Immunization Protocol

DTaP-containing Combination Vaccines (Infanrix®, Pediarix®, Kinrix®, Daptacel®, Pentacel®, Quadracel® and Vaxelis®)	
Last Reviewed	21 August 2025
Last Revised	11 July 2024
This order expires	31 August 2027

Table of contents

1. What's new

Reviewed for content, no substantive changes.

2. Oregon immunization 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.

F. Administer a 0.5-mL dose of DTaP-containing vaccine IM according to ACIP recommendations and age-appropriate schedules.

G. Menactra should not be given after Daptacel. It may be given before or at the same time.[4]

H. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks and use proper IM administration technique.

I. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

Health Officer Signature Date

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3. Vaccine schedule for DTaP[8]

Dose and Route – 0.5 mL, IM			
Dose	**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
5*	4–6 years	4 years	6 months dose 4 to 5

*Dose 5 not needed if dose 4 given at ≥4 years of age.

4. Licensed DTaP vaccines[1-7]

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
Daptacel	DTaP	0.5-mL single-dose vials	6 weeks – 6 years	None
Infanrix	DTaP	0.5-mL single-dose vials and prefilled syringes	6 weeks – 6 years	
Kinrix	DTaP-IPV	0.5-mL single-dose vials and prefilled syringes	4 years – 6 years	
Pediarix	DTaP-IPV-HepB	0.5-mL single-dose vials and prefilled syringes	6 weeks – 6 years	
Pentacel	DTaP-IPV-Hib	0.5-mL single-dose vials	6 weeks – 4 years	
Quadracel	DTaP-IPV	0.5-mL single-dose vials	4 years – 6 years	
Vaxelis	DTaP-IPV-Hib-HepB	0.5-mL single-dose vials	6 weeks – 4 years	

5. Recommendations for use

DTaP, single-antigen (Daptacel[4], Infanrix[1])			
Dose	**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
5	4–6 years	4 years	6 months dose 4* to 5
DTaP-IPV-Hep.B (Pediarix[2])			
Dose	**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	6 months	8 weeks dose 2 to 3
¶ Pediarix is licensed for 3 doses of the DTaP series, all 3 doses of the HepB series and the first 3 doses of the polio series. The remaining doses of DTaP should be completed with another licensed DTaP formulation.			
DTaP-IPV-Hib (Pentacel[5])			
Dose	**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 months	12 months	6 months dose 3 to 4
◊ Pentacel is licensed for 4 doses of the DTaP series, all 4 doses of the Hib series and the first 3 doses of the polio series. The remaining doses of DTaP should be completed with another licensed DTaP formulation.			
DTaP-IPV-HepB-Hib (Vaxelis[7])*			
Dose	**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	6 months	4 weeks dose 2 to 3
#Vaxelis is licensed for 3 doses of the DTaP series, all 3 doses of the HepB series, the first 3 doses of the polio series and the first 3 doses of a 4-dose Hib series. The remaining doses of DTaP should be completed with another licensed DTaP formulation.			

*DTaP-IPV-Hib-HepB (Vaxelis) is included in ACIP's preferential recommendation for American Indian and Alaska Native infants based on the Hib component, PRP-OMP (PedvaxHIB).[11]			
DTaP-IPV (Kinrix[3], Quadracel[6])			
Dose	**Preferred Age**	**Minimum Acceptable Age**	**Minimum Acceptable Spacing**
5*	4–5 years	4 years	6 months dose 4 to 5

*Dose 5 of the DTaP series is not needed if dose 4 given at ≥4 years of age.

6. Contraindications[1-7]

A. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of a previous pertussis-containing vaccine.
B. Severe allergic reaction to a previous dose or to a vaccine component, including latex found in syringes for Infanrix, Kinrix and Pediarix.

Vaccine	Vaccine Excipient Summary[1-7]
Daptacel	Aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol
Infanrix	Formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Kinrix	Formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80, neomycin sulfate, polymyxin B
Pediarix	Formaldehyde, aluminum hydroxide, aluminum phosphate, sodium chloride, polysorbate 80, neomycin sulfate, polymyxin B, yeast protein
Pentacel	Aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate
Quadracel	Formaldehyde, aluminum phosphate, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate, bovine serum albumin
Vaxelis	Polysorbate 80, formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, streptomycin sulfate, polymyxin B sulfate, ammonium thiocyanate, yeast protein, aluminum

7. Warnings and precautions

A. In clinical trials, Pediarix was associated with higher rates of fever, relative to

separately administered vaccines.[2]

B. Defer DTaP vaccination in children with progressive or unstable neurologic disorder, including infantile spasms, uncontrolled seizures or progressive encephalopathy until neurological status clarified and stabilized.[8]

