
OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
ENHANCED-POTENCY INACTIVATED
POLIOVIRUS-CONTAINING VACCINE: IPOL^{®1}

01-2016

- IPV for travelers under separate protocol
- Vaccination age changed to clients ≥ 7 years of age

I. OREGON IMMUNIZATION PHARMACY PROTOCOL:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥ 7 years of age 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. Give polio-containing vaccine as recommended:
 - Give single antigen IPV 0.5 mL IM or SQ as recommended for age and appropriate schedule.
6. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

Pharmacist Signature

Date

For multiple signatures see: 1.usa.gov/PharmacyImmunizationProtocols

II. LICENSED POLIO-CONTAINING VACCINES¹,

Product Name	Vaccine components	Recommended Age Range	Thimerosal
IPOL ^{®*}	Inactivated polio virus (IPV) serotypes 1, 2 and 3	≥6 weeks	None

* Less than 5 ng of neomycin, 200 ng of streptomycin, and 25 ng of polymyxin B per dose are present in vaccine.¹

III. IPV-CONTAINING VACCINE RECOMMENDATIONS AND VACCINE SCHEDULE

III. A. Inactivated Poliovirus Vaccine (IPOL[®])¹ Schedule for persons <18 years of age^{*}

Dose 0.5 ml	Recommended Age	Minimum Age ^{◇,§}	Recommended Interval to next dose	Minimum interval to next dose ^{◇,§}
1	2 months	6 weeks	2 months	4 weeks ³
2	4 months	10 weeks	2 months	4 weeks ^{§§3}
3 ^{**}	6–18 months ^{§§}	14 weeks	3–5 years	6 months ⁴
4 ^{◇◇}	≥4 years	4 years		

* The use of an IPV-containing combined vaccine is acceptable as long as the other antigen(s) are not contraindicated.²

◇ In the first 6 months of life, minimum age and intervals are only recommended if the infant is at risk for imminent exposure to circulating poliovirus (i.e., travel to polio-endemic area, or during an outbreak)^{3, 4}

§ 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.²

‡ The preferred interval between the 2nd and 3rd doses of IPV is 2 months. However, if accelerated protection is needed, the minimum interval between doses 1, 2 or 3 is 4 weeks.³

** If the 3rd dose of an all-IPV or all-OPV series is given on or after the fourth birthday, the series is complete. If the series is combined IPV/OPV, a 4th dose is required. If the immunization history is unclear, give a 4th dose of IPV to ensure completion of the series.²

◇◇ If 4 or more doses of an IPV-containing vaccine are administered prior to age 4 years, an additional dose should be administered at age 4–6 years.⁴

§§ The final dose in the IPV series should be administered at ≥4 years of age and ≥6 months after the previous dose regardless of the number of previous doses. If a 5th dose is required to complete the IPV series, the minimum spacing between the 4th and 5th dose is 6 months. In a 3-dose (e.g. late start or catch-up) polio schedule, the minimum spacing between the 2nd and 3rd dose is 6 months.⁴

III. B. Inactivated Polio Vaccine (IPOL[®])¹ Adult Schedule for Persons ≥18 Years of Age^{*}

DOSE 0.5 ml	PRIMARY SCHEDULE ^{◇,§}	ACCELERATED SCHEDULE for HIGH-RISK PERSONS ^{‡,**}
1		
2	1–2 months from dose 1 to 2	4 weeks from dose 1 to 2
3	6–12 months from dose 2 to 3	4 weeks from dose 2 to 3

* Routine polio vaccination of persons ≥18 years of age who reside in the U.S. is not necessary due to childhood immunity and minimal exposure risks. However, IPV is recommended for certain adults at an INCREASED RISK OF EXPOSURE TO POLIO (e.g., **international travelers, laboratory workers, healthcare personnel caring for polio cases, and contacts of cases during an outbreak**). See *Polio for Travelers* pharmacy protocols at: 1.usa.gov/PharmacyImmunizationProtocols

◇ The primary IPV series recommended for high-risk unvaccinated adults (with or without written record) is 2 doses separated by 1–2 months, and a 3rd dose 6–12 months after 2nd dose.³

[§] If previously completed a primary series of ≥ 3 doses, 1 more IPV dose can be given if high-risk.³

[‡] If 8 weeks are available before protection is needed, 3 doses 4 weeks apart are recommended. If 4–8 weeks are available before protection is needed, 2 doses should be given 4 weeks apart.³

^{**} If <4 weeks are available before protection needed, one dose of IPV is recommended. In all cases, the remaining doses should be given later at recommended intervals.³

IV. CONTRAINDICATIONS

- IPOL[®]:¹
 - A history of hypersensitivity to any component of the vaccine, including 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, and polymyxin B.
 - No further doses should be given if anaphylaxis or anaphylactic shock occurs within 24 hours of administration of one dose of vaccine.

VII. PRECAUTIONS AND WARNINGS

IPOL[®] 1

- 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. Deaths have been reported in temporal association with the administration of IPV.

