

# OREGON HEALTH AUTHORITY IMMUNIZING PHARMACIST PROTOCOL

ENHANCED-POTENCY INACTIVATED POLIOVIRUS VACCINE [IPV] <sup>1</sup> FOR <b>TRAVELERS</b>	
Last Reviewed	14 March 2019
Last Revised	14 March 2019
This order expires	31 July 2021

March 13, 2019

CDC reaffirmed and updated vaccine recommendations for travelers to countries where Wild Polio Virus (WPV) has circulated during the past 12 months and for workers in institutional settings (such as health care facilities, refugee camps, or humanitarian aid settings) in bordering countries, where the risk of exposure to imported WPV may be high.

Encourage all residents and long-term visitors (staying >4 weeks) of all ages to receive a dose of IPV (if available) between 4 weeks and 12 months before **exiting** or at least by the time of departure, from one of these countries\*.

•Ensure that the traveler receives proper documentation of their polio vaccination.

Because there is a global shortage of IPV, these countries\* may not be able to implement these guidelines. The priority in such countries is providing a single dose of IPV to children as part of the routine immunization schedule.

\*Temporary polio vaccine recommendations affect the following countries:

**Afghanistan, Democratic Republic of the Congo, Indonesia, Kenya, Niger, Nigeria, Pakistan, Papua New Guinea, and Somalia.**<sup>2</sup>

## I. OREGON IMMUNIZATION PHARMACY PROTOCOL:

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 Inactivated Polio Vaccine (IPV): 0.5 mL subcutaneously (SC) or intramuscularly (IM) as indicated for age and situation. See section II for schedules.
9. Simultaneous vaccination: may be given with all routine vaccines
10. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

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Immunizing Pharmacist

Date

**II. A. Table 1. IPV ACCELERATED VACCINE SCHEDULE FOR INFANTS AND CHILDREN TRAVELING WHO ARE UNVACCINATED, INCOMPLETELY VACCINATED, OR HAVE AN UNKNOWN VACCINATION STATUS <sup>\*◇</sup>**

Dose 0.5 mL	Preferred Age	Minimum Acceptable Interval to next dose
1	≥7 years	
2		≥4 weeks after the previous dose
3		≥4 weeks after the previous dose
4		≥6 months after dose 3

\* If the age-appropriate series is not completed before departure, the remaining IPV doses to complete a full series should be administered when feasible, at the intervals recommended for the accelerated schedule.<sup>2, 3, 6</sup>

◇ If doses are needed while residing in the affected country, the polio vaccine that is available (IPV or OPV) may be administered.<sup>2, 3, 6</sup>

**II.B. Table 2. RECOMMENDATIONS FOR ADULT TRAVELERS OF UNKNOWN VACCINE STATUS<sup>2, 3</sup>**

Dose 0.5 mL	Primary 3-Dose Schedule
1	
2	4–8 weeks from dose 1 to 2
3	6–12 months from dose 2 to 3

**II.C. Table 3. ACCELERATED SCHEDULE FOR ADULTS, UNVACCINATED, INCOMPLETELY VACCINATED OR WITH UNKNOWN VACCINE STATUS<sup>2, 3</sup>**

Time Interval to Travel	Number of Doses*	Interval Spacing
>8 weeks	3 doses	≥4 weeks apart
<8 weeks but >4 weeks	2 doses	≥4 weeks apart
<4 weeks	1 dose	

\* If <3 doses are administered, the remaining IPV doses to complete the 3-dose series should be administered when feasible, at appropriate intervals, if the person remains at increased risk for poliovirus exposure. If doses are needed while residing in the affected country, the polio vaccine that is available (IPV or OPV) may be administered.<sup>2, 6</sup>

**II. D. Table 4. RECOMMENDATIONS FOR FULLY VACCINATED TRAVELERS: Children, Adolescents, and Adults<sup>2, 3</sup>**

<b>Dose 0.5 mL</b>	<b>CDC recommends that travelers to any country with WPV or cVDPV circulation in the past 12 months protect their health by being fully vaccinated against polio, including a single lifetime polio vaccine booster for adults.<sup>2</sup></b>
1	<ul style="list-style-type: none"> <li>Administer to persons who are traveling to areas with documented wild polio virus (WPV) circulation within the last 12 months; staying &gt;4 weeks; have documented a complete series; and the most recent dose was administered &gt;12 months before the date of departure.</li> <li>Children who receive this additional dose as a fourth dose before their 4<sup>th</sup> birthday will still require an IPV booster dose at age ≥4 years</li> <li>If the time residing in the polio-exporting or polio-infected country is anticipated to be &gt;12 months, available polio vaccine (IPV or OPV) should be administered within the affected country 4 weeks to 12 months before departing that country</li> </ul>