C. 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]

D. Moderate or severe acute illness with or without fever.

E. 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. Other considerations

A. ACIP and AAP both recommend that children receive no more than 6 doses of diphtheria and tetanus toxoids (e.g., DTaP, DTP) before the seventh birthday because of concern about adverse reactions, primarily local reactions. Only documented doses (e.g., those recorded in an electronic or written record) count toward the maximum of 6 doses.[8]

B. Vaxelis and Pediarix can be used for the first 3 doses of the DTaP series but should not be used for the 4th and 5th doses.[9]

C. 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.

D. Completing the age appropriate DTaP series is recommended in patients with documented pertussis.

E. In children adopted internationally, providers can revaccinate a child with DTaP regardless of recorded doses; however, if a severe local reaction occurs, serologic testing for specific IgG antibody to tetanus and diphtheria toxins should be measured before administering additional doses. A protective concentration indicates that vaccination can continue as appropriate for age.

F. If Tdap is administered to a child under 7 years of age, it must be repeated if it was dose 1, 2 or 3 in the series. The repeat dose of DTaP may be given immediately or as soon as feasible. If the inadvertent Tdap dose was dose 4 or 5 in the series, it does not need to be repeated.[8]

G. Children without documentation of 3+ doses of DTaP that have clean minor wounds should receive a dose of DTaP. Children with serious or contaminated wounds should also receive a dose of tetanus immune globulin. A documented history of 3+ doses of DTaP is considered protective against tetanus.[8]

H. Children with altered immunocompetence may have reduced immune responses. An immunocompromised or HIV+ child with a serious or contaminated wound should receive tetanus immune globulin regardless of vaccination history.[8]

I. Hematopoietic stem cell transplant (HSCT) recipients should be revaccinated 6 months after HSCT. Children <7 years should receive 3 doses of DTaP. For patients ≥7 years, either 1) 3 doses of DTaP or 2) one dose of Tdap and 2 doses of Td are recommended.[10]

J. Fever-reducing medication, like acetaminophen, should not be used before or at the same time as vaccinations. It can be used for fever or discomfort that develops after vaccination. These medications have not been shown to prevent febrile seizures in children with a history of febrile seizures.

9. Side effects and adverse reactions[1-7]

Adverse Event	Frequency
Any local reaction—pain, redness, induration or swelling at injection site	Up to 75%
Redness ≥50 mm at injection site	Up to 18%
Severe pain, induration or swelling at injection site	Up to 9%
Any systemic reaction—fever, malaise, aches, persistent crying, drowsiness	Up to 50%
Severe (grade 3) systemic reactions—fever above 102°	Up to 3%

10. Storage and handling[1-7]

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
All	Store at 2°– 8°C (36°– 46°F)	Do not use if vaccine has been frozen. Protect from light.	Pentacel only – use immediately after reconstitution.

11. Adverse events reporting

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

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. 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)

12. References

1. Infanrix® package insert. Current as of Oct. 2023. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/infanrix. Accessed 21 Aug 2025.
2. Pediarix® package insert. Current as of April 2023. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/pediarix. Accessed 21 Aug 2025.
3. Kinrix® package insert. Current as of Oct. 2023. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/kinrix. Accessed 21 Aug 2025.
4. Daptacel® package insert. Current as of July 2022. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/daptacel. Accessed 21 August 2025.
5. Pentacel® package insert. Current as of Oct. 2022. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/pentacel. Accessed 21 August 2025.

6. Quadracel® package insert. Current as of July 2022. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/quadracel. Accessed 21 Aug 2025.
7. Vaxelis® package insert. Current as of April 2023. Available at: https://www.fda.gov/vaccines-blood-biologics/vaxelis. Accessed 21 Aug 2025.
8. Liang, JL, Tiwari, T, 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(2). Available at: http://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf. Accessed 21 Aug 2025.
9. Oliver, SE and Moore, KL. Licensure of a diphtheria and tetanus toxoids and acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b conjugate, and hepatitis B vaccine, and guidance for use in infants. MMWR 2020; 69(5):136–9. Available at: www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6905a5-H.pdf. Accessed 21 Aug 2025.
10. Rubin LG, Levin MJ, Ljungman P, et al: 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis 2014; 58:344–100. Available at: https://www.idsociety.org/practice-guideline/vaccination-of-the-immunocompromised-host/. Accessed 21 Aug 2025.
11. Collins, J. Evidence to Recommendations and Proposed Recommendations: Use of Vaxelis among American Indian and Alaska Native Infants. ACIP meeting presentation. 26 June 2024. Available at: https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/02-Vaxelis-Collins-508.pdf. Accessed 21 Aug 2025.

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: https://www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx.