

## Overview of the OCV Stockpile

The oral cholera vaccine, Shanchol™ is available through the stockpile for use during emergency situations. It is composed of killed whole bacterial cells of V cholerae and is provided in small glass vials containing 1.5 ml of liquid vaccine. The vaccine was prequalified by the World Health Organization in 2011 and a stockpile was created in 2013. In 2015, GAVI began supporting the costs for purchasing vaccine for the stockpile.

When needed urgently, the creation of the stockpile makes it possible to provide cholera vaccine very quickly to countries and agencies facing a cholera threat. Often the vaccine is used shortly after an outbreak is recognized in hopes the vaccine will reduce the magnitude and shorten the outbreak. Other times, vaccine may be used proactively, before an outbreak has started because the cholera risk is deemed to be very high, in hopes of preventing or minimizing the threat.

To obtain vaccine from the stockpile, a formal request must be made to the International Coordinating Group based at WHO-Geneva. The forms, once filled out, should be sent to the OCV-ICG Secretariat by email [ICGsecretariat@who.int](mailto:ICGsecretariat@who.int) or [outbreak@who.int](mailto:outbreak@who.int) or by fax +41 22 791 4198. While these forms must be completed to make the formal request, ministries of health or relief agencies should also be in communication with the WHO, Office of Pandemic and Epidemic Diseases to discuss the need for vaccine. If there is uncertainty about how to communicate with this office at WHO, the national or regional WHO office should be able to help. Alternatively, the DOVE project ([www.stopcholera.org](http://www.stopcholera.org)) can also provide assistance.

At present, the supply of vaccine is limited, so the number of doses normally used in a campaign can only accommodate relatively small programs which target groups at highest risk. The stockpile is not able to provide vaccine for the entire country and most deployments have been from 50,000 doses up to a few hundred thousand doses.

## ICG Process

When the application forms are received, they are circulated to the OCV ICG partners (MSF, UNICEF, WHO and IFRC) for their review. Each of these members is committed to respond within two days. The decision is then immediately communicated to the agency or ministry requesting vaccine. If the request is approved, the vaccine is sent by air to arrive in country within seven days from the day the request was approved. Sometimes the shipment is divided into smaller shipments, depending on its size and cold chain capacity. The requesting agency will be informed about the arrival date in country.

The ICG uses several criteria when deciding to allocate vaccine including a) how well the risk has been identified, b) the risk that an outbreak will spread to other areas, c) the feasibility of the immunization campaign and d) the availability of the vaccine.

Some important features of the oral cholera stockpile include the following:

1. The ICG members are knowledgeable about the control of cholera and are eager to help countries and agencies control cholera through an integrated approach, including vaccine.
2. The stockpile mechanism is rapid. The ICG will provide feedback immediately about the request for vaccine, and if vaccine is to be deployed, it will arrive in country within ten days.
3. Because GAVI is helping to support the stockpile, the vaccine is provided without cost if it is obtained through the stockpile. However, the country or agency requesting the vaccine must cover the “in-country costs” including the costs for maintaining a cold chain, in-country transportation and the program costs for vaccination.
4. The agency carrying out the vaccine campaign is expected to carry out monitoring and evaluation (M&E) of the campaign. Modules to assist with M&E are included in this DOVE toolkit. Suggested M&E activities are also on the WHO website. Different campaigns will use different M&E modules, depending

on the situation; but only rarely is a highly scientific “effectiveness” analysis needed.

The forms submitted to the ICG need to document the situation in sufficient detail so that the ICG can make an informed decision. This request must include a vaccination plan and a map of the area to be vaccinated as well adjacent areas at potential risk. The forms are comprised of 12 sections (A through L). The forms can be found [on the WHO website](#). They are now also available on the [DOVE website](#). If needed, the DOVE project is willing to provide assistance to groups who are considering applying for vaccine.

## Guidance on Using the Forms

- A. Epidemiological information. This form is used to describe the outbreak, or the risk of an outbreak. Using clinical case definitions for cholera as well as information about confirmation of some of the cases, a description of the outbreak should be provided. If possible, a graph showing the epidemic curve is helpful. If an outbreak has not occurred, but the risk of an outbreak is very high, evidence for this assessment should be provided. A Risk Assessment Tool provided with this toolkit can be useful in documenting the risk.
- B. Laboratory information. Information regarding confirmation of cholera should be included. At least some fecal samples will be sent to a central laboratory for culture and sensitivity to confirm the diagnosis and to guide antibiotic treatment of cases. A modified rapid test can also be useful to identify the outbreak as early as possible and to document the proportion of cases with confirmed cholera. A guide to obtaining samples for culture and for carrying out the modified dip stick test are found on the [www.stopcholera.org](http://www.stopcholera.org) web site.
- C. Risk of extension of the outbreak. This risk is assessed by such features as historical trends, civil unrest, and water / sanitation conditions. Again the Risk Assessment Tool may be helpful in assessing this risk.
- D. Capacity to control the outbreak. The occurrence of an outbreak generally demonstrates that the “normal” control measures are not sufficient; however, the basic strategies of providing emergency water and sanitation and providing health care services for patients must be strengthened. The vaccine is then integrated into this overall control strategy. An assessment of the capacity to control the outbreak may also guide