Clinicians performing overseas evaluations of immigrants and refugees migrating to the U.S. from polio-exporting or polio-infected countries should consult the 2014 *Technical Instructions for Panel Physicians* for vaccinations.<sup>7</sup>

### III. Table 5. LICENSED INACTIVATED POLIO VACCINE (IPV) \*

PRODUCT NAME	VACCINE COMPONENTS	PREFERRED AGE RANGE	Preservatives
IPOL <sup>®</sup> Sanofi Pasteur	Inactivated polio virus (IPV) serotypes 1,2 and 3  Less than 5 ng of neomycin, 200 ng of streptomycin, 25 ng of polymyxin B, and 0.5% of 2-phenoxyethanol and up to 0.02% (200 ppm) of formaldehyde as preservatives per dose are present in vaccine. <sup>5</sup>	≥6 weeks	None

\* OPV is recommended for additional doses administered outside of the United States unless the individual is immunocompromised.<sup>1</sup>

### IV. RECOMMENDATIONS FOR USE

CDC recommends that travelers to any country with Wild Polio Virus (WPV) or circulating vaccine--derived polioviruses circulating vaccine-derived polio virus type 2 (cVDPV2) circulation in the past 12 months protect their health by being fully vaccinated against polio, including a single lifetime polio vaccine booster.

**Temporary polio vaccine recommendations** of the CDC and the World Health Organization (WHO) for affected WPV exporting countries can be located at:  
<https://wwwnc.cdc.gov/travel/news-announcements/polio-guidance-new-requirements>

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For an expanded list including cVDPV see:

<https://reliefweb.int/report/nigeria/statement-twentieth-ihr-emergency-committee-regarding-international-spread-poliovirus>

## V. CONTRAINDICATIONS

1. Serious allergic or anaphylactic reaction (hives, swelling of the mouth and throat, difficulty breathing, hypotension, and shock) to a previous dose of IPV or its components, including 2-phenoxyethanol, formaldehyde, streptomycin, neomycin, or polymyxin B.<sup>1</sup>
2. Vaccination of persons with an acute, febrile illness should be deferred until after recovery.<sup>1</sup>

## VI. WARNINGS AND PRECAUTIONS

1. IPV may be administered to people with diarrhea. Minor upper respiratory illnesses with or without fever, mild to moderate local reactions to a previous dose of IPV, current antimicrobial therapy, and the convalescent phase of acute illness are not contraindications for vaccination.<sup>6</sup>

## VII. OTHER CONSIDERATIONS

1. 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.<sup>1,2</sup>
2. Individuals with altered immunocompetence may have reduced immune responses.<sup>1,2</sup>
3. If a pregnant woman is unvaccinated or incompletely vaccinated and requires immediate protection against polio because of planned travel to a country or area where polio cases are occurring, IPV can be administered as recommended for adults.<sup>8</sup>
4. Breastfeeding is not a contraindication to administration of polio vaccine to an infant or mother.<sup>1, 6</sup>
5. IPV may be administered safely to immunocompromised travelers and their household contacts. Although a protective immune response cannot be ensured, IPV might confer some protection to the immunocompromised person. People with certain primary immunodeficiency diseases should not be given live, attenuated OPV and should avoid contact with excreted OPV virus (such as exposure to a child vaccinated with OPV in the previous 6 weeks). Because OPV is no longer given in the United States, this situation would arise only if a child receives OPV overseas.<sup>7</sup>
6. Travelers staying in a polio-infected country longer than 12 months may receive available poliovirus vaccine (IPV or OPV) in the infected country to meet the departure requirement.<sup>2, 6</sup>
7. Oral Polio Vaccine is accepted for additional doses administered outside of the United States unless the individual is immunocompromised.<sup>2, 6</sup>
  - Healthcare workers in refugee camps and other humanitarian aid settings might be at particular risk for exposure to WPV.<sup>2</sup>
  - Very rarely, unvaccinated travelers may contract polio when exposed to vaccine-derived polio virus.<sup>2</sup>
  - A history of having recovered from polio disease should not be considered evidence of immunity, as 3 different poliovirus strains can cause polio.<sup>8</sup>

