

**OREGON HEALTH AUTHORITY  
IMMUNIZATION PROTOCOL FOR PHARMACISTS**

<b>Cholera</b>	
<b>VaxChora™</b>	
<b><u>NOT</u> ROUTINELY RECOMMENDED FOR MOST TRAVELERS</b>	
Last Reviewed	14 March 2019
Last Revised	14 March 2019
This order expires	31 July 2021

- Live oral cholera vaccine may be administered simultaneously or at any interval before or after administration of most other vaccines.
- Oral cholera vaccine should be administered before the oral typhoid vaccine, and at least 8 hours should separate the cholera vaccine and the first dose of typhoid vaccine.<sup>2</sup>

**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 18–64 years of age for contraindications.
3. Provide the VIS [www.cdc.gov/vaccines/hcp/vis/vis-statements/cholera.pdf](http://www.cdc.gov/vaccines/hcp/vis/vis-statements/cholera.pdf) and answer any questions.
4. Record all required data elements in the client’s permanent health record.
5. See section IV. B, for administration of VaxChora™<sup>1</sup> See section II for schedule.
6. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.
7. Stress to patients/clients that **safe food and water** and **personal hygiene** measures are keys to prevention of cholera.

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Immunizing Pharmacist

Date

**I. Table 1. VACCINE SCHEDULE: VaxChora**

Preferred Age	Doses in Series	Dose volume	Dose Schedule	Booster Dose*
18–64 years	1	100 mL	Single oral dose a minimum of 10 days before potential exposure to cholera	N/A

\*The safety and effectiveness of revaccination with CVD 103-HgR have not been established.

Based on expert opinion of how lyophilized CVD 103-HgR buffer might interfere with the enteric-coated Ty21a formulation, taking the first Ty21a dose  $\geq 8$  hours after ingestion of lyophilized CVD 103-HgR might decrease potential interference of the vaccine buffer with Ty21a vaccine.<sup>2</sup>

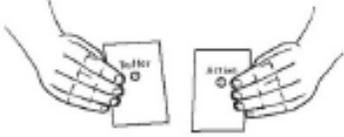
**A. Restrictions on Eating and Drinking<sup>1</sup>**

- Clients should avoid eating or drinking for 60 minutes before or after the oral ingestion of VaxChora (CVD 103-HgR)

**B. Preparation, Reconstitution and Administration: must be prepared in a setting equipped to dispose of medical waste. If the packets are reconstituted in the improper order, the vaccine must be discarded.<sup>1</sup>**

1. Reconstitution should be completed within 15 minutes of removing the carton from the freezer. Locate the 2 packets: the buffer component (Packet 1) and the active component (Packet 2).
2. Pour 100 mL of cold or room-temperature (41°F–72°F; 5°C–22°C) purified bottled water into a clean, disposable cup. Do not use tap water, non-purified bottled water, other beverages, or other liquids.
3. Use scissors to cut the top off the buffer component packet.
4. Empty buffer component packet contents into cup. Effervescence will occur.
5. Using a disposable stirrer, stir until the buffer component completely dissolves.
6. Use scissors to cut the top off the active component packet.
7. Empty the active component packet contents (lyophilized *V. cholerae* strain CVD 103-HgR) into the cup containing the buffer solution.
8. Stir for at least 30 seconds and until active component disperses to form a slightly cloudy suspension that may contain some white particulates. The active component may not dissolve completely.

9. CVD 103-HgR 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><b>1</b></p>  <p>Reconstitution should be completed within 15 minutes of removing the carton from the freezer [see <i>Storage and Handling</i> (16.2)]. Locate the 2 packets: the buffer component (Packet 1) and the active component (Packet 2).</p>	<p><b>2</b></p>  <p>Pour 100 mL of cold or room temperature (41°F-72°F; 5°C-22°C) purified bottled water into a clean, disposable cup. Do not use tap water, non-purified bottled water, other beverages, or other liquids.</p>	<p><b>3</b></p>  <p>Use scissors to cut the top off the buffer component packet.</p>
<p><b>4</b></p>  <p>Empty buffer component packet contents into cup. Effervescence will occur.</p>	<p><b>5</b></p>  <p>Using a disposable stirrer, stir until the buffer component completely dissolves.</p>	<p><b>6</b></p>  <p>Use scissors to cut the top off the active component packet.</p>
<p><b>7</b></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><b>8</b></p>  <p>Stir for at least 30 seconds and until active component disperses to form a slightly cloudy suspension that may contain some white particulates. The active component may not dissolve completely.</p>	<p><b>9</b></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>

**Disposal:** <sup>1</sup> Dispose of the cup, packets and stirrer according to standard procedures for medical waste. Inactivate any spilled vaccine and clean any non-disposable equipment used in preparation of CVD 103-HgR with 70% isopropyl alcohol or 10% bleach.