VIII. SIDE EFFECTS AND ADVERSE REACTIONS: IPOL[®]

Number followed for Safety	IPOL [®] N =211 Adverse Reaction %		IPOL [®] N=206 Adverse Reaction %		IPOL [®] N=74 Adverse Reaction %	
	2 months		4 months		18 months [‡]	
Local Reaction, Injection site [◇]	6 hours	48 hours	6 hours	48 hours	6 hours	48 hours
Pain	29.4	2.8	22.8	1.0	13.5	0.0
Redness	0.5	0.5	1.0	0.0	1.4	0.0
Swelling	11.4	0.9	11.2	1.9	2.7	0.0
Systemic Complaints [§]						
Irritability	64.5	17.5	49.5	11.7	14.7	8.0
Fever>102.2°F	1.0	0.5	2.0	0.0	0.0	4.2
Anorexia	16.6	4.3	6.3	2.4	2.7	2.7
Tiredness	60.7	7.1	38.8	6.3	9.3	4.0
Vomiting	1.9	2.8	1.9	1.0	1.3	0.0
Persistent Crying	Percentage of infants within 72 hours after immunization was 0.0% after dose one, 1.4% after dose two, and 0.0% after dose three.					
IPOL [®] package insert. Table 2, page 16 ¹						

Percentage of Infants Presenting with Local or Systemic Reactions at 6 and 48 Hours of Immunization with IPOL[®] Vaccine Administered Intramuscularly Concomitantly at Separate Sites with Sanofi* Whole Cell DTP Vaccine at 2 and 4 Months of Age and with Sanofi Acellular Pertussis Vaccine (Tripedia[®]) at 18 Months of Age.

* Sanofi Pasteur Inc. formerly known as Aventis Pasteur Inc.

◇ Data are from the IPOL vaccine administration site, given intramuscularly.

§ The adverse reaction profile includes the concomitant use of Sanofi whole cell DTP vaccine or Tripedia[®] vaccine with IPOL vaccine. Rates are comparable in frequency and severity to that reported for whole-cell DTP given alone.

‡ Children who have been vaccinated with Tripedia[®] vaccine.

VIII. OTHER CONSIDERATIONS

A. Post-Polio Syndrome

After an interval of 15–40 years, 25%–40% of persons who contract paralytic poliomyelitis in childhood 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. For further information contact:

- Post-Polio Health International; 4207 Lindell Blvd, Ste 110 St. Louis MO 63108-2915; 314-534-0475. info@post-polio.org and www.post-polio.org (2015)
- March of Dimes; Birth Defects Foundation; Community Services Department; 1275 Mamaroneck Ave.; White Plains, NY 10605; 914-428-7100. (2015)
- Katheryne Hoffman, M.D.: Roosevelt Warm Springs Rehabilitation and Specialty Hospital; (706) 655-5301. P.O. box 1000; 6135 Roosevelt Highway, Warm Springs, GA 30830 Admission criteria: (706) 655-5253 Warm Springs, GA 30830; (2015)

B. Vaccination of Internationally Adopted Children

- The recommended approach is to revaccinate adopted children with IPV according to the US schedule.⁵
- Alternative approaches are to order serologic testing for neutralizing antibody to poliovirus types 1, 2 and 3; or to administer a single dose of IPV, followed by serologic testing,⁵
- Children with protective titers against all three types do not need revaccination.⁵

C. 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. HCT recipients of all ages are at increased risk. Revaccination with 3 doses of IPV is recommended 6–12 months after HSCT.^{2, 6}

D. 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.¹

E. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses.¹

F. Lactation: It is not known whether IPOL is/ are excreted in human milk. Use with caution in nursing mothers.¹

G. Oral polio vaccine (OPV) has been unavailable in the United States since 1999.³

IX. Storage and Handling

All clinics and pharmacies enrolled with the VFC program must **immediately** report any storage and handling deviations to their Oregon Immunization Program health educator. The health educator assignment map is located at: http://bit.ly/HE_Map

IPOL® ¹	Store at 2°–8°C	Do not use if vaccine has been frozen. Report to health educator	Protect from light
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X. ADVERSE EVENT REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS online report form is available at <https://vaers.hhs.gov/esub/step1>. A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290-(2)(3).^{7, 8}

Table1. Adverse Events to Be Reported to VAERS

Inactivated Polio -IPV, DTaP-IPV, DTaP-IPV/HIB, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Any acute complication or sequelae (including death) of the above event (interval - not applicable) C. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert)
Oral Polio (OPV) Not available in the U.S.	A. Paralytic polio o in a non-immunodeficient recipient (30 days) o in an immunodeficient recipient (6 months)

<p>May be administered during international travel.</p>	<ul style="list-style-type: none"> o in a vaccine-associated community case (interval - not applicable) B. Vaccine-strain polio viral infection <ul style="list-style-type: none"> o in a non-immunodeficient recipient (30 days) o in an immunodeficient recipient (6 months)
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POLIO CASE INVESTIGATION: Notify Acute and Communicable Disease and Prevention (ACDP) 971-673-1111 immediately, day or night.

* **Effective date: November 10, 2008.** 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 manufacturers package insert. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.

[vaers.hhs.gov/resources/VAERS Table of Reportable Events Following Vaccination.pdf](http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) 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 protocol available at:

1.usa.gov/PharmacyImmunizationProtocols

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