

Examining the feasibility of a vaccination campaign is critical for making decisions about whether or not to use OCV in a particular situation. Conducting a feasibility assessment can avoid wasting time and resources if vaccination is not feasible. On the other hand, if the assessment shows that a vaccination program is feasible, it can provide reassurance and increase the commitment of health authorities, funders and campaign organizers. However, perhaps most importantly, the feasibility assessment provides an opportunity to identify potential problems and possible solutions in the planning and implementation of the vaccine program. The assessment should result in a clear decision on whether or not to move forward with the vaccination plan, and an awareness of the aspects of implementation that may be more challenging.

The following factors should be carefully evaluated when conducting a feasibility assessment:

A. Vaccine availability: An initial step in assessing the feasibility of an OCV campaign is to calculate the number of vaccine doses required. For this, it is necessary to determine which populations, age groups, and geographical areas to target for vaccination. This also includes identifying specific groups that might be excluded. Once the required number of vaccine doses is determined, availability of the vaccine should be checked with the World Health Organization (e.g., for use of the global cholera vaccine stockpile) and/or with the vaccine manufacturer. This is a critical step given that the available global supply of OCV is currently limited.

B. Importation regulations: Another crucial step is obtaining clearance for importation of the vaccine in the country. This may require registration of the vaccine by the country's national regulatory authority, or if the vaccine cannot be licensed in time, a special authorization for public health use from the Ministry of Health (MOH). MOH leadership in the decision-making process is essential to complete this step.

C. Commitment of the government and other partners: Government agencies, specifically the MOH, need to be committed to the campaign, while other

Key Factors for OCV Feasibility:

- Vaccine availability
- Importation regulations
- Commitment of Partners
- Funding availability
- Competing priorities
- Cold chain capacity
- Human resources
- Transport needs
- Security concerns
- Acceptability of communities
- Timeliness

Ministries and key decision makers may also need to be supportive. Other agencies can include local and international non-government organizations and local level government authorities. Those considering an OCV campaign should therefore identify the major stakeholders and decision-makers and anticipate potential bottlenecks. Meetings with these stakeholders will be useful to inform them about the current or potential cholera situation, discuss the control options, including vaccination, elicit their views, and address their concerns.

For those agencies who will participate in the campaign, a detailed description of the roles and responsibilities of each partner should be developed to ensure joint ownership and cooperation between agencies.

D. Funding availability: Funding to pay for the vaccine and operational costs for delivery need to be identified. GAVI-eligible countries affected by cholera epidemics or humanitarian crises can apply for free supply of vaccine through the global cholera vaccine stockpile. Non-GAVI-eligible countries in an emergency situation can also access vaccine through the global stockpile, but the cost of the vaccine will need to be reimbursed once the emergency is over.

The agency organizing the campaign should secure funding to cover the vaccine campaign implementation cost, which has varied in recent vaccination campaigns from US \$0.25 to \$1 per dose.¹ This cost primarily consists of three types of expenses: 1) the local transport of vaccine, 2) human resources, and 3) maintenance of the cold chain. In addition, WHO encourages that countries conduct a minimum set of monitoring and evaluation activities (e.g., an estimation of vaccination coverage), since knowledge on the most effective and efficient use of OCV is still needed. Although lack of funding to conduct these activities should not delay vaccination, countries or implementing agencies may consider seeking outside funding for these activities. Some funds for program costs are now available to Gavi eligible countries.

E. Competing priorities: The global OCV stockpile was created to quickly provide OCV in humanitarian crises and in areas currently experiencing, or at risk of, a cholera outbreak. In both situations, decisions for the emergency response need to consider timing and resources. There may be many competing priorities such as acute problems like malnutrition or measles outbreaks that might require immediate attention during humanitarian crises, and at first glance this may appear to reduce the time and resources for OCV provision, making it seem less feasible.

However, OCV need not compete against such priorities. In cholera outbreak settings, the first priority is to ensure adequate clinical management of cases to reduce mortality and to provide safe water—both of which require considerable resources. On the other hand, OCV campaigns can reduce the cholera case burden and workload of health facilities, thereby creating synergies to control the disease during major epidemics. Integrating cholera vaccination with other preventive efforts—such as measles vaccination, vitamin A supplementation, and food distribution—should also be considered, since this will increase synergies between interventions, improve the cost-effectiveness of the overall outbreak or humanitarian response, and potentially reduce the cost of vaccination. This perspective may change the assessment of feasibility of OCV implementation in a given setting.

F. Cold chain capacity: Cholera vaccine is currently only available in single-dose vials that need to be kept

cold (between 2° to 8°C) during storage, requiring a considerable amount of cold storage volume. An estimate of the cold chain requirements—at the central, regional, district and health facility levels as well as during transport—is required to ensure feasibility of the vaccination campaign. WHO has developed a tool to assist with this assessment for cholera vaccines.² While OCV should be stored cold, Shanchol and Euvichol—the main vaccines used in cholera-affected countries today—have a vaccine vial monitor (VVM) of 14, meaning that it can be kept at 37°C for up to 14 days, because of the heat stability of the lipopolysaccharide, the main component of the vaccine. This allows some flexibility of the exposure of the vaccine to heat during vaccination. This enables the vaccine to be taken out of the cold chain during the vaccination.^{3,4} In any case, an assessment of the availability of refrigerators, freezers (for ice packs), vaccine carriers, and temperature monitoring tools is needed to assess cold storage feasibility.

