

Information for Healthcare Professionals about the Cholera Vaccine-specific Screening Checklist

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references listed at the end.

1. Are you sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events.¹ However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as upper respiratory infections) are NOT contraindications to vaccination. Given the unique nature of cholera vaccine, current active diarrhea would be a relative precaution to vaccination. In addition, some antibiotics might interfere with an appropriate immune response to this live bacterial vaccine. Consult a provider and consider delaying the administration of the cholera vaccine if the patient has active diarrhea or is currently on antibiotics.

2. Are you between 2-64 years of age?: Cholera Vaccine is only FDA-approved for patients 2-64 years of age. No data currently exist about the safety and effectiveness of the vaccine in children and teens aged <2 years or adults aged ≥65 years.²

3. Have you had anything to eat or drink in the last 60 minutes? Vaxchora should not be administered to patients who have had anything to eat or drink during the hour prior to vaccination as recent food or drink may interfere with an appropriate immune response to this oral vaccine. They should also avoid eating or drinking for 60 minutes following vaccination.²

4. Do you have allergies to medication, food, or a vaccine component?

Persons with an anaphylactic reaction to a previous dose of cholera vaccine or any vaccine component to include yeast, casein (a protein derived from cow's milk) or lactose should not be vaccinated.²

5. Have you ever had a serious reaction to a vaccine in the past?

History of an anaphylactic reaction to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk, this decision should be made in consultation with the provider and patient.^{1,3}

6. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or a blood disorder? The safety of this live, attenuated bacterial cholera vaccine in people with these conditions has not been established. Consider the risks and benefits of vaccination in this population and discuss with the patient's provider for any questions or concerns. Of note, persons with medical conditions that would lead them to tolerate dehydration poorly, such as those with cardiovascular disease or kidney disease, might be at increased risk for poor outcomes from cholera infection. The patient and provider should consider the risks and benefits of vaccination carefully.^{1,3}

7. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem? Live bacterial vaccines such as cholera vaccine are usually contraindicated in immunocompromised people. The safety of this live, attenuated bacterial cholera vaccine in people with these conditions has not been established. The immunologic response to VAXCHORA may be diminished in immunocompromised individuals.^{1,3}

8. In the past 3 months, have you taken medications that affect your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or have you had radiation treatments?

Live vaccines should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement.^{1,5} Some immune mediator and immune modulator drugs (especially the antitumor-necrosis factor agents adalimumab, infliximab, and etanercept) may be immunosuppressive. The use of live vaccines should be avoided in persons taking these drugs.¹

9. Do you have any close contacts with weakened immune systems?

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.^{2,3}

10. Have you taken any antibiotics within the last 2 weeks? Avoid concomitant administration of VAXCHORA with systemic antibiotics since these agents may be active against the vaccine strain and prevent a sufficient degree of multiplication to occur in order to induce a protective immune response. Do not administer VAXCHORA to patients who have received oral or parenteral antibiotics within 14 days prior to vaccination. In addition, data from a study with a similar product indicate that the immune responses to VAXCHORA may be diminished when VAXCHORA is administered concomitantly with chloroquine. Administer VAXCHORA at least 10 days before beginning antimalarial prophylaxis with chloroquine.^{2,3}

11. Do you have at least 10 days before travel/anticipated exposure?

According to product labeling, administer a single oral dose of VAXCHORA a minimum of 10 days before potential exposure to cholera to ensure optimal protection to this disease.^{2,3}

12. For women: Are you pregnant or is there a chance you could become pregnant during the next month?

Pregnant women are at increased risk for poor outcomes from cholera infection. Pregnant women and their clinicians should consider the risks associated with traveling to areas of active cholera transmission. VAXCHORA is not absorbed systemically following oral administration, and maternal use is not expected to result in fetal exposure to the drug. 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. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VAXCHORA during pregnancy. To enroll in or obtain information about the registry, please call PaxVax at 1-800-533-5899.^{2,3}

REFERENCES

1. CDC. General best practice guidelines for immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/aciprecs/downloads/general-recs.pdf.
2. VAXCHORA™ Package insert, April 2019 at <https://www.fda.gov/media/128415/download>
3. Recommendations of the Advisory Committee on Immunization Practices for Use of Cholera Vaccine MMWR / May 12, 2017 / Vol. 66 / No. 18