STOP CHOLERA

Work Together. Stop Transmission. End Deaths.

Manual for Oral Cholera Vaccination Campaigns
For adaptation by program managers for training health care workers

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Acknowledgements

Acronyms

EPI   Extended Program on Immunization

IEC   Information, education and communication

OCV   Oral cholera vaccine

ORS   Oral rehydration solution

UNICEF   United Nations Children Fund

VVM   Vaccine vial monitor

WASH   Water, sanitation and hygiene

WHO   World Health Organization

Contents

1. Introduction

Purpose

This manual is meant to be used by immunization program managers to develop training sessions in preparation for carrying out oral cholera vaccine (OCV) campaigns. It is also intended to serve as a reference guide for health care workers conducting the campaigns and administering the vaccine.

The manual should enable program managers to prepare quality training sessions and their own training materials in a relatively short period of time. Timeliness is critical because cholera vaccination campaigns often must be organized and implemented in a matter of weeks or even days, especially during humanitarian crises and cholera outbreaks.

Audience

This manual is meant to be used by immunization program managers, Extended Program on Immunization (EPI) coordinators, supervisors, and health care workers preparing to administer OCV to target populations via specific OCV immunization campaigns.

Contents

This manual highlights best practices in managing and delivering OCV services. It contains information on the following subjects:

- Background on cholera
- General information on cholera vaccines
- How oral cholera vaccines are used
- Integrating cholera vaccination with other cholera interventions
- Educating and mobilizing the community for a vaccination campaign
- Planning and carrying out a cholera vaccination campaign
- Supervision and monitoring

In addition, the manual contains forms and other resources in the Annexes to assist in preparing, implementing and monitoring vaccination campaigns.

Other key resources for OCV

This manual assumes that the decision has been made to use OCV and that the population groups to receive the vaccination have already been determined. Thus this manual is not a guide for making the decision whether or not to use OCV or which groups to target for vaccination. It also does not cover topics such as vaccine procurement or distribution in detail. Other resources available from World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) cover many of these other areas, and should be used in conjunction with this manual. Those other resources include the following.

- Oral Cholera Vaccines in Mass Immunization Campaigns: Guidance for Planning and Use[1] and Addendum[2], published by WHO;
- Guidance on how to access the Oral Cholera Vaccine (OCV) from the ICG emergency stockpile[3], provided by the Global Cholera Vaccine Stockpile;
- Forms for requesting OCV from the Global Cholera Vaccine Stockpile[4], published by WHO;
- Framework for Developing an Integrated Communication Strategy for the Introduction of Oral Cholera Vaccine in Cholera Prevention and Control Programmes[5], published by UNICEF;

- Guidance note on the use of Oral Cholera Vaccines for UNICEF[6], published by UNICEF;
- Vaccination in acute humanitarian emergencies: a framework for decision making[7], published by WHO; and
- Principles and considerations for adding a vaccine to a national immunization programme: from decision to implementation and monitoring[8], by WHO.

How to use this document

The text throughout this document may be adapted to the specific needs of particular country and context. To assist planners, general information is provided along with instructions, comments and space for inserting information to make the manual country- and context-specific. The sections meant to be adapted by country planners include Section 2, "Background on cholera", and Section 5, "Integrating cholera vaccination with other interventions". Managers should feel free to adapt other parts of the manual as well, where appropriate and as time allows.

Training health workers

Before implementing a vaccination campaign, health workers need to be equipped with the knowledge and skills required to administer OCV and the ability to follow appropriate immunization practices. Training for health workers should provide information on key aspects of immunization, including handling of the vaccine while maintaining the appropriate cold chain for OCV, proper disposal of waste, and how to estimate vaccination coverage. Training should cover the eight learning objectives outlined in Box 1.

Box 1. Learning objectives for training health workers in conducting OCV campaigns

1. Acquire basic knowledge about cholera including its clinical presentation, case definitions, how it is transmitted, and ways to prevent it.

2. Acquire an understanding of the key aspects of oral cholera vaccine, including its composition, safety, protective efficacy, and how to handle and administer it.

3. Understand the different uses and objectives of cholera vaccination and the objectives of the planned campaign.

4. Be able to describe different vaccination delivery strategies and under what circumstances each should be used.

5. Be able to demonstrate how to administer cholera vaccine following appropriate clinical practices.

6. Acquire the skills and knowledge to properly handle the vaccine, including maintaining the cold chain and proper waste disposal.

7. Demonstrate the ability to effectively communicate to the public and clients about cholera and the vaccine, including providing accurate information about how to prevent cholera, where and when to seek health care, why the vaccine is being given, its safety, who is eligible to receive it, and the need for a second dose.

