

Immunization Pharmacy Protocol

Live, Attenuated Cholera Vaccine (VAXCHORA®)	
Last Reviewed	14 December 2022
Last Revised	14 December 2022
This order expires	31 December 2024

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1. What’s new

Updated to include the ACIP recommendation for children 7–17 years of age.

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 patients 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. See section 5, Recommendations for use for administration instructions.
- F. Stress to patients that **safe food and water** and **personal hygiene** measures are the key to prevention of cholera.³

I have read, understand, and agree to participate by the terms of this protocol.

Immunizing pharmacist

Date

3. Vaccine schedule for live, attenuated cholera vaccine³

Dose and Route – 100 mL (4×10^8 to 2×10^9 colony-forming units), oral			
Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing
1	7 years	7 years	

4. Licensed live, attenuated cholera vaccine

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
VAXCHORA ^{1,2}	Live, attenuated <i>Vibrio cholerae</i> O1 (CVD 103-HgR)	Single-dose carton containing two packets	7–64 years	None

5. Recommendations for use:³

- A. Cholera vaccine is not routinely recommended for U.S. travelers.
- B. Use in adults 7–64 years of age traveling to an area of active cholera

transmission. An area of active cholera transmission is defined as a province, state, or other administrative subdivision within a country with endemic or epidemic cholera caused by toxigenic *V. cholerae* O1 and includes areas with cholera activity within the last year that are prone to recurrence of cholera epidemics; it does not include areas in which only rare imported or sporadic cases have been reported.

C. Persons at higher risk of exposure:

- a. Travelers visiting friends or relatives;
- b. Health care personnel;
- c. Cholera outbreak response workers;
- d. Persons traveling to or living in a cholera-affected area for extended periods.

D. Persons at higher risk of poor outcomes:

- a. Persons with type O blood;
- b. Persons with low gastric acidity from antacid therapy, partial gastrectomy, or other causes;
- c. Pregnant persons;
- d. Persons with cardiovascular disease or kidney disease;
- e. Travelers without ready access to medical services.

6. Contraindications:

Persons who experienced an anaphylactic reaction to a previous dose of any cholera vaccine or to any vaccine component.^{1,2}

7. Warnings and precautions:

Persons with acute, moderate, or severe illness with or without fever may choose to delay immunization until symptoms have improved.^{1,2}

8. Other considerations:

- A. **Bottled water:** Buffer should be mixed with cold or room temperature purified, non-carbonated, non-flavored bottled or spring water. Do not use tap water, which can be chlorinated and affect vaccine potency.³
- B. **Palatability:**³

- a. Vaccine may be mixed with ¼–1 tsp. (1–4 g) of table sugar or 1 packet (1 g) of stevia sweetener (e.g., Truvia, Splenda Naturals) to improve palatability.
- b. Do not mix with other food or drinks (e.g., applesauce, apple juice, milk).
- c. Do not mix with medicinal flavorings containing propylene glycol, which could inactivate the vaccine.

C. **Food and drink:** Avoid eating or drinking for 60 minutes before and after vaccine administration.^{1,2}

D. **Antibiotics:** Do not administer cholera vaccine to patients who have received oral or parenteral antibiotics within the past 14 days.^{1,2}

E. **Antimalarial prophylaxis:** Do not administer concomitantly with chloroquine. Administer cholera vaccine at least 10 days before beginning a chloroquine regimen.^{1,2}

F. **Oral typhoid vaccine:** If a patient needs both cholera vaccine and oral typhoid vaccine (Vivotif), administer the cholera vaccine first, followed by the first dose of oral typhoid vaccine ≥8 hours later.³ No data are available on concomitant administration with other vaccines.^{1,2}

G. **Immunosuppression:** The safety and effectiveness of cholera vaccine in immunosuppressed patients has not been established. Cholera vaccine virus may be shed in the stool for at least 7 days. Use caution when considering whether to administer cholera vaccine to persons with immunocompromised close contacts.^{1,2}

I. **Pregnancy and Breastfeeding:** Cholera vaccine is not absorbed systemically following oral administration thus, maternal exposure to the vaccine is not expected to result in exposure to the fetus or breastfed infant to the vaccine.

