

## Development of a Cholera Vaccination Policy on the Island of Hispaniola, 2010–2013

Andrea S. Vicari,\* Cuauhtémoc Ruiz-Matus, Ciro de Quadros, and Jon K. Andrus

Comprehensive Family Immunization Unit, Pan American Health Organization, Washington, District of Columbia; Sabin Vaccine Institute, Washington, District of Columbia; Deputy Director Office, Pan American Health Organization, Washington, District of Columbia

**Abstract.** Deployment of oral cholera vaccine (OCV) on the Island of Hispaniola has been considered since the emergence of the disease in October of 2010. At that time, emergency response focused on the time-tested measures of treatment to prevent deaths and sanitation to diminish transmission. Use of the limited amount of vaccine available in the global market was recommended for demonstration activities, which were carried out in 2012. As transmission continues, vaccination was recommended in Haiti as one component of a comprehensive initiative supported by an international coalition to eliminate cholera on the Island of Hispaniola. Leveraging its delivery to strengthen other cholera prevention measures and immunization services, a phased OCV introduction is pursued in accordance with global vaccine supply. Not mutually exclusive or sequential deployment options include routine immunization for children over the age of 1 year and campaigns in vulnerable metropolitan areas or rural areas with limited access to health services.

### BACKGROUND

Cholera emerged on the Island of Hispaniola in October of 2010. During the first peak of the outbreak, which lasted from October of 2010 to March of 2011, 526,351 and 22,344 suspect and confirmed cases were reported in Haiti and the Dominican Republic, respectively.<sup>1</sup> Cholera transmission has continued thereafter, although at much decreased rates. Cholera surveillance data for the first 2 years of the Haitian outbreak have been reviewed.<sup>2</sup>

Since October of 2010, the Ministries of Health of Haiti and the Dominican Republic, the Pan American Health Organization (PAHO; the regional office for the Americas of the World Health Organization [WHO]), and partners have repeatedly considered the deployment of oral cholera vaccine (OCV) along with other prevention and control measures. At PAHO, the deliberations of the Technical Advisory Group on Vaccine-Preventable Diseases (TAG)—a group of public health experts that has advised the organization on national and regional immunization policies since 1983—provided the formal platform for the development of a regional policy on cholera vaccination. Before the emergence of cholera in Haiti, there had been no need for TAG to review the use of cholera vaccines. At the global level, the WHO Strategic Advisory Group of Experts on Vaccines and Immunization discussed the evidence on cholera vaccination and made recommendations in October of 2009.<sup>3</sup>

In the process of developing a regional policy, four elements have played a central role: the characteristics and availability of OCV offered globally, the progression of the cholera outbreak, the progressive recovery of the institutional capacities of the Haitian Government after the 2010 earthquake, and the creation of a regional partnership for the elimination of cholera transmission on the Island of Hispaniola. We review here how these elements evolved over time and their relation to the policymaking for the Island of Hispaniola.

**OCV characteristics and availability.** Two OCVs, trade names Dukoral (Crucell, Stockholm, Sweden) and Shanchol (Shanta Biotechnics, Hyderabad, India), are marketed glob-

ally. Both are whole-cell, inactivated vaccines that require at least two doses in a primary immunization series. However, they differ in indication, formulation, and presentation (Table 1).<sup>4</sup> Compared with Dukoral, Shanchol offers operational advantages: it does not require administration with a buffer solution, it requires significantly less cold chain volume, it can be administered from 1 year of age (versus 2 years of age), and its price is one-third per dose the price of Dukoral. The field implications of these characteristics were documented in several mass vaccination campaigns carried out after emergencies and/or cholera outbreaks.<sup>4</sup>

As of October of 2010, only Dukoral had been pre-qualified by the WHO. Shanchol was first pre-qualified in September of 2011. Pre-qualification is a systematic procedure by which the WHO independently evaluates the evidence on the safety and efficacy of vaccines and inspects their manufacturing facilities and processes.<sup>5</sup> Reevaluations at periodic intervals assure the sustained quality of the vaccines. The relevance of this procedure is that agencies and programs of the United Nations System can only purchase and deploy WHO-prequalified vaccines.

