Immunization Protocol

Inactivated Poliovirus-Containing [IPV] and Combination Vaccines (IPOL®, PEDIARIX®, Pentacel®, KINRIX®, Quadracel® and VAXELIS™)	
Last Reviewed	11 July 2024
Last Revised	11 July 2024
This order expires	31 March 2026

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1. What's new

On June 21, 2023, ACIP voted to recommend that all U.S. adults aged ≥18 years who are known or suspected to be unvaccinated or incompletely vaccinated against polio complete a primary polio vaccination series with IPV. Fully vaccinated adults at increased risk for poliovirus exposure may receive a single lifetime booster dose of IPV.

On June 26, 2024, ACIP's preferential recommendation for PRP-OMP (PedvaxHIB) for Native American/Alaskan Native infants was expanded to include DTaP-IPV-Hib-HepB (Vaxelis) based on the Hib component.

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. Ensure epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment are available for immediate use in case of anaphylactic or acute hypersensitivity reaction.

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

I. May be given with all routinely administered vaccines.

J. 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 dose 2 to 3
4	4–6 years	4 years	6 months dose 3 to 4

*In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.

4. Licensed polio-containing vaccines*

Product Name	Vaccine Components	Presentation	Acceptable Age Range
IPOL[1]	Polio	5-mL multi-dose vials	≥6 weeks
Pediarix[2]	DTaP-IPV-HepB	0.5-mL single-dose syringes	6 weeks – 6 years
Pentacel[4]	DTaP-IPV-Hib	0.5-mL single-dose vials	6 weeks – 4 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

*Note: None of the licensed polio-containing vaccines contain thimerosal.

5. Recommendations for use

Infants and children <18 years of age

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 was given ≥4 years of age and there was a 6-month interval between doses 2 and 3.

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 the first 3 doses of the DTaP and polio series, and any dose in the HepB series except the birth dose. 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, polio and Hib series and any dose in the HepB series except the birth dose. The remaining dose of polio vaccine should be completed with another licensed IPV 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).[13]			
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

IPV for adults ≥18 years of age[7]

Unvaccinated or incompletely vaccinated	
Dose	**Minimum acceptable spacing[o]**
1	
2	4–8 weeks after dose 1
3	6–12 months after dose 2
[o]If 3 doses cannot be administered within the recommended interval before protection is needed, an accelerated schedule is recommended. See Other Considerations section.	
Fully vaccinated and at increased risk for exposure[§]	
One lifetime booster dose	

[§]See Other Considerations section for situations that increase risk for poliovirus exposure.

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[9]
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.[10]

7. Warnings and precautions

A. Moderate or severe acute illness with or without fever.[10]

B. In clinical trials, Pediarix[2] and Vaxelis[12] 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. For unvaccinated adults who need protection sooner than the recommended intervals, an accelerated schedule can be used. If >8 weeks are available before protection is needed, 3 doses of IPV should be administered ≥4 weeks apart. If <8 weeks but >4 weeks are available before protection is needed, 2 doses of IPV should be administered ≥4 weeks apart. If <4 weeks are available before protection is needed, a single dose of IPV is recommended. The remaining doses should be administered later, at the recommended intervals.[7]

I. Adults who might be at increased risk for exposure to poliovirus include travelers to countries where polio is epidemic or endemic, laboratory and health care workers who handle specimens that might contain polioviruses, health care workers or other caregivers who have close contact with patients in a community with a polio outbreak, and other adults who are identified by public health authorities as being part of a population at increased risk for exposure to poliovirus because of an outbreak.[7]

J. Revaccination with 3 doses of IPV is recommended 6–12 months after hematopoietic stem cell transplantation.[10]

K. Individuals with altered immunocompetence may have reduced immune responses.[10]

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 05/2022. Available at: https://www.fda.gov/media/75695/download. Accessed 03 July 2024.
2. PEDIARIX package insert. Current as of 04/2023. Available at: www.fda.gov/media/79830/download. Accessed 03 July 2024.
3. KINRIX package insert. Current as of 01/2023. Available at: www.fda.gov/media/80128/download. Accessed 03 July 2024.
4. Pentacel package insert. Current as of 03/2022. Available at: www.fda.gov/media/146048/download. Accessed 03 July 2024.
5. Quadracel package insert. Current as of 07/2022. Available at: www.fda.gov/media/146047/download. Accessed 03 July 2024.
6. VAXELIS package insert. Current as of 10/2020. Available at: www.fda.gov/media/119465/download. Accessed 03 July 2024.
7. Kidd S, Clark T, Routh J, Cineas S, Bahta L, Brooks O. Use of Inactivated Polio Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR 2023;72:1327-30. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7249a3.htm. Accessed 03 July 2024.
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9. CDC. Vaccine Excipient Table. November 2021. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Accessed 03 July 2024.
10. Kroger A, Bahta L, Long S, Sanchez P. 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 03 July 2024.
11. 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 03 July 2024.

12. 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 03 July 2024.
13. 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/vaccines/acip/meetings/downloads/slides-2024-06-26-28/02-Vaxelis-Collins-508.pdf. Accessed 3 July 2024.

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