ **Pentacel's® lyophilized ActHIB® component needs to be reconstituted with the DTaP-IPV component to prepare for vaccine administration. Shake the reconstituted vial thoroughly until a cloudy, uniform suspension results, then vaccinate immediately.**[6]

II. E. COMBINATION KINRIX® and QUADRACEL® Preferred Vaccine Schedule (5^{TH} DTaP and 4^{TH} IPV)*

DOSE 0.5 mL	PREFERRED AGE	MINIMUM ACCEPTABLE AGE
1	4–6 years	4 years

***Kinrix® & Quadracel® are approved for the booster dose of DTaP and IPV (5^{th} dose of DTaP and the 4^{th} dose of IPV) at 4–6 years of age.** However, if either Kinrix® or Quadracel® is inadvertently administered for an earlier dose of the DTaP or IPV series, the dose should be counted as valid and does not need to be repeated, provided that minimum interval requirements have been met for all antigens.[12]

III. LICENSED DTaP-CONTAINING* VACCINES[2-7]

Product Name	Vaccine components	Preferred Age Range	Thimerosal
Infanrix® (GSK)	DTaP	6 weeks – 6 years	
Pediarix®◊ (GSK)	DTaP, IPV, HepB	6 weeks – 6 years	
Kinrix®‡ (GSK)	DTaP and IPV	4–6 years	
Daptacel®** (s. pasteur)	DTaP	6 weeks – 6 years	
Pentacel®§ (s. pasteur)	DTaP, IPV, Hib	6 weeks – 4 years	
Quadracel®** (s. pasteur)	DTaP and IPV	4– 6 years	

*When feasible, the same brand of vaccine should be used for all doses of the series. If a previous brand is unknown or unavailable, rather than deferring vaccination, any vaccine should be used to complete the series. [8]

◊Pediarix® is licensed for three doses of the DTaP series. It is not approved for the 4th polio dose and should not be administered to infants <6 weeks of age or to children ≥7 years of age. Pediarix ® can be used interchangeably before or after any individual DTaP, HepB or IPV dose in the primary series.[3]

§Pentacel® is licensed for 4 doses of the DTaP series, the first 3 doses of the IPV series and the 4 doses of the Hib series from 6 weeks through 4 years of age (doses 1, 2, or 3)[6]

‡Kinrix® is licensed for the 5th dose in the DTaP series and the 4th dose in the IPV series between 4–6 years of age. The tip cap and the rubber plunger of the pre-filled syringes contain dry natural latex rubber.[4]

**Quadracel is licensed for the 5th dose in the DTaP series and the 4th dose in the IPV series. The final dose in the DTaP series should be administered at ≥4 years of age and ≥6 months after the previous dose regardless of the number of previous doses.[7]

For retrospective checking, doses that violate the minimum spacing 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 appropriate for age.[13]

IV. RECOMMENDATIONS FOR USE: See section II

V. CONTRAINDICATIONS

DT®[1] Infanrix ®[2] Pediarix®[3] and Kinrix®[4] Daptacel ®[5] Pentacel®[6]and Quadracel®[7]

- **Severe allergic reaction** (e.g., anaphylaxis) after a previous dose of any diphtheria toxoid, tetanus toxoid, pertussis, hepatitis B, or poliovirus-containing vaccine, or to any component thereof, including neomycin and polymyxin B.
- **Encephalopathy** (e.g., coma, decreased level of consciousness and prolonged seizures) not attributable to another identifiable cause within 7 days of a previous pertussis-containing vaccine.

VI. PRECAUTIONS AND WARNINGS

DT®[1] Infanrix ®[2] Pediarix®[3] Kinrix®[4] Daptacel ®[5] Pentacel®[6]and Quadracel®[7]

- In clinical trials, Pediarix®[2] was associated with higher rates of fever, relative to separately administered vaccines.
- **Progressive or unstable neurologic disorder**, including infantile spasms, uncontrolled seizures or progressive encephalopathy; defer DTaP until neurological status clarified and stabilized.
- **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 [8 p. 3]
- **Moderate or severe acute illness** with or without fever[8]
- If **Guillain-Barré** syndrome occurs <6 weeks after a previous dose of tetanus or diphtheria toxoid-containing vaccine, the decision to vaccinate should be based on potential benefits and risks.[8]
- **Latex**: Infanrix®, Pediarix® and Kinrix®: tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive-individuals.
- **Apnea** following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine to infants born prematurely should be based on

consideration of the individual infant's medical status, and the potential benefits and possible risks of the vaccination.[2,3,5,6]