### VIII. Table 6. SIDE EFFECTS AND ADVERSE REACTIONS

Percentage of Children Presenting with Local or Systemic Reactions at 6 and 48 Hours of Immunization with IPOL<sup>®</sup> Vaccine Administered Intramuscularly Concomitantly at Separate Sites with Sanofi Acellular Pertussis Vaccine (Tripedia<sup>®</sup>) at 18 Months of Age. No adult studies available.

Number followed for Safety	Adverse Reaction (%) (n = 74)	
	Time after Vaccination	
Local Reaction, Injection site*	6 hours	48 hours
Pain	13.5	0.0
Redness	1.4	0.0
Swelling	2.7	0.0
Systemic Complaints		
Irritability	14.7	8.0
Fever > 102.2°F	0.0	4.0
Anorexia	2.7	2.7
Tiredness	9.3	4.0
Vomiting	1.3	0.0
Persistent Crying during the 72 hours after immunization was seen in 0 of recipients after dose one, 1.4% after dose two, and 0 after dose three.		
IPOL <sup>®</sup> package insert. Table 2, page 16		

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



## IX. Table 7. 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	Temp	Storage Issues	Notes
IPOL <sup>®1</sup>	Store at 2°–8°C	Do not use if vaccine has been frozen.	Protect from light

## X. ADVERSE EVENTS REPORTING

Private providers are to report events directly to VAERS and can read about options on how to do so at <https://vaers.hhs.gov/reportevent.html>

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).<sup>9</sup>

Electronic copy of this standing order is available at:

[1.usa.gov/PharmacyImmunizationProtocols](https://www.fda.gov/oc/ohrt/1.usa.gov/PharmacyImmunizationProtocols)

**Table 8. VAERS Reporting Table \***

[https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS%20Table%20of%20Reportable%20Events%20Following%20Vaccination.pdf) Accessed 28 June 2018.

Event and interval from vaccination	
<b>IPV</b>	<ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>C. Vasovagal syncope (7 days)</li> <li>D. Any acute complication or sequelae (including death) of the above event (interval - not applicable)</li> <li>E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
<b>OPV</b>	<ul style="list-style-type: none"> <li>A. Paralytic polio               <ul style="list-style-type: none"> <li>o in a non-immunodeficient recipient (30 days)</li> <li>o in an immunodeficient recipient (6 months)</li> <li>o in a vaccine-associated community case (interval - not applicable)</li> </ul> </li> <li>B. Vaccine-strain polio viral infection               <ul style="list-style-type: none"> <li>o in a non-immunodeficient recipient (30 days)</li> <li>o in an immunodeficient recipient (6 months)</li> <li>o in a vaccine-associated community case (interval - not applicable)</li> </ul> </li> <li>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>

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.

## REFERENCES

1. IPOL® v 0.1 059 IPOL® 969640 package insert. Available at: [www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf) Accessed 18 March 2019.
2. CDC Clinical update. Interim CDC guidance for travel to and from countries affected by the polio vaccine requirements and recommendations. March 13, 2019. Available at: <https://wwwnc.cdc.gov/travel/news-announcements/polio-guidance-new-requirements> Accessed 18 March 2019
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4. International Certificate of Vaccination or Prophylaxis as Approved by the World Health Organization (Package of 100). U.S. Government Book Store. Available at: <https://bookstore.gpo.gov/products/international-certificate-vaccination-or-prophylaxis-approved-world-health-organization-0> Accessed 18 March 2019
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6. CDC and G. W. Brunette. (2018) Health information for international travel 2018. ("Yellow Book") Poliomyelitis. Chapter 3. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/poliomyelitis> Accessed 18 March 2019.
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9. Oregon Secretary of the State. Board of Pharmacy, Chapter 855; Division 19; Licensing of Pharmacists. OAR 855-019-0270, 0280, and 0290. Available at: <https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3967> Accessed 18 March 2019.