### III. Table 2. LICENSED VACCINE

Product Name	Vaccine Component(s)	Preferred Age Range	Dose Volume
Vaxchora™ <sup>1</sup>	Live, attenuated, orally administered $4 \times 10^8$ to $2 \times 10^9$ CFU* of <i>V. cholerae</i> strain CVD 103-HgR constructed from serogroup O1 classical Inaba strain 569B. Also contains sucrose, lactose and ascorbic acid.	18–64 years	100 mL oral solution

\*CFU = colony forming units

### IV. RECOMMENDATIONS FOR USE<sup>1, 2</sup>

#### A. Persons for whom CVD 103-HgR vaccination is recommended

CVD 103-HgR oral cholera vaccine is recommended for individuals aged 18–64 years who:

- will be traveling to an area of active cholera transmission,\* including
  - Travelers visiting friends and relatives,
  - Long-term travelers,
  - Travelers who do not follow safe food and water precautions and personal hygiene measures,
  - Healthcare workers and response workers expected to have direct contact with body fluids (vomit or stool) from cholera patients;

#### AND

- will be at increased risk of toxigenic *V. cholerae* O1 exposure; or
- whose individual risk factors or travel situations carry increased risk of poor clinical outcome if infected, including
  - Travelers without ready access to rehydration therapy and medical care

- Travelers with a condition that carries increased risk of poor clinical outcomes from cholera:
  - ✓ Blood type O
  - ✓ Low gastric acidity
  - ✓ Pregnancy
  - ✓ Immunocompromising conditions
  - ✓ Cardiovascular disease, renal disease, or who would tolerate dehydration poorly

**Safe food and water and personal hygiene measures are keys to prevention of cholera.**

\*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 1 year that are prone to recurrence of cholera epidemics; it does not include areas where only rare, imported or sporadic cases have been reported. Most travelers from the United States do not visit areas with active cholera transmission, so the vaccine is not routinely recommended for U.S. travelers.<sup>2</sup>

**B. Limitations of Use**

- The effectiveness of CVD 103-HgR has not been established in persons living in cholera-affected areas.<sup>1</sup>
- The effectiveness of CVD 103-HgR has not been established in persons who have pre-existing immunity due to previous exposure to *V. cholerae* or receipt of a cholera vaccine.<sup>1</sup>
- CVD 103-HgR has not been shown to protect against disease caused by *V. cholerae* serogroup O139 or other non-O1 serogroups.<sup>1</sup>
- The duration of protection conferred by the primary dose beyond the evaluated 3-month period is unknown. There is no recommendation for use of booster doses at this time.<sup>2</sup>

## V. CONTRAINDICATIONS<sup>1</sup>

1. Do not use in persons who have a history of severe allergic reaction (e.g., anaphylaxis) to any ingredient of CVD 103-HgR or to a previous dose of any cholera vaccine (e.g., Dukoral<sup>®</sup> or Shanchol<sup>®</sup>).

## VI. WARNINGS AND PRECAUTIONS<sup>1, 2</sup>

1. **Age:** No safety data exist about safety and effectiveness of the currently available vaccine in persons <18 or ≥65 years of age.
2. **Immunocompromised Persons:** The safety and effectiveness of Vaxchora<sup>™</sup> have not been established in immunocompromised persons.
3. **Pregnancy and Breastfeeding:** No data exist on use of CVD 103-HgR in pregnant and breastfeeding women. Pregnant women are at increased risk for poor outcomes from cholera infection. Pregnant women and their clinicians should consider the risks of traveling to areas of active cholera transmission. The vaccine is not absorbed systemically: thus, maternal exposure to the vaccine is not expected to result in exposure of the fetus or breastfed infant. However, the vaccine strain might be shed in the stool for ≥7 days after vaccination, and could, theoretically, be transmitted to an infant during vaginal delivery.
4. **Shedding and Transmission:** CVD 103-HgR may be shed in the stool of recipients for at least 7 days. There is a potential for transmission of the vaccine strain to non-vaccinated close contacts (e.g., household contacts). Use caution when considering whether to administer Vaxchora<sup>™</sup> to individuals with immunocompromised close contacts.