8. Be able to correctly complete the management and campaign monitoring tools (vaccination cards, tally sheets, etc.), including estimating coverage.

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2. Background on cholera

This section contains a review of cholera, including how it is transmitted, its clinical characteristics and who is at risk for the disease.

2.1 What is cholera?

Cholera is an acute diarrheal disease transmitted by the fecal–oral route by ingesting food or water contaminated with the bacterium *Vibrio cholerae* (serogroups O1 and, less frequently, O139)[9]. Cholera affects both children and adults and can kill within hours. About 75% of people infected with *V. cholerae* do not develop symptoms; however, the bacteria are present in their feces for several days after infection and are shed back into the environment, potentially infecting other people. Of those who do develop symptoms, most have mild or moderate symptoms, while a few will develop the severe form of the disease with profuse, watery diarrhea and severe and frequent vomiting. People with a severe case of cholera can pass one liter of stool per hour or more, and this massive fluid loss results in severe dehydration. If the disease is left untreated, death will occur, most often within the first day of the illness. Cholera is one of the most rapidly fatal infectious illnesses known. Case fatality rates in severe, untreated cases can reach 30% to 50%.

> ### Box 2. Of the people infected with cholera...
>
> - Around 75% have no symptoms
> - Around 20% have mild or moderate diarrhea (which can produce dehydration)
> - Around 5% have severe diarrhea, vomiting, and severe dehydration

KEY MESSAGE

- Cholera can rapidly lead to severe dehydration and death if left untreated.

2.2 Cholera transmission

Cholera is a disease of poverty, occurring mainly in areas with poor sanitation and lack of clean drinking water. A person becomes ill if they ingest a large number of bacteria (usually at least 1 million organisms are needed to cause human illness). If the number of bacteria ingested is high, the likelihood of becoming ill increases. When people ingest water or food contaminated with *V. cholerae*, the bacteria multiplies rapidly in the gut, making humans an "amplifying host" of the organism. In areas with poor sanitation, the feces of those infected with cholera—which is full of trillions of cholera organisms—can contaminate surface and well water, leading to an epidemic.

Cholera often contaminates surface water, water in shallow wells, and even piped water. Contamination of water can also occur in the home, when unwashed hands come into contact with stored water. Bathing or washing cooking utensils in contaminated water can also transmit the disease.

Food is also a frequent source of cholera when, for instance, it is prepared by someone who has the infection or has cleaned an infected baby. Moist foods that are lightly contaminated after cooking and allowed to remain at room temperature for several hours provide an excellent environment for the growth of *V. cholerae*. Moist grains

such as rice, millet or sorghum are common vehicles for cholera transmission, especially when they are served at room temperature. Other foods that can transmit the infection include raw or undercooked seafood (especially shellfish) and raw fruits and vegetables.

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Box 3. Common sources of cholera

- Surface, well or tap water used for drinking that has become contaminated
- Water stored in home containers in which people who have cholera have placed their hands, thus contaminating the water
- Raw vegetables washed with contaminated water
- Food prepared by people who have cholera who have not washed their hands after using the toilet
- Contaminated food not thoroughly cooked or left at ambient temperatures for several hours, allowing the bacteria to multiply
- Raw or undercooked seafood from contaminated waters

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2.3   How do you know cholera is occurring?

In cholera-endemic countries, children are at greatest risk of getting the disease. However, unlike some diarrheal diseases such as rotavirus, cholera can cause severe illness and even death in healthy adults and children alike. This is especially true during epidemics and in areas where cholera is not endemic.

In fact, the WHO case definition of suspected cholera in nonendemic areas is severe dehydration of acute watery diarrhea in people 5 years of age and older (Box 4). In areas where it is endemic, cholera should be suspected in patients of all ages when symptoms of painless, acute, watery diarrhea and/or rapid, severe dehydration are present (Figure 1). A cholera case or outbreak is confirmed when *V. cholerae* O1 or O139 is isolated and confirmed by a laboratory from the stool of an individual who is a suspected case. Individuals who are suspected of having cholera should be treated and reported to health authorities even if the case is not yet confirmed by a laboratory or it is never confirmed.