VII. A. OTHER CONSIDERATIONS

A. ACIP and AAP both recommend that children receive no more than 6 doses of diphtheria and tetanus toxoids (e.g., DT, DTaP, DTP) before the seventh birthday because of concern about adverse reactions, primarily local reactions. Half doses of DTaP are also not recommended under any circumstances, and should not be counted as part of the vaccination series. Only documented doses (e.g., those recorded in an electronic or written record) count toward the maximum of 6 doses.[13]

B. **Stable neurologic condition:** Infants and children with a stable neurologic condition, including well-controlled seizures, may be given DTaP-containing vaccines. A family history of convulsions is not a contraindication for pertussis-containing vaccines.[8]

C. **Pertussis infection:** Although well-documented pertussis infection may confer short-term protection against reinfection in children, the duration of such protection is unknown, and completing the DTaP series is recommended regardless of a patient's history of pertussis infection.[8]

D. **Internationally Adopted Children**: Vaccination providers can revaccinate a child with DTaP without regard to recorded doses; however, if a revaccination approach is adopted and a severe local reaction occurs, serologic testing for specific IgG antibody to tetanus and diphtheria toxins can be measured before administering additional doses. A protective concentration indicates that subsequent vaccination should occur as appropriate for age.[13]

E. **Misadministration: Tdap inadvertently given to Persons aged 2 months–6 years of age.** If Tdap is administered inadvertently instead of DTaP as any one of the first 3 doses of the tetanus-diphtheria-pertussis vaccination series, the Tdap dose should not be counted as valid, and a replacement dose of DTaP should be administered. The replacement dose of DTaP can be administered as soon as feasible at any interval after the inadvertent Tdap dose. The remaining doses of the DTaP series should be administered on the routine schedule, with at least a four-week interval between the replacement dose of DTaP and the next dose of DTaP. The adolescent Tdap dose should be administered as recommended when the child is aged 11–12 years.
If Tdap is administered inadvertently as the fourth or the fifth dose in the tetanus-diphtheria-pertussis vaccination series, the Tdap dose should be counted as valid and does not need to be repeated; the child who received Tdap as a fourth dose

should complete the pediatric DTaP schedule. The adolescent Tdap dose should be administered as recommended when the child is aged 11–12 years.[8]

F. **Hematopoietic stem cell transplant** (HSCT) recipients: Antibody titers to vaccine-preventable diseases (e.g., tetanus, poliovirus, measles, mumps, rubella and encapsulated bacteria) decrease 1–4 years after autologous or allogeneic HCT if the recipient is not revaccinated. HSCT recipients of all ages are at increased risk. Revaccination with 3 doses of IPV is recommended 6–12months after HSCT.[14]

G. **Adverse Events**: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[2–7]

H. **Immunocompromised:** Individuals with altered immunocompetence may have reduced immune responses. [2–7]

I. Evidence does not support use of **antipyretics** before or at the time of vaccination; however, they can be used for the treatment of fever and local discomfort that might occur following vaccination. Studies of children with previous febrile seizures have not demonstrated antipyretics to be effective in the prevention of febrile seizures.[13]

VII. B. TETANUS WOUND MANAGEMENT AMONG CHILDREN ≤6 YEARS OF AGE[8]

Vaccination History	Clean, minor wounds		All other wounds	
	DTaP[◊]	TIG[§]	DTaP	TIG
Unknown or < than 3 doses	Yes	No	Yes	Yes[§]
≥ 3 doses	No	No	No	No[§]

[◊]For children younger than 7 years of age, DTaP is recommended; if pertussis vaccine is contraindicated, DT is given. [7] p12

