Immunization Protocol

Inactivated Poliovirus-Containing [IPV] and Combination Vaccines (IPOL®, PEDIARIX®, Pentacel®, KINRIX®, Quadracel® and VAXELIS™)	
Last Reviewed	27 July 2021
Last Revised	27 July 2021
This order expires	31 July 2023

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1. What's new

Added VAXELIS, a new, hexavalent combination vaccine containing DTaP, IPV, Hib and Hep. B.

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 IM injection.

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

G. Give polio-containing vaccine as recommended for age and vaccination status.

H. May be given with all routinely administered vaccines.

I. Ask client to remain seated on the premises 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 IPV[7]

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	6–18 months	6 months	4 weeks 2 to 3
4	4–6 years	4 years	6 months dose 3 to 4

4. Licensed polio-containing vaccines

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
IPOL[1]	Polio	5-mL multi-dose vials	≥6 weeks	None
PEDIARIX[2]	DTaP-IPV-Hep.B	0.5-mL single-dose syringes	6 weeks – 6 years	
Pentacel[4]	DTaP-IPV-Hib	0.5-mL single-dose vials	6 weeks – 6 years	
KINRIX[3]	DTaP-IPV	0.5-mL single-dose vials	4 years – 6 years	
Quadracel[5]	DTaP-IPV	0.5-mL single-dose vials	4 years – 6 years	
VAXELIS[6]	DTaP-IPV-Hib-Hep. B	0.5-mL single-dose vials	6 weeks – 4 years	

5. Recommendations for use

IPV (IPOL)[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	6–18 months	6 months	4 weeks dose 2 to 3
4	4–6 years*	4 years	6 months dose 3 to 4

*Dose 4 not needed if dose 3 given ≥4 years of age.

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 Hepatitis B series and the first 3 doses of the polio series. The remaining dose of polio should be completed with another licensed IPV formulation.			
DTaP-IPV-Hib (Pentacel)[4]			
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 dose of polio should be completed with another licensed IPV formulation.			
DTaP-IPV-Hep. B-Hib (VAXELIS)[6]			
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
#VAXELIS is licensed for 3 doses of the DTaP series, all 3 doses of the Hepatitis B series and the first 3 doses of the polio series. The remaining dose of polio should be completed with another licensed IPV formulation.			
DTaP-IPV (KINRIX[3], Quadracel[5])			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
4 or 5	4–6 years	4 years	6 months dose 4 to 5
Unvaccinated adults ≥18 years[7]			
Not routinely recommended*			

*For international travel, see Polio for Travel Standing Order

6. Contraindications

A. Severe allergic reaction to a previous dose or to a vaccine component, including latex (KINRIX[3] and PEDIARIX[2] syringes)

Vaccine	Vaccine Excipient Summary[8]
IPOL	calf bovine serum albumin, 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, M-199 medium
KINRIX	Formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
PEDIARIX	formaldehyde, aluminum hydroxide, aluminum phosphate, sodium chloride, polysorbate 80 (Tween 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

B. For DTaP-containing vaccines, 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.[9]

7. Warnings and precautions

A. Moderate or severe acute illness with or without fever.[9]

B. In clinical trials, Pediarix[2] and VAXELIS[11] were associated with higher rates of fever, relative to separately administered vaccines.[2]

C. Although no causal relationship between IPOL vaccine and Guillain-Barré Syndrome (GBS) has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine.[1]

8. Other considerations

A. IPV (IPOL) can also be given by the subcutaneous route.[1]

B. Polio vaccine given outside the United States is valid if written documentation indicates that all doses were given after 6 weeks of age and the vaccine received was IPV or trivalent OPV (tOPV). Recipients receiving both tOPV and IPV require a total of 4 doses.[10]

C. OPV given before April 1, 2016, can be assumed to be trivalent and valid.[10]

D. OPV doses given in April of 2016, can only be counted as valid if the documentation indicates that it was trivalent.[10]

E. OPV given after May 1, 2016, should not be counted as valid because it was a bivalent or monovalent vaccine.[10]

F. Persons <18 years of age with doses of OPV that do not count should receive IPV to complete the series.[10]

G. Oral polio vaccine (OPV) has been unavailable in the United States since 1999.[10]

H. After an interval of 15–40 years, 25%–40% of survivors of paralytic poliomyelitis may experience muscle pain and exacerbation of existing weakness or develop new weakness or paralysis. This disease entity, referred to as post-polio syndrome, has been reported only in persons infected during the era of wild poliovirus circulation. This is not an infectious process.[7]

I. Revaccination with 3 doses of IPV is recommended 6–12 months after hematopoietic stem cell transplantation.[7]

J. 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.[9]

K. Individuals with altered immunocompetence may have reduced immune responses.[9]

L. It is not known whether polio-containing vaccines are excreted in human milk. Use with caution in nursing mothers.[1]

9. Side effects and adverse reactions

IPV and combination vaccines[1-6]	
Any local reaction – pain, redness, induration or swelling at the injection site	Up to 75%
Redness ≥50 mm at injection site	Up to 18%
Severe pain, induration or swelling at the injection site	Up to 9%
Any systemic reaction – fever, malaise, aches, persistent crying, drowsiness	Up to 50%
Severe (grade 3) systemic reactions including fever above 102°	Up to 3%

10. 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[1-6]	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. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert).

12. References

1. IPOL package insert. Current as of 12/2019. Available at: www.fda.gov/media/75695/download. Accessed 16 July 2021.
2. PEDIARIX package insert. Current as of 10/2019. Available at: www.fda.gov/media/79830/download. Accessed 16 July 2021.
3. KINRIX package insert. Current as of 10/2019. Available at: www.fda.gov/media/80128/download. Accessed 16 July 2021.
4. Pentacel package insert. Current as of 2/2021. Available at: www.fda.gov/media/74385/download. Accessed 16 July 2021.
5. Quadracel package insert. Current as of 2/2021. Available at: www.fda.gov/media/91640/download. Accessed 16 July 2021.
6. VAXELIS package insert. Current as of 10/2020. Available at: www.fda.gov/media/119465/download. Accessed 16 July 2021.
7. CDC. Poliomyelitis prevention in the United States: updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2000;49(RR-5). Available at: www.cdc.gov/mmwr/PDF/rr/rr4905.pdf. Accessed

16 July 2021.

8. CDC. Vaccine Excipient Table. February 2020. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Accessed 16 July 2021.
9. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Available at: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed 16 July 2021.
10. Marin M, Patel M, Oberste S, Pallansch MA. Guidance for assessment of poliovirus vaccination status and vaccination of children who have received poliovirus vaccine outside the United States. MMWR 2017; 66:23–5. Available at: www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6601a6.pdf. Accessed 16 July 2021.
11. Oliver SE, 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; 69:136–9. Available at: www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm?s_cid=mm6905a5_w. Accessed 27 July 2021.

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: standing orders

13. Appendix A

Not applicable