STOP CHOLERA

Work Together. Stop Transmission. End Deaths.

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 vaccines currently recommended by the World Health Organization (WHO) are killed, whole-cell vaccines that are orally administered. These vaccines are different from the injectable vaccine, which was widely used prior to 1980.

Shanchol and Euvichol are two examples of killed oral vaccines that have the same composition, and are relatively less expensive. Both are prequalified and are available through the global stockpile. Other brands of oral vaccine are similar in composition, safety and effectiveness, but are either more expensive and logistically challenging (Dukoral), or are not yet WHO prequalified (mORC-Vax).

Shanchol and Euvichol are presented in single dose vials containing 1.5 ml liquid. Individuals taking the vaccine should mix the vaccine by shaking the vial, open the vial by breaking the seal at the top, and then drink the contents directly from the vile. Two doses of vaccine are recommended with the second dose given about two weeks after the first. The vaccine must be kept cold during storage and transport. However, during a vaccination campaign, the vaccine can be taken out of the cold chain on the day of vaccine administration. This will simplify the logistics of the campaign and lower costs. Studies are ongoing to determine if the vaccine can be kept at room temperature even longer.

It should be noted that studies are ongoing to determine how flexible the dose schedule can be. For example, in certain situations, the interval between doses might be increased depending on the epidemiologic situation and the logistics in the country. In other situations a single dose (rather than two doses) may be more appropriate when this strategy increases the number of people who can be vaccinated quickly during a campaign. As plans for a vaccine campaign are developed, the specific dosing plans should be developed in collaboration with WHO.

Licensed Killed OCV Available Through the Global Stockpile

- Shanchol (Shantha Biotechnics, India): licensed in India in 2009, prequalified by WHO in 2011, contains killed whole cells of *V. cholerae* serogroups O1 and O139.

- Euvichol (EuBiologics Co., Ltd, Korea): licensed in Korea in 2015, prequalified by WHO in 2015, contains killed whole cells of *V. cholerae* serogroups O1 and O139.

Source: International Vaccine Institute

Source: Eubiologics Pharmaceuticals

Other Licensed Killed OCV

- Dukoral (Crucell, Netherlands): first licensed in 1991, prequalified by WHO in 2001, contains killed whole cells of *V. cholerae* serogroup 01 and recombinant B-subunit of cholera toxin.

- mORC-Vax (Vabiotech, Vietnam): available only in Vietnam, contains killed whole cells of *V. cholerae* serogroups O1 and O139.

- Vaxchora (PaxVax, USA): Vaxchora contains attenuated live oral vaccine and can be used as a single dose. It is licensed in the USA for use in travelers and is not WHO prequalified. Its public health utility for use in developing countries is not established.

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] or Dukoral[2] 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 outweigh any potential risk for women at risk of cholera, and that OCV campaigns should provide the vaccine to 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 better 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.[3]

Some specific recommendations include the following:

Endemic areas: *"OCV should be used in conjunction with other prevention and control strategies…and should be considered in areas at risk for outbreaks…Where resources are limited, immunization should be targeted at high-risk children aged ≥1 year."*

Outbreaks: *"Pre-emptive vaccination should be considered by local health authorities to help prevent potential outbreaks or the spread of current outbreaks to new areas…[During large and prolonged outbreaks] reactive vaccination could be considered by local health authorities as an additional control measure…Pre-emptive or reactive vaccination should cover as many people as possible who are eligible to receive the vaccine."*

OCV Stockpile

In 2013, WHO initiated a stockpile of OCV so that it could be made available quickly when needed. Guidance on obtaining OCV is available on the WHO website.[4] 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.

[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): e0004274.

[2] 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): e1743.

[3] World Health Organization. Cholera vaccines: WHO position paper. Weekly Epidemiological Record 2010; 85:117-128.

[4] World Health Organization. Oral Cholera Vaccine Stockpile. http://www.who.int/cholera/vaccines/ocv_stockpile_2013/en/ index.html.

Basic information for Shanchol and Euvichol	
Composition	Killed whole cells of *V. cholerae* serogroups O1 and O139
Presentation	Single dose vials containing 1.5 ml of liquid vaccine
Cold chain requirement	2 - 8°C during transport and storage. Can be taken out of cold chain on the day it is administered.
Recommended age	≥1 year old
Recommended dosage	2 doses, 2 weeks apart for all age groups[a]
Buffer requirement	None
Efficacy[b]	85% after 6 months for those >12 months of age;[5] 65% after 5 years for >5 year olds; 43% after 5 years for 1–5 year olds[6]
Duration of protection[b]	At least 5 years
Cost[c]	$1.85/dose

a. Two week interval between doses is recommended, but the interval can be longer if logistically necessary. In some circumstances a single dose is recommended. One should consult WHO to prepare plans for specific circumstances.
b. Efficacy rates are from double-blind placebo-controlled trials.
c. Cost listed is the cost for purchase through the UN system. Cost of OCV in the private market varies.

Further Information

Please visit our website (www.stopcholera.org) and follow us on Twitter @stopcholera. You may also contact the Delivering Oral Cholera Vaccine Effectively (DOVE) Project directly at Info@stopcholera.org.

[5] Luquero, Francisco J., et al. "Use of Vibrio cholerae vaccine in an outbreak in Guinea." New England Journal of Medicine 370.22 (2014): 2111-2120.

[6] Bhattacharya, Sujit K., et al. "5 year efficacy of a bivalent killed whole-cell oral cholera vaccine in Kolkata, India: a cluster-randomised, double-blind, placebo-controlled trial." The Lancet infectious diseases 13.12 (2013): 1050-1056.