

Protocol for Cholera Vaccine (VAXCHORA®)

1. What's New

- A. Updated to include ACIP recommendation for children 7-17 years of age.
- B. VAXCHORA® may be consumed within 30 minutes of reconstitution if sucrose/non-flavored stevia is added or within 4 hours of reconstitution if no flavoring is added.
- C. VAXCHORA® is no longer stored in the freezer.

2. Immunization Protocol^{2,3}

- A. Administer a 100-mL dose, oral, of cholera vaccine to persons ≥7 years traveling to cholera-affected areas, as recommended in Section 5.
- B. Stress to patients that **safe food** and **water** and **personal hygiene** measures are the key to prevention of cholera.

3. Vaccine Schedule

Cholera Vaccine (VAXCHORA)® Dose and Route – 100 mL (4 x 10 ⁸ to 2 x 10 ⁹ colony-forming units), oral		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	7-64 years	

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
VAXCHORA® ^{1,2}	Live, attenuated <i>Vibrio cholerae</i> O1 (CVD 103-HgR)	Single dose carton containing two packets: Buffer Component Packet Active Component Packet	2-64 years	None

5. Recommendations for Use^{2,3}

- A. Cholera vaccine is not routinely recommended for U.S. travelers.
- B. Use in recipients 7–64 years of age ≥10 days before 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

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- 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^{2,3}

- A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Contains
VAXCHORA®	Anhydrous lactose, Ascorbic acid, Sucrose

7. Warnings and Precautions

- A. Persons with acute, moderate, or severe illness with or without fever may choose to delay immunization until symptoms have improved.³
- B. VAXCHORA® 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® to individuals with immunocompromised close contacts.²

8. Other Considerations^{2,3}

- 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.^{2,3}
- D. **Antibiotics:** Do not administer cholera vaccine to patients who have received oral or parenteral antibiotics within the past 14 days.^{2,3}
- E. **Antimalarial prophylaxis:** Do not administer concomitantly with chloroquine. Administer cholera vaccine at least 10 days before beginning a chloroquine regimen.^{2,3}
- 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.^{2,3}
- 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.^{2,3}

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H. **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.^{2,3}

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
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 Handling¹

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
VAXCHORA®	36°F to 46°F (2° to 8°C) vaccine & diluent	Store buffer components and active components packets in the refrigerator protected from light and moisture. Packages may be stored at 48°F to 77°F (9°C to 25°C) for no more than 5 days prior to reconstitution.	Packets should not be out of refrigeration for more than 12 hours prior to reconstitution. Packets should not be exposed to temperatures above 80°F.

11. References

1. Cholera Vaccine Information. Centers for Disease Control and Prevention. Updated April 5, 2023. Accessed April 12, 2023. <https://wwwnc.cdc.gov/travel/page/cholera-travel-information>
2. Emergent Travel Health. VAXCHORA® (Dec 2022) package insert. Available at: <https://www.fda.gov/media/128415/download>. Accessed 12 April 2023.

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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: <https://www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7102a1-H.pdf>. Accessed 12 April 2023.

12. Appendix

- A. N/A

PROPOSED