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Box 4. World Health Organization case definition of cholera in nonendemic areas or during an epidemic

Suspected case:

- In an area where the disease is not known to be present, a patient aged 5 years or older develops severe dehydration or dies from acute, watery diarrhea
- In an area where there is a cholera epidemic, a patient aged 5 years or older develops acute, watery diarrhea with or without vomiting

Confirmed case:

- A suspected case in which Vibrio cholerae O1 or O139 has been isolated from stool, thereby confirming the diagnosis

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Figure 1. Signs of severe dehydration

Sunken eyes, lethargy and slow recall of skin

2.4 Where and when cholera occurs and its risk factors

Cholera can occur as an endemic disease or in epidemics (outbreaks). Both endemic and epidemic cholera occur in high-risk areas or "hot spots" and can occur during certain seasons. Common areas at high risk for endemic or epidemic cholera are these:

- Periurban and urban slums without adequate water and sanitation systems
- Rural areas with poor access to clean water for drinking and poor sanitation
- Coastal areas with rudimentary sanitation systems (e.g., fishing communities)
- Camps for refugees or internally displaced people that have poor water and sanitation conditions
- Areas that experience a natural or man-made disaster (e.g., earthquake, war) where the water and sanitation systems have been destroyed
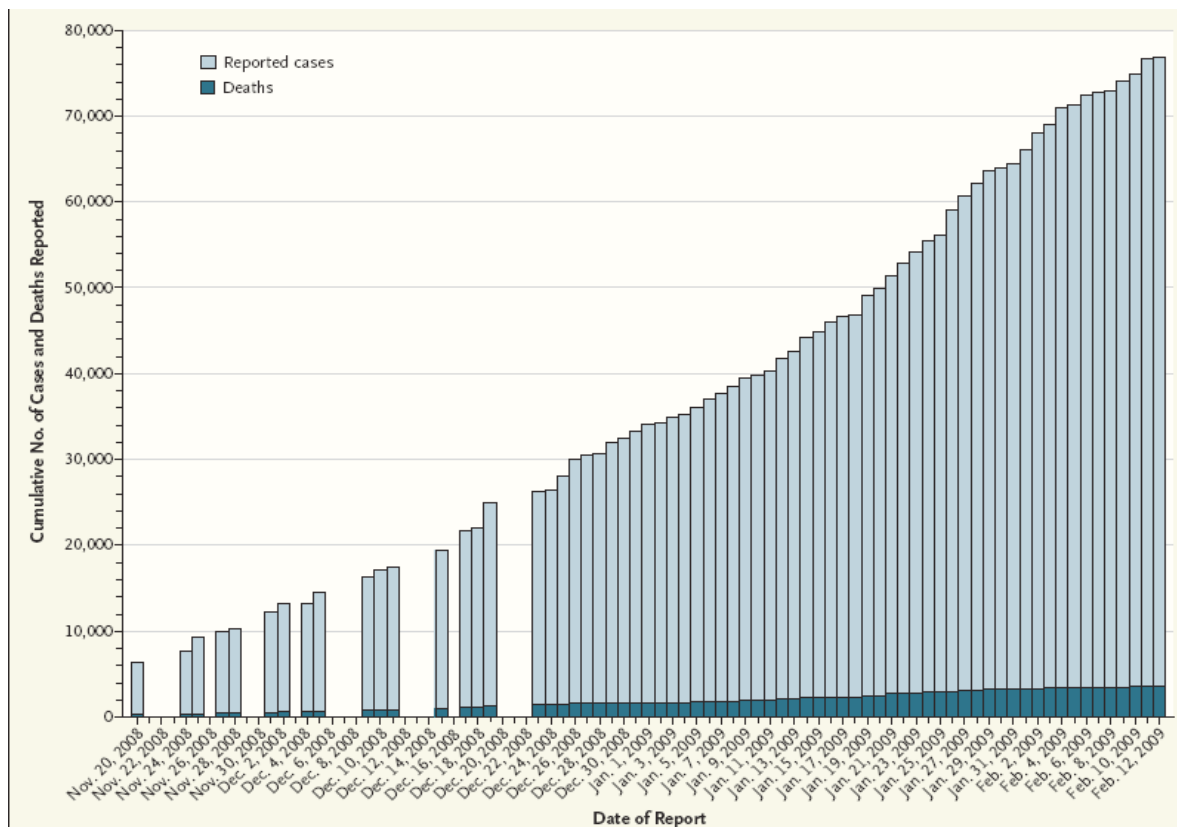- Areas where acute humanitarian emergencies have occurred

Endemic cholera

In areas where cholera is endemic, the disease tends to occur during certain seasons. In some areas the highest numbers of cases occur during the rainy season, but in other areas more cases occur during dry, hot seasons. Floods can lead to the mixing of contaminated waste with sources of drinking water, which can cause outbreaks. In countries where the disease is endemic, the cholera seasons are often predictable from year to year. These seasonal peak periods of cholera incidence can take place once or twice a year, so to prevent as many cases as possible, the best time to conduct a cholera vaccination campaign is shortly before the cholera season begins.