Prospective travelers who are pregnant and their clinicians should consider the risks associated with traveling to areas with active cholera transmission. However, the vaccine strain might be shed in stool for ≥7 days after vaccination, and theoretically, the vaccine strain could be transmitted to an infant during vaginal delivery. A breastfed infant theoretically could receive benefit from maternally derived vaccine antibodies present in maternal milk.

There is a pregnancy registry that monitors pregnancy outcomes in persons who receive cholera vaccine during pregnancy. To enroll in or to receive more information call 800-533-5899.^{1,2}

9. Side effects and adverse reactions

VAXCHORA	
Fatigue, headache	Up to 32%*
Abdominal pain, nausea, vomiting, lack of appetite	Up to 19%*

Diarrhea	Up to 4%
Fever	Up to 0.6%*

*Similar rates in placebo recipients

10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) or Vaccine Access Programs must immediately report any storage and handling deviations to the Oregon Immunization Program at 1-800-980-9431.

Vaccine	Temp	Storage Issues	Notes
VAXCHORA ¹	2° to 8°C	Store buffer components and active components packets in the refrigerator protected from light and moisture.	Packets should not be out of refrigeration for more than 12 hours prior to reconstitution. Packets should not be exposed to temperatures about 80°F.
VAXCHORA ² (frozen)	-25° to -15°C	Store buffer components and active components packets in the freezer protected from light and moisture.	Packets should not be out of freezer for more than 15 minutes prior to reconstitution. Packets should not be exposed to temperatures about 80°F.

11. Adverse events reporting

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

VAERS Reporting Table:

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Event and interval from vaccination
A. N/A

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](https://www.oregon.gov/oha/ohahp/immunization/policies-procedures/855-019-0290).

12. References

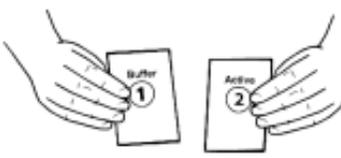
1. Emergent Travel Health. VAXCHORA (Nov 2020) package insert. Available at: www.fda.gov/media/128415/download. Accessed 11 May 2022.
2. PaxVax. VAXCHORA (frozen) (Jun 2016) package insert. Available at: www.fda.gov/media/98688/download. Accessed 11 May 2022.
3. Collins J, Ryan E, Wong K, et al. Cholera vaccine: recommendations of the Advisory Committee on Immunization Practices, 2022. MMWR Recommendations and Reports 2022; 71(2):1–8. Available at: www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7102a1-H.pdf. Accessed 12 December 2022.

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 protocol is available at: [standing protocols](#)

Electronic copy of this pharmacy protocol is available at: [pharmacy protocols](#)

13. Appendix A

<p>1</p>  <p>Remove the carton from the refrigerator [see <i>Storage and Handling (16.2)</i>]. Locate the 2 packets: the buffer component (Packet 1) and the active component (Packet 2).</p>	<p>2</p>  <p>Pour 100 mL of cold or room temperature (41°F-72°F; 5°C-22°C) purified bottled or spring bottled water into a clean, disposable cup. Do not use tap water, sparkling (carbonated) water, non-purified or non-spring bottled water, other beverages, or other liquids.</p>	<p>3</p>  <p>Use scissors to cut the top off the buffer component packet.</p>
<p>4</p>  <p>Empty buffer component packet contents into cup. Effervescence will occur.</p>	<p>5</p>  <p>Using a disposable stirrer, stir until the buffer component completely dissolves. For children less than 6 years of age, discard half of the buffer solution.</p>	<p>6</p>  <p>Use scissors to cut the top off the active component packet.</p>
<p>7</p>  <p>Empty the active component packet contents (lyophilized <i>V. cholerae</i> CVD 103-HgR) into the cup containing the buffer solution.</p>	<p>8</p>  <p>Stir for at least 30 seconds and until the active component disperses to form a slightly cloudy suspension that may contain some white particulates.</p>	<p>9</p>  <p>VAXCHORA must be consumed within 15 minutes of reconstitution. The recipient should drink the full contents of the cup at once. Some residue may remain in the cup and should be discarded with the cup.</p>