Results of the Shanchol clinical trial conducted in Kolkata, India, show a 66% overall efficacy after 3 years of follow-up.<sup>6</sup> This trial is a cluster-randomized study, which includes 66,900 individuals (31,932 individuals received the vaccine, and 34,968 individuals received a placebo); its primary end point is culture-confirmed *Vibrio cholerae* O1 diarrheal episodes that required treatment. To our knowledge, this trial is the main large-scale evaluation of Shanchol efficacy.

Effectiveness of OCVs may be greater than their efficacy because of herd protection.<sup>7</sup> Incidence rates of cholera among placebo recipients in a clinical trial of Dukoral's predecessor vaccine were inversely related to the levels of vaccine coverage achieved in their neighbors (7.01 cases per 1,000 in neighbors with < 28% coverage versus 1.47 cases per 1,000 in neighbors with coverage > 51%; *P* for trend = 0.0001).<sup>8</sup> A similar result occurred in an observational cohort study conducted with Dukoral in Zanzibar, East Africa (2.93 cases per 1,000 unvaccinated residents in neighbors with < 40% coverage versus 0.73 cases per 1,000 unvaccinated residents in neighbors with > 54% coverage; *P* for trend = 0.014).<sup>9</sup> At the clinical trial site of Shanchol in Kolkata, indirect protection was observed in analyses using a geospatial approach but not a cluster design approach.<sup>10</sup>

\*Address correspondence to Andrea S. Vicari, Comprehensive Family Immunization Unit, Pan American Health Organization, 525 23rd Street NW, Washington, DC 20037. E-mail: vicarian@paho.org

TABLE 1  
Characteristics of the WHO pre-qualified OCVs

Characteristics	Dukoral	Shanchol
WHO prequalification	Yes (October of 2001)	Yes (September of 2011)
Licensed ages	≥ 2 years	≥ 1 year
Number of doses for primary immunization	Age 2–5 years: three doses; age ≥ 6 years: two doses	Two doses
Interval between doses	≥ 7 days (but < 6 weeks)	≥ 14 days
Booster	Age 2–5 years: after 6 months; age ≥ 6 years: after 2 years	After 2 years
Administration	Oral with bicarbonate buffer (75 mL for ages 2–5 years; 150 mL for ages ≥ 6 years)	Oral
Food and water restrictions	No food or water 1 hour before and after vaccine ingestion	No restriction
Packaging	3-mL single-dose vial and effervescent granules in sachet	1.5-mL single-dose vial
Storage temperature	Storage at 2–8 °C	Storage at 2–8 °C
Packed volume per dose (centimeter <sup>3</sup> )	136	17
Price per dose (US dollars)	4.75	1.85

OCV availability remains a significant constraint to planning the scope and timeline of its deployment. When cholera broke out in Haiti, only 250,000–300,000 Dukoral doses were available; no recent data on this vaccine's availability are public. Shanchol's manufacturer indicated in October of 2012 the immediate availability of up to 600,000 doses and the capacity to scale up the production to 2–4 million doses in 2013 and 10–20 million doses in 2014 and thereafter, provided that there is demand. Nonetheless, this availability is not exclusively reserved for deployment on the Island of Hispaniola. In fact, WHO and partners are working to the launch of a 2-million-dose global OCV stockpile in the second half of 2013.<sup>11</sup>