## VII. SIDE EFFECTS AND ADVERSE EVENTS<sup>2</sup>

Studies with the currently available vaccine formulation found a slightly higher prevalence of diarrhea (mostly mild) among vaccine recipients (3.8%) than among unvaccinated groups (1.6%). No other differences were detected between vaccinated and unvaccinated groups in the occurrence of any adverse events.

Additional information can be found in the package insert.

## VIII. OTHER CONSIDERATIONS<sup>1</sup>

1. **Antibiotics:** Do not administer CVD 103-HgR to patients who have received oral or parenteral antibiotics within 14 days prior to vaccination. Avoid concomitant administration of CVD 103-HgR with systemic antibiotics since these agents may be active against the vaccine strain and prevent multiplication sufficient to induce a protective immune response.
2. **Chloroquine antimalarial Prophylaxis:** Immune responses to CVD 103-HgR may be diminished when administered concomitantly with chloroquine. Administer CVD 103-HgR at least 10 days before beginning antimalarial prophylaxis with chloroquine.
3. **Immunosuppressive Treatments:** Including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response.
4. **Pregnancy:** <sup>1, 2</sup> Call the pregnancy registry at 800-533-5899 if CVD 103-HgR is given at any time during pregnancy. Notify VAERS of any doses given during pregnancy.

### IX. Table 3. 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
CVD 103-HgR <sup>1</sup>	Store at -13°F to -5°F (-25°C to -15°C)	Packets should not be out of frozen storage for more than 15 minutes.  When out of frozen storage, temperatures should not exceed 80°F (27°C).	Protect from light and moisture

### 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>5</sup>

Electronic copy of this standing order is available at: [1.usa.gov/PharmacyImmunizationProtocols](http://1.usa.gov/PharmacyImmunizationProtocols)

## REFERENCES

1. Vaxchora™ (2016) package insert. Available at: [www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM506235.pdf](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM506235.pdf). Accessed 21 May 2018.
2. CDC. Recommendations of the Advisory Committee on Immunization Practices (ACIP) for the use of cholera vaccine. MMWR 2017;66:482–5. Available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/cholera.html>. Accessed 21 May 2018.
3. CDC. Vaxchora™ (lyophilized CVD 103-HgR). Available at: [www.cdc.gov/cholera/vaccines.html](http://www.cdc.gov/cholera/vaccines.html). Accessed 21 May 2018.
4. For a current list of areas of active cholera transmission, see CDC. “Clinical Update: Cholera Vaccine for Travelers.” Available at: [wwwnc.cdc.gov/travel/news-announcements/cholera-vaccine-for-travelers](http://wwwnc.cdc.gov/travel/news-announcements/cholera-vaccine-for-travelers). Accessed 21 May 2018.
5. 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 16 August 2018.

### Appendix: PATIENT COUNSELING INFORMATION<sup>1</sup>

Prior to administration of this vaccine, the health care professionals should counsel recipients as follows:

- Advise vaccine recipients to exercise caution regarding food and water consumed in cholera-affected areas, in accordance with the recommendations from the Centers for Disease Control and Prevention for the prevention of cholera in travelers.
- Educate vaccine recipients regarding the most common adverse reactions occurring within 7 days post-vaccination with CVD 103-HgR (tiredness, headache, abdominal pain, nausea/vomiting, lack of appetite, and diarrhea).
- Inform vaccine recipients that CVD 103-HgR is a live, attenuated vaccine and has the potential for transmission of the vaccine strain to close contacts (e.g., household contacts). For at least 14 days following vaccination with CVD 103-HgR, vaccine recipients should wash their hands thoroughly after using the bathroom and before preparing or handling food.
- Instruct vaccine recipients to report adverse reactions to their healthcare provider.