Cholera outbreaks

An outbreak of cholera is said to occur when there is a sudden increase in the number of cholera cases that are linked by time and place. The term "epidemic" is often used to describe these outbreaks, especially if the numbers of people reported to be ill are much higher than usual. If outbreaks are not controlled early, they can spread very rapidly, as occurred in Zimbabwe in 2008-2009 (Figure 2) and in Haiti in 2010. It seems that cholera outbreaks appear to be getting larger and lasting longer in recent years. The outbreak in Zimbabwe, for example, lasted 11 months and caused around 100,000 reported cases.

**Figure 2. Cumulative cholera cases and deaths in Zimbabwe,
November 20, 2008–February 12, 2009**

Source: Presentation by Eric Mintz at the April 2009 meeting on Focus on Neglected Tropical Infectious
Diseases: Integrating Vaccines into Global Cholera Control Efforts, Fondation Merieux, Annecy, France,
April 14–17, 2009 (data from the UN Office for Coordination of Humanitarian Affairs).
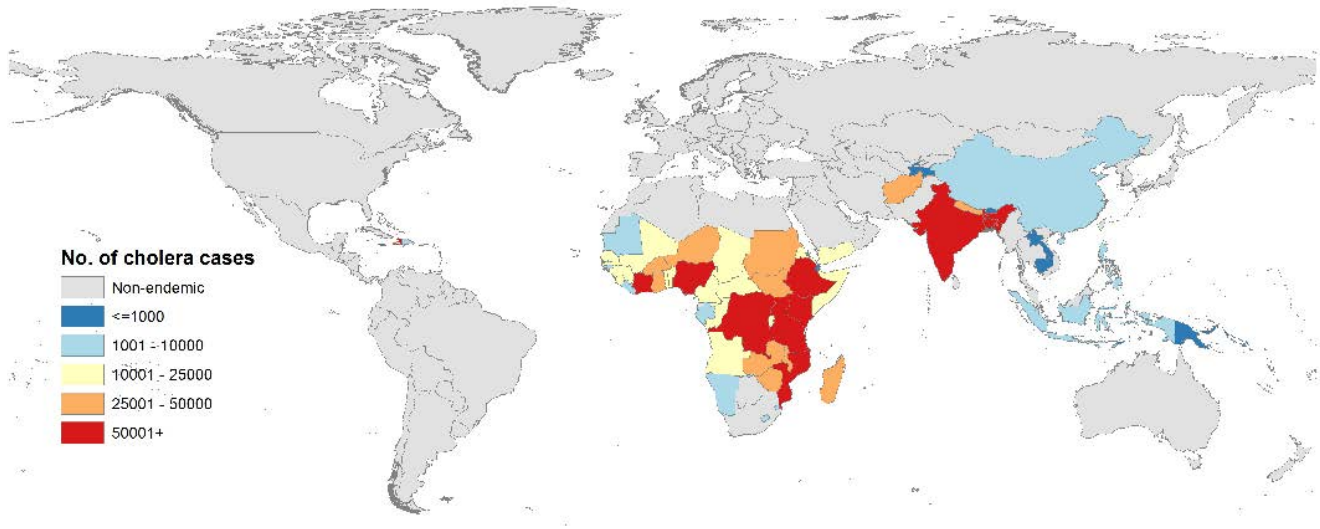
The global picture of cholera

A 2015 analysis estimates that on average around 2.9 million cases of cholera illness and 95,000 deaths occur globally each year[10]. However, in 2013, WHO received reports of only around 130,000 cases and 2,000 deaths. Most of the world's cholera cases occur in the following areas (Figure 3):

- **South Asia,** including Bangladesh, India, Nepal, and Pakistan, and especially around the Bay of Bengal. Cholera is endemic in parts of these countries, but frequently occurs in seasonal outbreaks.
- **Sub-Saharan Africa,** where many countries experience outbreaks every 2 to 5 years. The disease is, however, becoming endemic, with cases reported every year in some areas such as eastern Democratic Republic of Congo.
- **Haiti,** where the disease first appeared in 2011.

Many countries in South and Central America experienced cholera outbreaks in the 1990s after the disease appeared in Peru in 1991, following a century without it. Cholera has now essentially disappeared from Latin America in part thanks to major improvements that have been made in sanitation, water systems and hygiene.

In recent years, a new variant strain of *V. cholerae* O1 has appeared that produces the classical cholera toxin and appears to cause more severe clinical disease. That strain has now become dominant globally.

Figure 3. Where cholera occurs in the world

Although the global estimates are useful guides, implementing an OCV campaign requires more specific information about the country where the campaign will occur. Filling in the information in the box below will provide a useful framework of information with which to get started. You may not have access to detailed data on the number of cases and deaths or case fatality rates, for example, but any information will be helpful. Data often are available from the Ministry of Health, but a web search using PubMed may identify publications on cholera and other relevant information may be found on Promed.