Data on the population at risk on the Island of Hispaniola are also an important consideration to put the global OCV availability into perspective. In 2013, 20.6 million people live on the Island of Hispaniola and are equally split into 10.3 million people in each country<sup>12</sup>; 1.2 million children age ≤ 4 years live in Haiti, and 1.0 million children age ≤ 4 years live in the Dominican Republic. Population density is high in both countries (371 persons per km<sup>2</sup> in Haiti and 241 persons per km<sup>2</sup> in the Dominican Republic), and urbanization pace is accelerated, with 59.5% of the Haitian population living in urban settings (24.3% in the metropolitan area of Port-au-Prince) and 71.1% of the Dominican population living in urban settings (33.0% in the metropolitan area of Santo Domingo). In Haiti in 2010, an estimated 31% of the population got water from unimproved sources and surfaces (15% and 49% for the urban and rural areas, respectively), and 68% of the population used unimproved sanitation facilities or open defecation (52% and 84% in rural and urban areas, respectively).<sup>13,14</sup> The situation was better in the Dominican Republic, with 14% of the population getting water from unimproved sources (13% and 16% in urban and rural areas, respectively; 0% from surfaces) and 6% of the population using unimproved sanitation facilities and open defecation (3% and 12% in rural and urban areas, respectively).<sup>15,16</sup> In comparison, 6% of the whole Latin American and Caribbean population got water from unimproved sources, and 13% of the total population used unimproved sanitation facilities and open defecation.<sup>17</sup> Overall, these data show that water and sanitation insecurity is widely present in both urban and rural areas, particularly in Haiti, and affects millions of people. Given a limited vaccine supply, those risk factors alone are of little aid in prioritizing populations and areas for vaccination.

People living in camps that arose after the January of 2010 earthquake could represent a geographically identifiable pop-

ulation at greater cholera risk. As of March of 2013, an estimated 320,051 persons lived in 385 camps.<sup>18</sup> Although 74% of these internally displaced people received drinking water in March of 2011, only 9% did in March of 2013. In contrast, provision of sanitation remained stable (toilet provision coverage of 82% and 88%, respectively).

**Progression of the cholera outbreak and inference on the population susceptibility profile.** A key consideration for optimizing OCV deployment on the Island of Hispaniola is the analysis of the epidemiologic data to assess the immunological susceptibility profile of the population. Preferably, vaccination should be directed at populations that are immunologically more susceptible. Before the emergence in October of 2010, cholera had not been reported for several decades in both Haiti and the Dominican Republic (not even during the epidemic that affected 14 countries and caused a reported 1.3 million cases in South and Central America between 1992 and 1999).<sup>19</sup> In October of 2010, the population of the Island of Hispaniola was immunologically naive and fully susceptible to a *V. cholerae* infection, a situation that must have contributed greatly to the explosive nature of the cholera outbreak in Haiti. By September of 2012, the 2-year cumulative attack rate was 6% nationally and ranged from approximately 2% to 9% for the 10 departments.<sup>2</sup> Compared with the 12-month period between October of 2010 and September of 2011, attack rates were substantially lower in the 12-month period from October of 2011 to September of 2012. A seroepidemiologic survey carried out in the Artibonite River delta during March and April of 2011 (after cholera transmission had already subsided in the area) shows 2.5 unapparent cholera infections per each reported clinical cholera case.<sup>20</sup> From the cumulative attack rates reported for the two subsequent 12-month periods and the fraction of unapparent to apparent infections, it can be inferred that, in some areas, large strata of the population got infected and that the majority of people actually got infected in the first months of the outbreak. Models predict that the immunity elicited by a natural El Tor infection remains unabated for the first 3 years after the infection.<sup>21</sup>

As of 2013, cholera remains a significant public health problem on the Island of Hispaniola. Between September 30, 2012 and March 23, 2013, 53,466 suspect and confirmed cases and 440 cholera-related deaths (case-fatality ratio [CFR] = 0.82% [calculated as 440 deaths per 53,466 cases × 100]) were reported in Haiti and 1,978 cases and 26 deaths (CFR = 1.31%) were reported in the Dominican Republic.<sup>1</sup> Attack rates were undoubtedly lower than during the first 6 months of the outbreak. This situation likely reflects a profile of

greater immunity in the population, but whether and how long the immunity will last is difficult to anticipate. Models forecast an increase in incidence when immunity from the first epidemic wave wanes.<sup>22</sup> Although it is complex to infer areas for prioritization based on attack rates, those communities that had the highest cumulative attack rates in the previous year should not be prioritized for vaccination.

**Recovery of the institutional capacities.** In addition to causing large numbers of deaths and injuries, the January of 2010 earthquake that had its epicenter near the capital city of Port-au-Prince had an immediate debilitating effect of Haitian institutions. Directly, the earthquake affected authorities, officials, and health personnel; indirectly, it destroyed the place of work for many of them. In the aftermath, the needs for the recovery exacted an additional toll. Against this backdrop, the fulminant emergence of cholera strained additional institutional capacities. A circumstance that added complexity was that national elections were due in March of 2011, casting the potential of social unrest in the months leading up to the ballot. From the onset, the Haitian Government that took office in mid-2011 inherited huge challenges.

**Creation of a regional coalition for the elimination of cholera transmission on the Island of Hispaniola.** In January of 2012, the presidents of Haiti and the Dominican Republic, together with representatives of the PAHO/WHO, United Nations Children's Fund (UNICEF), and the US Centers for Disease Control and Prevention (CDC), issued a call to action to eliminate cholera transmission from both countries through new investments in infrastructures for clean water and sanitation. This call led, in June of 2012, to the creation of the Regional Coalition on Water and Sanitation for the Elimination of Cholera Transmission on the Island of Hispaniola; the goal was to bring together the necessary technical expertise, raise new funds, and mobilize previously committed pledges.<sup>23</sup> As of April of 2013, the Coalition has expanded to include 18 signatory partners, and it presents a unique opportunity to reach out more extensively to the private sector and non-governmental organizations.

During 2012, the Haitian Government started the consultation for and redaction of a National Plan for the Elimination of Cholera covering the 10-year period from 2013 to 2022.<sup>24</sup> This plan was officially presented on February 27, 2013, and it outlines a comprehensive set of actions for cholera prevention and control, included the deployment of OCVs.

**Chronology of the development of a cholera vaccination policy for the Island of Hispaniola.** Deployment of OCV has been considered since October of 2010. In the first days and weeks of the outbreak, considering the rapidly spreading epidemic and the limited vaccine supplies, the PAHO recommended focusing emergency efforts on time-tested measures for cholera outbreak response, namely treatment to prevent deaths and traditional preventative actions to halt transmission (i.e., delivery of safe, potable water, provision of supplies for handwashing and other hygienic measures, sanitation, and proper waste disposal). In mid-December of 2010, the PAHO convened an expert consultation. Experts recommended to use the limited vaccine supply on the global market at the time (250,000–300,000 doses) for demonstration projects and initiate efforts to increase OCV availability.

Accordingly, the non-governmental organizations Haitian Group for the Study of Kaposi's Sarcoma and Opportunistic Infections (GHESKIO) and Zanmi Lasante/Partners in Health

conducted two separate but coordinated cholera vaccination campaigns between April and June of 2012 in one urban and one rural area of Haiti, respectively.<sup>25,26</sup> Overall, 97,725 persons received at least one vaccine dose, and completion rate for the two-dose immunization series was 91%. Key experiences from these demonstration projects were community acceptance of cholera vaccination and feasibility of administering the vaccine on a large scale in both rural and urban settings. The demonstration underscored the need for substantial planning before vaccination, a reliable cold chain and other logistic resources, ongoing monitoring of the vaccination, and communication activities involving the community, opinion leaders, and the media. Concurrently to those projects, OCVs were being deployed in April and May of 2012 in the Boffa region of Guinea Conakry, where over 170,000 persons were pre-emptively vaccinated in an area experiencing a cholera outbreak.<sup>27</sup>

In August and October of 2012, TAG formally reviewed for the second and third times the matter of cholera vaccination on the Island of Hispaniola. The recommendations made in October of 2012 remain the main guidance for the region as of August of 2013.<sup>28</sup> OCV deployment in Haiti represents the opportunity to complement and strengthen other cholera measures as well as the national immunization program. In particular, OCVs should be leveraging delivery to strengthen the provision of other cholera prevention measures (i.e., social mobilization and active case finding) and national immunization services. To reach this objective, incremental advances are needed in integrating OCV use with Water, Sanitation, and Hygiene (WASH) development plans, assuring sufficient OCV availability and financial sustainability of its purchase and delivery, and developing operational and monitoring immunization capacities. These advances need to build national and local capacity of immunization programs and the health system as a whole.

TAG also anticipated that the timeframe during which vaccination is needed depends on the actual advances in access to potable water and provision of sanitation as well as the evolution of natural and vaccine-induced immunities at population level. Contingent on firm orders, global OCV production capacity could be scaled up to 2–4 million doses in 2013 and 10–20 million doses in 2014 and thereafter. Therefore, experts agreed that a phased introduction based on the global supply will need to be followed in Haiti.

Four options for OCV deployment that are not necessarily mutually exclusive and sequential were spelled out (Table 2). First, OCV could be introduced as part of the routine national schedule for children age 1 year and older linked to the delivery of the first dose of a combined measles-rubella vaccine. Second, supplemental immunization activities (SIAs) could be carried out in the metropolitan area, targeting internally displaced persons residing in camps (i.e., a group with low immunity likely transitioning to higher-risk circumstances). Third, SIA could target larger populations residing in shanty towns (i.e., a group with current moderate to high immunity but ongoing high-risk circumstances). Fourth, SIA could be carried out in rural areas, targeting the population that has difficult access to healthcare facilities. Because vaccination in rural areas could encompass up to 4.2 million persons, prioritization would be necessary and should be based on geospatial analyses of a defined set of criteria defined *a priori*.

As mentioned above, the Haitian Government presented the National Plan for the Elimination of Cholera in Haiti in

TABLE 2  
Options for deployment of OCVs in Haiti

Option	Population group	Strategy	Estimate of population size
1. Routine vaccination of children age > 1 year	Children > 1 year	Routine (part of the national immunization schedule)	250,000 per year
2. SIA in camps for internally displaced persons	In principle, all ages	Campaigns to be repeated every 3 (5) years in metropolitan setting	320,000 (March of 2013)
3. SIA in shanty towns	Same	Same	Uncertain (up to 800,000)
4. SIA in rural areas without access to healthcare	Same	Campaigns to be repeated every 3 (5) years in rural setting	Uncertain (up to 4.2 million)

February of 2013.<sup>24</sup> This plan outlined a comprehensive set of actions for cholera prevention and control, including the OCV deployment, detailed for three consecutive periods of 2013–2022. Overall, the October of 2012 TAG recommendations on OCV use are adopted. During the period 2013–2015, the plan foresees the implementation of a cholera vaccination campaign in certain densely populated agglomerations in urban areas and certain remote rural communities that are difficult to access. Epidemiological analysis defines the target areas. On the medium and long terms, OCV may continue to be deployed, leveraging its distribution to strengthening the provision of other cholera prevention measures (such as social mobilization and active case search) and national immunization services.

As of August of 2013, the Haitian Ministry of Health is vaccinating 80,000 eligible people living in two municipalities of two different departments. In the target areas, everyone was eligible for vaccination, except for children age < 1 year and pregnant women. Later in 2013 and early in 2014, the Ministry plans on vaccinating an additional 520,000 people living in still undefined sites.

## DISCUSSION

The experience on the development of a policy on cholera immunization for the Island of Hispaniola offers several considerations and lessons that are not limited to OCV and the specific region. Rather, they highlight challenges that should be common to neglected diseases affecting countries with intrinsic vulnerabilities.

**Iterative process in the development of a vaccination policy during an outbreak.** The policy development of a vaccine addressing an outbreak involves a periodic reevaluation. This iterative process is necessary, because competing needs related to the emergency response or ongoing health programs exist; also, the epidemiological situation is bound to change. Over the time, four main elements have warranted a reconsideration of OCV deployment on the Island of Hispaniola. First, cholera transmission is ongoing 3 years after the outbreak began. Second, a second OCV (Shanchol) that eased some operational challenges was pre-qualified by the WHO in September of 2011. Third, prospects for OCV availability over the next 3–5 years have become clearer. Fourth, vaccination initiatives carried out in April and June of 2012 in urban and rural areas of Haiti showed that, although substantial planning and logistic resources were required, OCV deployment is feasible on the Island of Hispaniola.

**Vaccination as one component of the elimination plan.** Elimination of cholera transmission can be defined as cholera no longer being a public health burden. Although this goal might seem excessively ambitious, countries in South and Central America achieved elimination of transmission during

the epidemics of the 1990s through important investments in infrastructures for the provision of clean water and sanitation.<sup>29</sup> If those infrastructures are adequate, *Vibrio* species can be present in the environment without causing disease. Elimination of cholera transmission on the Island of Hispaniola could similarly be achieved in the long run through considerable investments to sustainably reach a significant fraction of households. This goal will require the mobilization of billions of dollars and take years to accomplish.

To bridge that long-term vision, several short-term actions also need to be considered, including the expanded use of OCV. However, if water and sanitation are not improved in the long run, the Island of Hispaniola will likely remain vulnerable to repeated outbreaks, even with a large-scale cholera vaccination program in place. OCV deployment cannot distract from the long-term investments. Regardless of the time and eventual scope of a cholera vaccination program, additional resources and funds will be needed for the vaccination program to be successful. Without ongoing attention to strengthening water, sanitation, and hygiene, OCV deployment will not prevent long-term risk of disease outbreaks and resurgence.

**Sufficient vaccine availability.** The amount of available vaccine determines the spectrum of deployment options that can be considered. Below a certain amount, authorities will see little or no benefit or even risks to a vaccine deployment. The then Haitian Government considered that the 250,000–300,000 doses of OCV available in October of 2010 were insufficient to allow an orderly deployment in a setting that was already at risk of social unrest because of an imminent national election.

In the second half of 2013, the WHO and partners are launching a 2 million global OCV stockpile, making it the third vaccine for which such a global mechanism is available to the countries.<sup>11</sup> The two existing global stockpiles are for the yellow fever and meningococcal vaccines. OCV doses going to the stockpile could break the impasse between demand and production and provide a needed momentum for increased production. However, a significant fraction of the 2013 production may be for the establishment of this stockpile and likely be directed at use in new outbreaks. Relying on demand for outbreak use may also not lead to a regular and sufficient production of vaccine, because demand would remain unpredictable. As opposed to pre-emptive or reactive use in outbreaks, routine vaccination is more likely to provide a predictable and sustained demand.

**Vaccination targets.** Decision makers and other public health professionals instinctively prioritize vaccination to areas that recently had the highest cholera attack rates. These areas certainly reflect the presence of exposure risk factors. However, a large fraction of the population in those areas (80% or higher in some municipalities) would have had a recent infection and is, in principle, immune to cholera for

several months. An arguably better use of the vaccine is then to target areas that have not been affected yet or were affected > 36 months before. Access to cholera treatment centers is highly variable across 140 Haitian communes, and the level of care and travel time to facilities across departments is also variable. Care-seeking and reporting patterns among administrative areas can, thus, bias an inference from attack rates on the population susceptibility profile.

The definition of vaccination targets should also consider ethical implications.<sup>30</sup> In Haiti, water and sanitation insecurity affects millions of people residing in both urban and rural areas, and access to healthcare services is especially difficult in the central plateau. Within the integral framework of the national plan for cholera transmission elimination, three of four vaccination options proposed for Haiti are essentially directed at mitigating those vulnerability factors.

**Vaccine product profiles adequate for field use.** Vaccines that are intended to address neglected diseases, which will, by definition, occur in resource-scarce countries, must be developed with a product profile adequate for the settings of their likely use. Initially, experts voiced contrasting opinions on the value of a vaccine (Dukoral) that demands a complex administration process and delivery of two doses and that offers protection for a limited duration. The WHO pre-qualification of a second OCV (Shanchol) in September of 2011 eased some of the logistical concerns.

Although two single-dose oral vaccine candidates are in clinical development,<sup>31–33</sup> no such vaccine is currently licensed and produced. Single-dose vaccines would greatly improve the prospects of vaccination during or before a cholera outbreak, regardless of whether for pre-emptive or reactive purposes. The development of single-dose vaccines that have a product profile adequate for use in vulnerable conditions is needed.

**Knowledge gaps and research opportunities.** Some knowledge gaps on OCVs persist. Efficacy data of the current two-dose vaccines when vaccinated people only receive one dose would give insight on the necessity and importance to complete the primary immunization series. An analysis of data collected in 2009 in Zanzibar found no evidence of a harmful effect of a gestational exposure to the Dukoral vaccine.<sup>34</sup> Additional assessments of OCV use in pregnant women are needed to support safety in this population group that is at increased risk in endemic settings.<sup>3</sup> Other research priorities include occasional environmental bacteriology testing, seroepidemiologic surveys to determine which fraction of the population is already immune to cholera, assessment of the coadministration of OCV with childhood vaccines, and effectiveness studies of vaccination (including nested case-control studies).

Operational research should be an integral part of any OCV deployment, because the evidence it generates can be critical to elicit future increased support for and investment in OCV use. In Haiti, for instance, a series of activities are being considered in the communities targeted for OCV immunization during 2013: a survey of knowledge, attitudes, and practices before and after vaccination; a coverage survey; an effectiveness study; and an evaluation of operational costs. Activities fostered by the PAHO's ProVac Initiative can also be envisioned to strengthen the decision making on the future OCV use grounded in the evidence generated locally.<sup>35</sup> These activities may include the strengthening of the decision-making process (for instance, with the creation of a National Immunization Technical Advisory Group), the realization of eco-

nomical analyses with a national multidisciplinary team, and medium- and long-term planning to guarantee the logistical and financial sustainability of the OCV use.

## CONCLUSION

Limitations in current vaccines and medium-term vaccine availability suggest that OCV use alone cannot eliminate cholera transmission in Haiti. However, within the framework of a comprehensive elimination initiative, cholera vaccination can strengthen both other cholera control measures and the national immunization program. Cholera vaccination can also mitigate cholera burden over the short- and medium terms until significant and sustained advances in infrastructures for sanitation and delivery of potable water are achieved.

Incremental advances are needed in integrating OCV use with WASH development plans, assuring sufficient OCV availability and financial sustainability of its purchase and delivery, and developing operational and monitoring immunization capacities. These advances need to build national and local capacity of immunization programs and the health system as a whole.

The timeframe during which vaccination will be needed depends on the advances in access to potable water and provision of sanitation and the evolution of natural and vaccine-induced immunities at the population level. Regardless of the time and eventual scope of a cholera vaccination program, additional resources and funds will be needed for the program to be successful; without ongoing attention to strengthening water, sanitation, and hygiene, OCV use will not prevent long-term risk of disease outbreaks and resurgence.

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**Authors' addresses:** Andrea S. Vicari and Cuauhtémoc Ruiz-Matus, Comprehensive Family Immunization Unit, Pan American Health Organization, Washington, DC. E-mails: vicarian@paho.org and ruizcuau@paho.org. Ciro de Quadros, Sabin Vaccine Institute, Washington, DC. E-mail: Ciro.deQuadros@Sabin.org. Jon K. Andrus, Deputy Director Office, Pan American Health Organization, Washington, DC. E-mail: andrusjo@paho.org.

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