G. Human resources: OCVs are safe and easy to administer, and recent campaigns have been implemented by non-medical staff such as community health workers.⁵ This reduces the strains on health personnel to implement vaccination campaigns, therefore making OCV implementation more likely to be feasible. However, when assessing feasibility it is important to ensure there are enough personnel for social mobilization, communication, supervision, and coordination of the vaccine program.

H. Transport needs: OCV can be shipped to most countries in the world. However, special circumstances, such as conflicts or natural disasters, could make it challenging or even impossible to ship the vaccine to a given location. Limited transportation infrastructure within a country can also complicate the feasibility of local transport of vaccines to vaccination sites. This is especially true during rainy seasons, floods, and other natural disasters.

² http://www.who.int/entity/cholera/vaccines/Annexes_OCV_ICG_Requestv9Oct2013.xls?ua=1

³ Ciglencecki I, Sakoba K, Luquero FJ et al. Feasibility of mass vaccination campaign with oral cholera vaccines in response to an outbreak in Guinea. *PLoS Med.* 2013; 10(9):e1001512.

⁴ Luquero FJ, Grout L, Ciglencecki I et al. Use of *Vibrio cholerae* vaccine in an outbreak in Guinea. *N Engl J Med.* 2014; 370(22):2111-2120.

⁵ Kar SK, Sah B, Patnaik B et al. Mass vaccination with a new, less expensive oral cholera vaccine using public health infrastructure in India: the Odisha model. *PLoS Negl Trop Dis.* 2014; 8(2):e2629.

¹ Martin A, Lopez AL, Bellos A et al. Post-licensure deployment of oral cholera vaccines: a systematic review. *Bulletin of the World Health Organization.* 2014; 92(12):849-924.

I. Security concerns: The security situation should be considered during the planning of the campaign, especially since vaccination teams will be deployed on the ground. Areas with landmines, security check points or civil unrest, represent frequent threats in conflict situations that should be carefully evaluated.

J. Acceptability of communities: An important step in the planning of a cholera vaccination campaign is to discuss the anticipated perceptions and acceptability of the OCV campaign by members of the community with local health providers and community leaders. Vaccination procedures should be adapted as much as possible to increase the acceptability and performance of the campaign, for example, by involving representation of different ethnic groups in the vaccination campaign planning.

K. Timeliness of the campaigns: Time is of the essence when vaccinating against cholera during an epidemic or emergency. Rapid decisions and actions are required both in humanitarian crises and in outbreak situations to reduce the risk in affected populations. A delayed response during an outbreak might greatly reduce the impact of vaccination on cholera cases and deaths. If the vaccination is delayed too much, it will have little impact on the course of the outbreak.

In endemic countries, seasonal outbreaks may be predicted based on the occurrence of past years; thus, vaccination campaigns should be timed according to local cholera seasonal patterns in order to increase the impact of the vaccination program.

The following checklist can be used to ensure that an adequate feasibility evaluation has been conducted before requesting the vaccine.

Feasibility Checklist for an Oral Cholera Vaccination (OCV) Campaign			
Factor	Done (Yes/No/Not Applicable)	Problems identified	Actions to be taken
A. Vaccine availability			
Determination of the target populations, ages, and eligibility criteria (including pregnancy)			
Estimation of the number of doses required			
Availability of vaccines confirmed with WHO and/or manufacturer			
Permission to import cholera vaccine granted by the Ministry of Health (through license or special authorization)			
B. Importation regulations			
Determine if OCV is licensed in the country			
If not licensed, obtain approval for importing OCV			
C. Commitment of Partners			
Identification of key stakeholders, decision-makers, and partner institutions (MOH, EPI program, international, and local NGOs)			
Assessment of the commitment by key stakeholders and national authorities			
Assignment/description of roles and responsibility of each partner			
D. Funding availability			
Development of a detailed budget for the campaigns			
Identification of funding sources for the vaccine			
Identification of funding sources for operational costs			
E. Competing priorities			
Appropriate clinical management of cholera cases is ensured			
Evaluation of the importance of cholera vaccination in light of other public health priorities			
F. Cold chain capacity			
Estimation of the cold storage requirements at all levels of the health system, including during transport			
Availability of freezers for cold packs			
Availability of refrigerators			
Availability of vaccine carriers and ice packs			

Feasibility Checklist for an Oral Cholera Vaccination (OCV) Campaign			
Factor	Done (Yes/No/Not Applicable)	Problems identified	Actions to be taken
Availability of thermometers and temperature logs			
G. Human resources			
Availability of vaccinators			
Availability of persons/groups to conduct social mobilization/ IEC campaigns			
Availability of supervisors			
Availability of team leaders			
H. Transport needs			
Availability of international transport			
Feasibility of local transport of the vaccine to the vaccination sites			
Assessment of difficulties in accessing targeted areas during floods or other natural disasters			
I. Security concerns			
Evaluation of possible conflicts or civil unrest that can impede vaccination			
Evaluation of other security threats			
J. Acceptability of communities			
Discussion of the vaccination plans and procedures with local health officials			
Discussion of the vaccination plans and procedures with local community leaders (e.g., religious, tribal, political)			
K. Timeliness			
Feasibility of implementing the campaign before the end of the epidemic in the case of an outbreak response			
Evaluation of the best timing for vaccination considering seasonality in endemic areas			
In humanitarian emergencies, re-evaluation of whether vaccination is still a relevant and high-priority intervention, once the actual implementation dates are determined, given that conditions often change quickly in such situations			