ADAPT TO YOUR CONTEXT

Box 5. What is the cholera situation in your country?

Cholera in _____**(insert country name)**

- Brief history of cholera in country:

- Where it occurs ("hot spots") and high-risk groups, numbers of persons at risk, etc.:

- Recent outbreaks (locations, number of cases and deaths, case fatality rates, etc.):

- Common sources of infection and risk factors:

- Cholera seasonality (in endemic countries):

- National cholera control plans and outbreak response measures:

2.5 Preventing, treating and controlling cholera

Preventing cholera and controlling outbreaks

The primary way to prevent cholera is to ensure that people have access to clean water and proper sanitation. Extensive piped water, water treatment, and sewage systems are expensive and may take many years to reach impoverished people who need them. However, short- to medium-term measures such as constructing latrines and distributing products to purify water or prevent contamination in the home can greatly help prevent cholera (Box 6).

Another key prevention measure (especially during an outbreak) is health education to promote basic, good hygienic practices such as the importance of handwashing with soap and proper food handling to avoid contamination. These messages should be spread through a variety of means such as talks by community and religious leaders, lessons given by teachers to pupils in schools, public service announcements, and interviews with experts on radio, TV programs, newspapers and other print media. See Section 5.1 for examples of how to combine vaccination and other cholera prevention and control programs.

Strengthening cholera surveillance and implementing an early warning system are key strategies to prevent the spread of the outbreak to new areas. Surveillance helps detect the first cases and thus enables communities to put control measures in place early on. More information and excellent resources on cholera prevention and control can be found in the UNICEF Cholera Toolkit[12].

Treating cholera and case management

Cholera is easy to treat[9]. The main means to treat cholera and prevent deaths is to reverse or prevent dehydration caused by the illness. Most patients can be treated successfully with oral rehydration solution (ORS) using a WHO/UNICEF standard sachet. However, patients with severe dehydration require immediate intravenous fluids, preferably Ringer lactate solution. Patients with cholera should also be given an appropriate antibiotic, one that works against the circulating strains of cholera. Antibiotic use shortens the duration of diarrhea, reduces the volume of rehydration fluids needed, and shortens the duration of *V. cholerae* excretion in the stool, thus reducing the risk of it being spread in the community. Mass distribution of antibiotics is not recommended, however, because it can contribute to the development of antibiotic resistance (targeted antibiotics, given to very high risk family members need to be evaluated further).

During an outbreak, cholera treatment centers should be set up in the affected areas to ensure that people have quick access to good-quality treatment. With proper and prompt treatment the case fatality rate of cholera should remain below 1%, but this cannot happen unless people are educated to recognize the signs and symptoms of cholera, and know when and where to seek treatment. Public information about health-seeking and when and how to use ORS is thus an important part of controlling the disease and keeping case fatality rates low. See Section 5 of this manual for suggested key messages to promote health-seeking when an individual is suspected of having cholera.

3. General information about oral cholera vaccines

This section contains general information about OCVs currently available through the global stockpile. Additional information about them can be found in the StopCholera Toolkit[12].

3.1 Currently available OCVs

Three OCVs prequalified by WHO are currently available (Figure 4). All three consist of inactivated (killed) whole cells of *V. cholerae*:

- **Shanchol** (Shantha Biotechnics, India) contains killed whole cells of V. cholerae serogroups O1 and O139. The vaccine was first licensed in India in 2009, was prequalified by WHO in 2011 and is available worldwide.
- **Dukoral** (Crucell Sweden AB) consists of killed whole cells of V. cholerae serogroup O1 and a recombinant B subunit of the cholera toxin. The cholera toxin component also helps the vaccine provide short-term protection against enterotoxigenic Escherichia coli (for around 3 months). Dukoral is used primarily by people from industrialized countries who travel to countries where cholera occurs.
- **Euvichol** (Eubiologics, Republic of Korea) is identical to Shanchol and was prequalified by WHO in late 2015.

Figure 4. Currently available WHO prequalified cholera vaccines

In addition to the three prequalified killed oral vaccines, another cholera vaccine, mORC-Vax, also identical to Shanchol, is being manufactured and licensed in Vietnam, but it has not yet been prequalified by WHO.

These new oral vaccines are very different from the injectable vaccines that had been used in the past. Previous vaccines had significant side effects such as fever and muscle soreness, and they offered only short-term protection against cholera. Injectable cholera vaccines are no longer available.

Although Shanchol and Euvichol are identical, for ease of reading, this manual refers to OCVs in general as Shanchol, primarily because it is the most recognized product name and the one used in most developing countries currently. Shanchol and its equivalents are easier to use than Dukoral under difficult field conditions (e.g., no buffer is needed) and are less expensive than Dukoral. The main characteristics of Shanchol are shown in Box 7.