where the vaccine is to be deployed. For example, persons living in remote areas may not be well served by hospital care, so these remote areas may assume a higher priority for vaccine if these areas can be reached.

- E. Cold chain. The vaccine needs to be kept at refrigerated temperature after arrival in country and when transported within country. It is however relatively thermostable and can be distributed at room temperature on the day it is administered. Plans for the cold chain will need to be described in the application.
- F. Planned OCV vaccination campaign. The vaccination plan is needed to allow the ICG to assess the feasibility of the OCV campaign. The table on the following page provides an outline of the plan to include.
- G. Licensing/registration of product in country. Both Dukoral® and Shanchol™ are prequalified by WHO, but Shanchol™ is currently the vaccine available through the stockpile. If Shanchol™ is registered in country; this may help the importation requirements. In any case, approval for importation and custom clearance of OCV from the emergency stockpile will be needed.  
  
Vaccine companies in Korea and Vietnam are now producing licensed oral cholera vaccine which is essentially the same as Shanchol; however these others are not yet WHO prequalified. In an emergency, countries or agencies could choose to purchase these vaccines directly from the manufacturer; but they are not available from the OCV stockpile. Also, permission to import these vaccines will require approval from national authorities. Nevertheless, since these vaccines are licensed in their own country, they are considered high quality vaccines.
- H. Vaccine stockpiles in the country. If there is already vaccine supplies in the country, these should be described.
- I. Request for advance of Operational Costs Support. At present, the operational costs are assumed to be paid by the implementing agency and there are no specific funds available for operational costs in country. However, the financial needs can be communicated to the ICG to determine if funds can be located for these costs.

- J. Reimbursement. Prior to 2015, the cost for the vaccine was to be reimbursed to the stockpile to maintain a rotating stock. However, now that GAVI is supporting the purchase of vaccine, reimbursement is not required.
- K. Monitoring and Evaluation (M&E). Plans for M&E need to be described. The DOVE toolkit provides guidance on possible ways to carry out the M&E.

The link to the WHO web page which provides additional guidance on the process for applying to the stockpile is [found here](#).

The following outline is an example of the OCV campaign plan outline. By following this outline, the plans for the campaign can be communicated to the ICG clearly.

## Further Information

Please visit our website ([www.stopcholera.org](http://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](mailto:Info@stopcholera.org).

OCV Vaccination Campaign Plan Outline	
<b>Introduction, Rationale, &amp; Objectives</b>	<ul style="list-style-type: none"> <li>- Brief description and analysis of the country's cholera situation</li> <li>- Regional and district context</li> <li>- Objectives of mass vaccination</li> <li>- Planned vaccination date</li> </ul>
<b>Profile of affected area and target population group</b>	<ul style="list-style-type: none"> <li>- Affected population profile</li> <li>- Special risk factors</li> <li>- Targeted geographical area</li> </ul>
<b>Vaccine needs</b>	<ul style="list-style-type: none"> <li>- Target vaccine coverage</li> <li>- Calculation of vaccine needs</li> </ul>
<b>Organization and coordination</b>	<ul style="list-style-type: none"> <li>- National and local committees</li> <li>- Partners involved and their roles</li> <li>- Coordination, water and sanitation, curative</li> <li>- Comprehensive outbreak response plan</li> </ul>
<b>Selection of vaccination sites and priority areas</b>	<ul style="list-style-type: none"> <li>- Vaccination sites</li> <li>- Vaccination strategy (fixed sites, mobile posts, or combination)</li> <li>- Expected number of vaccinations per day and per team</li> </ul>
<b>Social mobilization</b>	<ul style="list-style-type: none"> <li>- Plans for social mobilization</li> </ul>
<b>Micro plan and organization of the campaign</b>	<ul style="list-style-type: none"> <li>- Composition and number of vaccination teams</li> <li>- Supervision</li> <li>- Training of vaccination and supervisors teams</li> </ul>
<b>Logistics</b>	<ul style="list-style-type: none"> <li>- Cold chain at regional, district, and vaccination post levels</li> <li>- Local transportation</li> <li>- Waste management strategy, means, and human resources</li> </ul>