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

Persons with a history of an Arthus reaction following a previous dose of a tetanus toxoid-containing vaccine should not receive a tetanus toxoid-containing vaccine until >10 years after the most recent dose; this interval is recommended regardless of the wound condition (e.g., even if contaminated or severe). In all circumstances, the decision to administer TIG should be based on the primary vaccination history for tetanus.[8]

VIII. ADVERSE EVENTS

EVENT	FREQUENCY
Local reactions (pain, erythema, induration, and swelling) More exaggerated Arthus-like reaction *	More common following 4th or 5th doses • 1.3–39% after 3rd dose of Infanrix®◊ • 17–40% after 3rd dose of Pediarix®§ • Kinrix®‡ • 0.3–40% after 3rd dose of Daptacel®** • 17–56% after 4th dose of Pentacel® ◊◊ • 77% Quadracel®§§ Occasionally (most often in adults)
Mild systemic reactions (fever, drowsiness, fretfulness, and anorexia) Temp ≥100°F(38°C)	Occasionally 3–5% with Infanrix®*◊, DT®*◊, Daptacel®** 28–34% with Pediarix®§, Hib and PCV vaccines together 7% with Kinrix®‡ 6–16% with Pentacel® ◊◊ 6% with Quadracel®§§
Moderate to Severe systemic reactions Fever ≥105°F or febrile seizures	Rarely reported with DTaP vaccines
Symptoms present as extensive painful swelling, often from shoulder to elbow; they generally begin 2–8 hours after injection and are usually due to the presence of very high serum antitoxin levels in persons who have received frequent doses of diphtheria or tetanus toxoid. *DT® ◊Infanrix® §Pediarix® 2016 package insert, Table 1, p7. ‡Kinrix® 2016 package insert, Table 1, p 6.	

**Daptacel®
◊◊Pentacel® 2013 package insert, Table 2, p.12.
§§Quadracel® 2015 package insert, Table 1, p7

IX. 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	Temperature	Storage Issues	Notes
DT®1	Store at 2°–8°C (36°–46°F)	Do not use if vaccine has been frozen. Report to health educator	Protect from light
Infanrix®2			
Pediarix®3			
Kinrix®4			Use immediately after reconstitution
Daptacel®5			
Pentacel®6			
Quadracel®7			

X. ADVERSE EVENT REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/esub/step1.

- Save a copy of the report number for your records
- Send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278).

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

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

Table1. Adverse Events to Be Reported to VAERS

Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	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)
Pertussis in any combination; DTaP, DTP, DTP-Hib, Tdap, P, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 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.

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:
http://1.usa.gov/OregonStandingOrders

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2. Infanrix® package insert. Available at: *www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM124514.pdf*. Accessed 17 July 2018.

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APPENDIX:
Tetanus- and pertussis-containing vaccines; total antigen
DT, DTaP, DTP, Td and Tdap.

				Pertussis Components			
Antigens	**P/ A**	**Tetanus Toxoid**	**Diphtheria Toxoid**	**PT**	**FHA**	**Pertactin**	**Fimbriae types 2, 3**
Daptacel Sanofi	P	5 Lf	15 Lf	10 µg	5 µg	3 mcg	5 µg
Pentacel Sanofi	P	5 Lf	15 Lf	20 µg	20 µg	3 µg	5 µg
Quadracel Sanofi	P	5 Lf	15 Lf	20 µg	20 µg	3 µg	5 µg
Infanrix GSK	P	10 Lf	25 Lf	25 µg	25 µg	8 µg	
Pediarix GSK	P	10 Lf	25 Lf	25 µg	25 µg	8 µg	
Kinrix GSK	P	10 Lf	25 Lf	25 µg	25 µg	8 µg	
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	2.5 µg	5 µg	3 µg	5 µg
Boostrix GSK	A	5 Lf	2.5Lf	8 µg	8 µg	2.5 µg	

P = Pediatric **A = Adult**

REFERENCES FOR APPENDIX

Liang JL, Tiwari T, Moro P, et al. Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2018;67(RR-2):1–44. DOI: http://dx.doi.org/10.15585/mmwr.rr6702a1. Accessed 30 August 2018.

Both DTP and monovalent tetanus toxoid (TT) vaccines are no longer manufactured or available in the United States. [7]