Box 7. Characteristics of Shanchol	
Contents	Killed whole cells of *V. cholerae* (serogroups O1 and O139)
Producer	Shantha Biotechnics, Hyderabad, India
Year pre-qualified by WHO	2011
Eligible ages	1 year old and older
Number of doses and schedule	2 doses given 2 weeks apart for all age groups (this interval can be extended if logistically necessary)
Dose size and formulation	1.5 ml liquid vaccine
Efficacy	65% over 5 years for >5 year olds 43% over 5 years for 1–5 year olds
Duration of protection	At least 5 years
Time required for immune response	Immune response develops within 7–10 days of the first dose
Buffer required?	No
Presentation	Single-dose vials
Cold requirements	Storage should be at 2–8°C, but the vaccine can be taken out of cold chain on the day of vaccination
Vaccine vial monitor (VVM)	VVM 14
Shelf life	30 months

3.2 Features and performance of Shanchol

Schedule

Shanchol is given in two doses with a recommended interval of 2 weeks between the first and second doses. The immune response is the same if the interval between the doses is 4 weeks[13]. In the future, longer intervals will be evaluated, but until these alternative intervals are validated, it is best to give the second dose 2 to 4 weeks after the first dose. The vaccine may be given to individuals age 1 year and older.

Efficacy and duration of protection of Shanchol

A large field trial in Kolkata, India, found that Shanchol provides sustained protection of 67% over 2 years and 65% over 5 years[14]. However, it is less effective in children age 5 years and younger. The duration of protection of the vaccine is therefore considered to be at least 5 years.

Shanchol has been shown to confer indirect protection, meaning that in a community with many vaccinated individuals, even those who have not been vaccinated will have a lower risk of contracting the disease because less *V. cholerae* is being transmitted in the community. This protection is especially important for children too young to be vaccinated (<1 year of age). Even vaccinated people are further protected by the reduced transmission of infectious bacteria in the community.

The combination of direct protection (via people who are vaccinated) and indirect protection (via everyone, including those who have not been vaccinated) means that cholera vaccines are more effective than the 5-year efficacy rate of 65% would indicate. However, indirect protection works only if a certain percentage of the overall population in a target area is vaccinated (e.g., >50%)[15,16].

3.3 Safety of oral cholera vaccines

OCVs consist of inactivated bacterial cells, meaning the cells in the vaccine have been killed and thus they cannot become virulent and cause cholera.

Shanchol and Dukoral have been used widely used and determined to be very safe. More than 29 million doses have been given to people in Asia, Africa, and Haiti with no serious side effects reported. About 2 percent of people who receive an OCV complain of mild gastrointestinal upset that lasts only a few hours and does not require treatment[17-22]. Additionally, unlike the old injectable cholera vaccines, OCVs do not cause muscle soreness or fever, since they are given by mouth.

Some people complain about the bad taste of the vaccine, but in past campaigns, most people (70–85%) returned for the second dose[19,23].

3.4 Use of OCVs in pregnant women

Pregnant women are at increased risk of losing their fetus if they become ill with cholera due to severe dehydration. In some countries, such as Haiti, rates of miscarriage or stillbirths among pregnant women with cholera can be five times greater than the rate in the general population of pregnant women. Therefore, WHO recommends that pregnant women be considered for cholera vaccination in high-risk areas[24]. A summary of the evidence regarding OCV and its use during pregnancy is found in the document, In Brief: Cholera and the Use of Oral Cholera Vaccines in Pregnant Women[25] in the StopCholera Toolkit.

Data documenting the safety of Shanchol continues to be accumulated, but because it is a new vaccine there is little experience regarding its safety during pregnancy. The current package insert for Shanchol does not recommend administering the vaccine during pregnancy and contains the following message:

"Shanchol is a killed vaccine that does not replicate, is given orally and acts locally in the intestine. Therefore, in theory, Shanchol should not pose any risk to the human fetus. Administration of Shanchol to pregnant or lactating women may be considered after careful evaluation of the benefits and risks in case of a medical emergency or an epidemic."

Two retrospective surveys, conducted in Guinea and Zanzibar, examined the birth outcomes among pregnant women who were vaccinated compared with those who were not. Neither study found significantly more side effects, miscarriages, or stillbirths among vaccinated and nonvaccinated women[21,26].

Because OCV campaigns are usually implemented only in settings where a high risk for cholera exists, consistent with the recommendations of the WHO, it is advisable that pregnant women be included in vaccine campaigns. Women who are considering taking the vaccine should be given the following information:

a) The vaccine has been made from bacteria that have been killed.
b) Use of the vaccine has not been specifically evaluated in pregnant women.
c) There is no indication of a higher risk of adverse events in pregnant women.

