

Conclusions of the SAGE Working Group on oral cholera vaccines and proposed recommendations

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Key Conclusions of the OCV WG

- Significant cholera burden globally including since 2010.
- Prequalified WC, killed OCVs are available for global use.
- **Vaccine Safety**: Currently available WC, killed OCVs are safe for use among individuals ≥ 1 year of age, including pregnant women.
- **Vaccine Efficacy and Effectiveness**: Available evidence indicates that a single dose is efficacious and effective for at least 6 months; a two-dose schedule is efficacious and effective for at least 3 years among adults, but not young children 1 – 5 years old; and, according to 2 studies, WC, killed OCVs are effective for at least 5 years.

Key Conclusions of the OCV WG

- **Feasibility and acceptability:** OCVs campaigns have been demonstrated to be feasible and acceptable in multiple endemic, epidemic and humanitarian emergency settings.
- **Cost-effectiveness:** Most studies and evaluations have reported costing data only, however, modeling studies suggest that cholera vaccination has the potential to be a cost-effective intervention for cholera control in countries at high risk for cholera.

General Recommendations

- **Given the current availability of pre-qualified WC killed oral cholera vaccines (OCV) and data on their safety, efficacy, field effectiveness, feasibility, impact and acceptability in cholera-affected populations, these vaccines should be used in conjunction with other cholera prevention and control strategies:**
 - in areas with endemic cholera,
 - in humanitarian crisis with high risk of cholera,
 - during cholera outbreaks.

General Recommendations

- **Vaccination should be done in synergy with other activities such as appropriate case management, WaSH interventions, surveillance and community mobilization, which remain cornerstones for cholera control.**
- **Mass vaccination campaigns are usually the most practical option for delivering OCV. Schools, religious institutions and other community settings can be appropriate venues for vaccination campaigns using fixed sites.**
 - **Campaigns should be accompanied by WaSH interventions.**

General Recommendations

- **Epidemiological and laboratory surveillance is essential to estimate the burden of disease and understand the impact of vaccination and other interventions.**
- **A stockpile has been in operation since 2013 to ensure that underserved populations have equitable access to OCVs for use in both emergency response and endemic settings.**
- **Requests to access OCV in any setting should follow the established mechanisms for stockpile management.**

General Recommendations

In all settings the decision to vaccinate should consider:

- The risk of cholera among targeted populations.
- The susceptibility and vulnerability of the population and the risk of spatial extension.
- Programmatic factors such as the local capacity to organize and conduct a campaign, ability to provide other priority health interventions and population acceptability.
- Cholera vaccination should generally not be conducted if an OCV campaign has been conducted in the previous 3 years in the same population

General Recommendations

Countries and agencies accessing the OCV stockpiles need to implement Monitoring and Evaluation (M&E) to measure:

- The impact of OCV to control and prevent cholera outbreaks.
- The impact of OCV on cholera transmission in endemic settings and during humanitarian situations.
- The vaccine effectiveness using different vaccination strategies and in different age groups.
- The cost effectiveness of different vaccination strategies and in various settings and age groups.

General Recommendations

- **Pregnant women should be included in OCV vaccination campaigns.**
- **OCV should be considered for emergency / relief workers who are likely to be directly exposed to cholera patients or to contaminated food or water.**
- **Vaccination is generally not recommended for long- or short-term travelers to cholera-affected countries.**

Control of endemic cholera

- **Cholera vaccination should be targeted in priority to high-risk areas or groups, regularly affected by cholera; with culture-confirmed cases detected in at least three out of the last five years and evidence of local transmission.**
- **Cholera vaccination in endemic areas should be contingent on multisectoral interventions as part of a long term plan for cholera prevention and control endorsed at the local and national levels by the relevant ministries and should be budgeted for.**

Control of endemic cholera

- **Universal vaccination (throughout a country without regard to risk) is not recommended in most countries.**
- **Follow up campaigns in the same areas may be considered after 3 years in case of persistent transmission.**
- **Strategies targeting specific age groups at higher risk may be considered.**

Humanitarian emergencies

- **Vaccination with OCV should be systematically considered during humanitarian emergencies with a risk of cholera.**
- **The decision to vaccinate should be guided by a thorough investigation of the current and historical epidemiological situation, an assessment of the actual risk of cholera, and a clear identification of geographical areas and populations to be targeted.**

Humanitarian emergencies

- **Campaign planning and preparation should be carried out to ensure that vaccination takes place prior to any known cholera season and that vaccination starts immediately once the vaccines become available in country.**
- **In areas of protracted emergencies with persistent risk of cholera and especially with population movement, follow up campaigns may be considered after 3 years or less.**

Control of cholera outbreaks

- **Based on available evidence on short term protection, a single dose strategy could be considered in areas experiencing cholera outbreaks. Considering the limited evidence about the duration of protection of a single vaccine dose, additional vaccination might be needed to ensure longer-term protection.**

Need for additional research and evaluation

1. Vaccine coverage

- **Conducting coverage surveys focusing on missed vaccination in high risk groups may provide essential information to improve overall impact and cost effectiveness of OCV campaigns.**

Need for additional research and evaluation

2. Adverse Events Following Immunization (AEFI).

- As OCVs have been used extensively in multiple global settings and have been proven to be safe, AEFI monitoring using routine passive surveillance based on country-level policies may be conducted. Active surveillance should be reserved for new delivery strategies or a newer generation of cholera vaccines as they become available.

Need for additional research and evaluation

3. Economic analysis

- It is important to perform systematic economic analyses to measure intervention cost, cost effectiveness, and cost benefit in different settings where campaigns have been conducted.

Need for additional research and evaluation

4. Vaccine efficacy and effectiveness

- **Additional research is needed to better inform number of doses, optimal dosing interval (dose spacing) and issues related to duration of protection in different settings. More information is needed on the effectiveness in children aged 1-5 years.**
- **Further assessment of herd protection is needed.**

Need for additional research and evaluation

5. Vaccination impact

- **There is a need to further work on methodologies to measure the impact of vaccination by better defining relevant and meaningful comparison groups and identify standardized indicators across geographies and settings.**

Need for additional research and evaluation

6. Alternative strategies for OCV delivery

- **Alternative delivery strategies covering self-administration, outside-the-cold-chain (CTC / ECTC), linking OCV with other health interventions should be further evaluated in a larger variety of settings.**
- **More information is needed on co-administration of OCV with other vaccines, especially with oral vaccines such as OPV and rotavirus vaccine.**