

Oral Cholera Vaccine (OCV): What You Need to Know

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OCV as a Cholera Prevention Tool

Cholera vaccines protect against cholera, a severe, potentially epidemic, life-threatening diarrheal disease caused by the bacterium *Vibrio cholerae*. Oral cholera vaccine (OCV) provides protection against cholera by stimulating the intestinal immune response. This intestinal immune response limits *V. cholerae* colonization of the gut if one is subsequently exposed. Oral cholera vaccine should be used as part of an integrated cholera control strategy (including safe water, improved sanitation, and high-quality case management). The vaccine reduces the risk of getting sick with or dying of cholera.

Composition and Use of OCV

The OCV vaccine currently recommended by the World Health Organization (WHO) which is available from the Global Stockpile is called Euvichol-Plus. It contains killed whole cells of *V. cholerae* serogroups O1 and O139 and is presented in single dose plastic tubes containing 1.5 ml liquid and is given by mouth. To take the vaccine, one should shake the tube, twist open the tip and drink the contents directly from the tube. Two doses of vaccine are recommended with the second dose given about two weeks after the first. However, recent studies have shown that the interval can be considerably longer, even up to a year between doses. The vaccine must be kept cold during storage and transport. However, clinical studies show that during a vaccination campaign, the vaccine can be taken out of the cold chain on the day of vaccine administration. Taking the vaccine out of the cold chain during the day of the campaign is not allowed by the package insert but has often been done to simplify the logistics of the campaign and lower costs.

To be clear, OCV is much different from the old injectable vaccine which was widely used prior to 1980. Although Euvichol is the only WHO-prequalified OCV available now, others are in development and are expected to be licensed within the next few years. (Shanchol, another killed OCV that is virtually identical to Euvichol-Plus, was used until recently, but the company stopped manufacturing it in 2023.)

While the vaccine is approved based on a two-dose schedule, there are situations where only a single dose is provided to control an outbreak when there is a shortage of vaccine. Giving a single dose allows the campaign to give vaccine to more people. While the duration of protection of the single dose is likely shorter, it is estimated to reduce the number of cases during an outbreak relative to two doses. In fact, beginning in 2022, because of the shortage of vaccine and with so many cholera outbreaks, a single dose was implemented during all the campaigns. When the vaccine supply improves, we anticipate that the routine will revert to a two-dose schedule.

When the two-dose schedule is used, all persons in the catchment area should be offered the vaccine during each round. If a person did not receive the vaccine during the first round, they can receive a dose during the second round. The intention is to vaccinate a population, not just the individuals.

Safety and Side Effects of OCV

More than 30 million doses of killed OCV have been administered globally. Experience with these vaccines has found no serious adverse reactions. During controlled clinical trials, a few people taking these vaccines experienced gastrointestinal discomfort, however symptoms were mild and occurred in similar frequencies among those taking vaccine and placebo. WHO recommends that OCV should be provided to pregnant women during vaccine campaigns given that contracting cholera during pregnancy can cause complications, including miscarriage and preterm delivery. Follow-up of women who received Shanchol^{1,2} or Dukoral^{3,4} when pregnant have not revealed a significant increase in adverse pregnancy outcomes. The vaccine is composed of killed bacteria and is not absorbed from the intestine; thus, there is no reason to believe that it will harm the mother or the fetus. However, given the lack of definitive data demonstrating safety during pregnancy, the vaccine label includes cautions about its use during pregnancy. Most experts conclude that the benefits from vaccination far outweigh any potential risk for women at risk of cholera, and that OCV campaigns should provide the vaccine to all people over age 1 year, including pregnant women, when vaccine campaigns are carried out.

Direct and Indirect (Herd) Protection

Oral cholera vaccine provides significant protection for those who receive the vaccine. In addition, if a large proportion of the community receives vaccine, the vaccine protects the community because of indirect, or “herd,” protection. This means that in a community with many vaccinated individuals, even those who did not receive the vaccine, will have a lower risk of cholera because the transmission of the infectious agent is reduced. The fact that OCV confers both direct protection to the individual as well as herd protection to others is very important to cholera control.

WHO Recommendations for Use

The World Health Organization has recommended that OCV be more widely used by countries in a variety of cholera endemic and outbreak situations. A full description of the policy is available.⁴

Some specific recommendations include the following:

“Given the current availability of killed whole cell OCVs and data on their safety, efficacy, field effectiveness, feasibility, impact and acceptability in cholera affected populations, these vaccines should be used in areas with endemic cholera, in humanitarian crises with high risk of cholera, and during cholera outbreaks. The vaccines should always be used in conjunction with other cholera prevention and control strategies.”

OCV Stockpile

In 2013, WHO initiated a stockpile of OCV so that it could be made available quickly when needed. For GAVI eligible countries, the vaccine can be provided without cost to national programs. Countries that are not GAVI eligible can still obtain OCV through the stockpile to control cholera in their country.

For more information you may contact dsack1@jhu.edu

¹ Grout, Lise, et al. “Pregnancy outcomes after a mass vaccination campaign with an oral cholera vaccine in Guinea: a retrospective cohort study.” PLoS Negl Trop Dis 9.12 (2015)

² Ali M, et al. “Safety of a killed oral cholera vaccine (Shanchol) in pregnant women in Malawi: an observational cohort study.” Lancet Infect Dis 17: 538-544 (2017)

³ Hashim, Ramadhan, et al. “Safety of the recombinant cholera toxin B subunit, killed whole-cell (rBS-WC) oral cholera vaccine in pregnancy.” PLoS Negl Trop Dis 6.7 (2012)

⁴ . Cholera vaccines: WHO position paper - August 2017. Wkly Epidemiol Rec 92: 477-98