Countries may have their own policy on the use of OCVs during pregnancy, so organizations and agencies administering OCVs should follow the national policy.

Box 8. What is the policy on administering oral cholera vaccination to pregnant women in your country?

State the country policy on adminstering OCV to pregnant women here:

KEY MESSAGES

- Shanchol and other oral cholera vaccines have few side effects.
- Two doses given 2–4 weeks apart provide 65% protection over 5 years (less protection in children <5).
- Indirect effects of vaccination lead to an overall effect of the vaccine in a community.
- The vaccine should not be given to children <1 year of age.
- WHO recommends the vaccine be given to women who are pregnant but each country must decide whether or not to do so.

4. How oral cholera vaccines are used

This section describes how OCVs are used and how to develop plans for organizing a vaccination campaign.

Vaccination against cholera is different from other vaccinations in the following ways:

- It is not administered nationwide; rather, usually it is targeted to specific populations and specific areas in a country.
- It is usually given to people of all ages (except infants <1 year), including adults.
- It is administered through campaigns, not through routine immunization programs. Campaigns usually take place within the course of a few days or a week (similar to measles, polio or yellow fever supplemental immunization activities).
- Two doses are required and thus there needs to be two rounds of the campaign—generally 2 to 4 weeks apart. There are circumstances in which a single dose is used, rather than two doses. These circumstances will be determined by the national Ministry of Health in coordination with the WHO.

4.1 Objectives of cholera vaccination and different types of campaigns

There are three main objectives for conducting OCV campaigns and three settings in which OCV may be warranted (Figure 5):

1) To control the disease in areas where cholera is considered endemic. WHO defines an endemic area as one where cholera diarrhea has taken place in 3 out of the past 5 years. Endemic areas may include regions, districts or several districts, but very rarely an entire country. WHO particularly recommends the use of cholera vaccine in endemic settings and settings at risk for cholera outbreaks.

2) To prevent cholera from occurring during an emergency. OCV campaigns may take place after a natural disaster such as an earthquake or severe flood, or a man-made crisis such as war. In some situations cholera may not have occurred yet, but the area has had cholera in the past and people are living in conditions that place them at high risk for contracting the disease. In addition, the health system in these settings may have collapsed or deteriorated.

   The purpose of these campaigns is to preempt (or prevent) cholera outbreaks from occurring as a result of poor living conditions. Such preemptive vaccination campaigns have occurred when refugees and internally displaced people live in situations such as camps with poor water and sanitation.

3) To stop the spread of an outbreak that has already started. Some countries have started to add vaccination to their response to a cholera outbreak. Known as reactive vaccination, the purpose is to reduce the number of people who become ill and to stop the spread of the disease to new areas that are considered high-risk, such as those with poor water and sanitation. Another example of a reactive campaign may occur when a cholera outbreak occurs in a neighboring country and health officials wish to reduce the risk of the disease spreading across the border.

Figure 5. Settings where oral cholera vaccination can be warranted

Credit: Lorenz Von Seidlein, 2015.

Endemic settings

Credit: Jacob Kuehn, Medecins Sans Frontieres, 2015

Humanitarian emergency

Credit: Thomas Freteur, Medecins Sans Frontieres, 2014

Cholera outbreak response

Box 9. Examples of different types of past OCV campaigns and their objectives and strategies

Reactive vaccination

Malawi 2015:
- Objective: To stop an outbreak among people in Nsanje district living in camps and displaced by floods by vaccinating 90% of the target population with two doses of vaccine along with other cholera control measures
- Target population: 160,000 camp residents age 1 year and older
- Other control measures:
  - Provide safe drinking water, promote good hygiene and improve sanitation conditions
  - Reinforce social mobilization and communication messages to prevent cholera

Guinea 2012:
- Objective: To stop an outbreak in two coastal districts, Boffa and Forecariah, where an outbreak began to spread
- Target population: 209,000 people age 1 year and older
- Other control measures:
  - Health education
  - Distribution of soap
  - Distribution of chlorine for household water treatment

Preemptive vaccination:

South Sudan 2014:
- Objective: To prevent cholera among internally displaced people living in camps and among the host population of Mikmamann payam, Awerial State
- Target population: 80,000 internally dispersed people living in camps
- Other control measures:
  - Measles vaccination
  - Water and sanitation interventions

Vaccination to control cholera in endemic settings

Democratic Republic of Congo 2014:
- Objective: To permanently control cholera in the most affected health areas of Kalemie by vaccinating the entire population as part of a comprehensive set of cholera control measures
- Target population: 50,000
- Other control measures:
  - Improved case management
  - Enhanced surveillance
  - Reconstruction of the water distribution system
  - Sanitation and health promotion

4.2 Target populations for cholera vaccination campaigns

Endemic settings

Target populations for cholera vaccination are generally people who live in geographic areas with a high risk of cholera due to poor water and sanitation conditions. This includes people in urban and periurban slums and rural areas with poor sanitation. People in rural areas may be targeted to receive an OCV because without access to treatment, they have a higher risk of dying from cholera if the disease strikes their community.

