PAHO Position on Cholera Vaccination in Haiti
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Currently, PAHO does not recommend use of cholera vaccination in Haiti as an emergency response, but recognizes that as conditions change, the use of this vaccine may be advisable in the future. This document provides the basis for this position.

At the current stage of the cholera outbreak in Haiti, all efforts need to be directed at minimizing the number of cases and deaths. PAHO considers the prime objectives to provide adequate and timely treatment to affected persons, to improve water and sanitation, and to mobilize communities. The emphasis of preventive strategies is on ensuring clean water, promoting good personal hygiene, and food handling practices, including hand washing and avoiding defecation in open areas.

Whether in endemic or epidemic settings, vaccination is also a potential preventive strategy. The Strategic Advisory Group of Experts on Immunization of the World Health Organization (WHO) thoroughly reviewed in October of 2009 the new evidence on cholera vaccines and their use [1]. This review lead to update WHO’s position paper on cholera vaccines [2], replacing an earlier paper that dated back to 2001. In addition to providing background information on available cholera vaccines, the position paper discusses the use of cholera vaccines in endemic situation and during outbreaks. In the latter situation, distinction between pre-emptive and reactive vaccination is made.

Cholera vaccines exist in two formulations, one delivered via an injection and another orally [2]. WHO advises against the use of injectable vaccines because of their limited efficacy and short duration of protection. Two oral cholera vaccines are currently available globally. The first oral vaccine — product name Dukoral — has been prequalified by WHO for its acquisition though UN purchase mechanisms, such as

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1 WHO position papers on vaccines are concerned primarily with the use of vaccines in large-scale immunization programs; they summarize essential background information on diseases and http://www.who.int/cholera/choleratravelandtradeadvice161107.pdf vaccines, and conclude with the Organization’s current position on the use of vaccines in the global context.
PAHO Revolving Fund [3]. A limited number of doses may become available for use during the next months. Dukoral needs to be stored and transported under refrigeration. The estimated per-dose requirement of cold chain capacity may be as many as 30 times that of a measles-rubella vaccine. To avoid inactivation by gastric acid, the vaccine needs to be diluted in a buffer that requires availability of drinking water for its preparation. Dukoral is not licensed for children aged <2 years. Primary immunization with Dukoral in persons aged ≥6 years consists of two doses given at least one week apart (but <6 weeks apart, otherwise primary immunization needs to be restarted); in children aged 2–5 years, three doses are required.

Protection may be expected approximately one week after delivery of the last scheduled dose. Protective efficacy for fully-immunized people was generally found to be >80%; results on protection achieved with a single dose vary. A prelicensure efficacy trial was conducted in 1985 in Bangladesh; 89,596 children and adolescents aged 2–15 years and women aged ≥15 years received at least one dose and 62,285 three doses [4, 5]. This trial found that, at 4–6 months following immunization, the protective efficacy against El Tor and classical cholera combined was 85% for persons aged ≥2 years (95% confidence interval [CI]: 56–95%) [4]. Protective efficacy dropped over time more sensibly among young children than older children and adults [5]. The follow-up over three years also showed that administration of only one dose seemed to confer little protection against cholera. A similar trial was realized in 1994 among Peruvian military personnel aged 16–45 years [6]. Among 1,426 persons who received the two prescribed doses, vaccination conferred 86% protection against El Tor cholera during the first 4–5 months after vaccination. The authors observed that, if the second dose could be administered at least two weeks before an outbreak began, the vaccine could provide significant protection. Finally, an observational study realized in 2004 in Beira, Mozambique, a city where cholera is endemic and there is a high prevalence of HIV, found 84% vaccine effectiveness at 1–6 months after vaccination (95% CI: 43–95%; per-protocol analysis) among people who received two doses [7]. Effectiveness among those who received either one or two doses resulted somewhat lower 78% (95% CI: 39–92%) — higher among children aged 2–4 years (82%) than among persons aged ≥5 years (67%).
However, most vaccinated persons did receive two doses. All cholera cases in this study were related to an El Tor infection.

The second oral vaccine — product name Shanchol — is undergoing review for prequalification by WHO. It is administered in two doses 14 days apart for persons aged >1 year; it does not require dilution in a buffer. In a study conducted in more than 65,000 persons of an endemic region of India, Shanchol showed 67% efficacy against cholera (99% lower boundary confidence limit [LBCL]: 35%) [8]. Efficacy in children aged 1–5 years was 49% (99% LBCL: 6%), but dropped to 40% (99% LBCL: 6%) when only one dose was administered or doses were incompletely ingested. Both oral cholera vaccines are safe.

WHO considers that cholera control should be a priority in areas where the disease is endemic. In conjunction with other prevention and control strategies, immunization with oral cholera vaccines is indicated in those areas. However, vaccination of entire population is not warranted and vaccination should rather be targeted at high-risk areas and population groups (i.e, preschool-aged and school-aged children; as far as not contraindicated, pregnant women and HIV-infected individuals). Periodic mass vaccination campaigns are viewed as a practical option for delivering oral cholera vaccines in endemic settings. A demonstration project of such mass vaccination was carried out during 2003–2004 in the city of Beira, Mozambique, where the disease is endemic with a marked seasonal pattern [9]. Vaccination was performed the month prior the usual appearance of cholera cases and targeted a densely populated neighborhood with roughly 22,000 inhabitants (out of a total city population of 450,000 distributed in 22 neighborhoods). It resulted in 54% coverage with two doses. The rather low coverage was attributed to the need to offer vaccination to persons from other areas of Beira which eventually hampered the access of people from the targeted neighborhood. The campaign required thorough planning and preparation as well as considerable logistical

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2 The suggested definition for endemic cholera is “the occurrence of fecal culture-confirmed cholera diarrhea in a population in at least 3 of the past 5 years.”
support; its cost was relatively high (roughly US$ 2 per fully-immunized individual without vaccine costs).

Use of oral cholera vaccines related to outbreak control needs to be differentiated between pre-emptive and reactive vaccination. Pre-emptive vaccination is a vaccination that is carried out in yet unaffected areas but that are at an imminent risk of being affected; reactive vaccination is a vaccination that is carried out in affected areas (i.e., area where persons are being infected). Vaccination should not disrupt the provision of other high priority health interventions to prevent or control an ongoing cholera outbreak.

After emphasizing that the basis of cholera outbreak control is to provide adequate and timely treatment to affected persons, to improve water and sanitation, and to mobilize communities, WHO position paper on cholera vaccines states that pre-emptive vaccination should be considered to help prevent potential outbreaks or the spread of current outbreaks to new areas. As opposed to vaccination in cholera-endemic areas where targeting high-risk groups is recommended, pre-emptive vaccination should cover as many people as possible in a selected area and should be completed quickly.

A WHO expert consultation reviewed in 2005 the use of oral cholera vaccines in complex emergencies [10]. It was concluded that, once an outbreak of cholera has begun, a reactive vaccination campaign with a two-dose vaccine is almost impossible essentially due to logistical and operational issues. Among the recommendations of this consultation, three exclusion criteria for use of oral cholera vaccines in emergencies were spelled out explicitly: vaccination with two-dose vaccines once a cholera outbreak has started; interference of vaccination campaign with other critical public health interventions; and a series of collateral circumstances (very high mortality from a range of causes, basic unmet needs, and untenable security situation). Overall, evidence on the feasibility and impact of vaccination in halting ongoing outbreaks is lacking [2]. Post-disaster cholera vaccination in absence of active transmission were carried out after the

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3 Strictly speaking, vaccination in a cholera-endemic area with marked seasonal pattern before the annual upsurge in cases, such as one mentioned-above in Beira, Mozambique, could also be viewed as pre-emptive.
2004 tsunami in the Indonesian province of Aceh (69% of 78,870 persons targeted received two doses) and in 2004 in two camps for internally-displaced people of Darfur, Sudan (87% of 53,537 persons) [11]. In spite of two very different settings and outcomes, both experiences illustrate the complexity related to the feasibility and relevance of cholera vaccination during complex emergencies. With regard to mass cholera vaccination, Haiti would clearly represent the double challenge of an active outbreak occurring in a post-disaster setting — an unprecedented situation in recent decades.

PAHO does not recommend vaccination of health care workers. First, person-to-person transmission, including in hospitals and health care facilities, is extremely rare. Second, basic personal hygienic measures, such as hand washing, are very effective in preventing transmission. Adding vaccination would have questionable benefits and could actually lead to a false sense of security. This recommendation also applies to all other service workers.

Travelers to Haiti should be informed on the potential risks of cholera, symptoms, precautions to avoid the disease, and when and where to report cases either during their stay in Haiti or upon their return to their countries [13]. PAHO does not recommend vaccination of its own staff traveling to Haiti, visiting expert consultants, or its staff already working on the ground.

References


3. World Health Organization (2010). WHO prequalified vaccines. Available online at: 