Preemptive vaccination

Target populations of preemptive vaccination campaigns include refugees, internally displaced people, and those in areas where a flood, tsunami, or earthquake has occurred.

Reactive vaccination

Reactive vaccination is meant to vaccinate people in areas with ongoing cholera transmission to stop its spread. The sooner vaccination and other control measures take place after cases have been detected, the more effective the vaccination will be, otherwise many people will already have become infected or ill and the campaign will have less effect in reducing cases and deaths. People living in nearby areas with poor living conditions may also be targeted.

Ages

Generally, anyone 1 year and older is eligible to receive Shanchol or its equivalent. The purpose of vaccinating everyone except infants is to reduce the rate of infection and transmission as quickly as possible. This also maximizes the indirect effects of the vaccine.

Vaccinating both children and adults has always been the strategy used for preemptive and reactive vaccination campaigns. If resources are limited, WHO suggests that the primary target population be preschool and school-aged children[24].

4.3 Vaccine delivery strategies and sites

Carrying out an OCV campaign (Figure 6) may entail a mix of these strategies:

- **Use of permanent facilities.** Fixed-site facilities such as health centers allow OCVs to be administered all day during a campaign. Health care facilities can also serve as depots for storing and distributing vaccines to outreach sites.
- **Outreach.** In an effort to vaccinate as many people as possible, mobile teams set up temporary vaccination sites in the community such as in schools, churches, camps, work sites, health outposts, and market areas.
- **Door-to-door delivery.** This strategy can increase vaccination coverage, especially in remote areas with hard-to-reach populations. It can also be effective in reaching people who spend much of their time at home, such as women in conservative societies. This strategy is generally more time-consuming and costly than other strategies.

Figure 6. Vaccine delivery strategies

Credit: Christelle Esomba, Medecins Sans Frontieres, 2015.

Fixed Sites

Credit: Monica Burns, Medecins Sans Frontieres, 2014.

Outreach teams

Credit: ACPalomino, Courtesy of Photoshare, 2005.

Door-to-door

4.4 Campaign timing and scheduling

During an outbreak, humanitarian crisis or natural disaster, cholera vaccination campaigns must be organized and carried out quickly. Ideally, preventive vaccination campaigns in endemic areas should take place before the cholera season (if the season is known on the basis of past experience). Preventive vaccination campaigns can also occur during other vaccination or child health campaigns (see Section 5.2).

Some people will have missed the first round of the campaign and request their first dose during Round 2. Campaign managers should offer the first dose and find a way to administer the second dose. Some options include:

- Individuals who received their first dose during Round 2 of the campaign are asked to return to the nearest health center in 2 weeks. Health centers must be prepared to retain additional doses for the purpose of administering second doses.
- A smaller third round, also known as a "mop-up" round is held specifically for people to complete their immunization.

If the number of vaccines available is insufficient to provide everyone with a second dose, it is important to inform people that the first dose will provide some protection, although protection is lower than with two doses and will last for a shorter period of time. Additional information about the potential benefits from a single dose has been published[27].

KEY MESSAGES

- Cholera vaccination will have a greater effect if it is targeted toward:
    - People and areas at high risk of contracting the disease (e.g., areas with poor water and sanitation conditions)
    - People most at risk of dying from cholera (e.g., areas with no or few health services)
- Two weeks are recommended between the two vaccination doses, but the second dose can be administered up to 4 weeks or more after the first dose
- The first dose induces protection, but two doses are recommended to maximize protection and extend the duration of protection

4.5 Key information about planning a vaccination campaign

Immunization program managers should be able to outline a plan for their vaccination campaign using the information provided thus far, and their own knowledge of the area where vaccinations will be offered. The template below can be filled in to outline this plan.

Box 10: Outline a plan for your vaccination campaign

Objectives of the campaign:

Location(s) of the campaign and target population:

Vaccination dates:

- Round 1

- Round 2

- (Round 3 or mop-up)

Eligible population (ages, inclusion or exclusion of pregnant women, etc.):

Policy regarding people coming for first dose in Round 2:

Size of the eligible population:

Target coverage rate (% of the population expected to receive two doses):

Vaccine delivery strategies and sites to be used:

Plans for integrating OCV with other preventive and control measures (see Section 5):
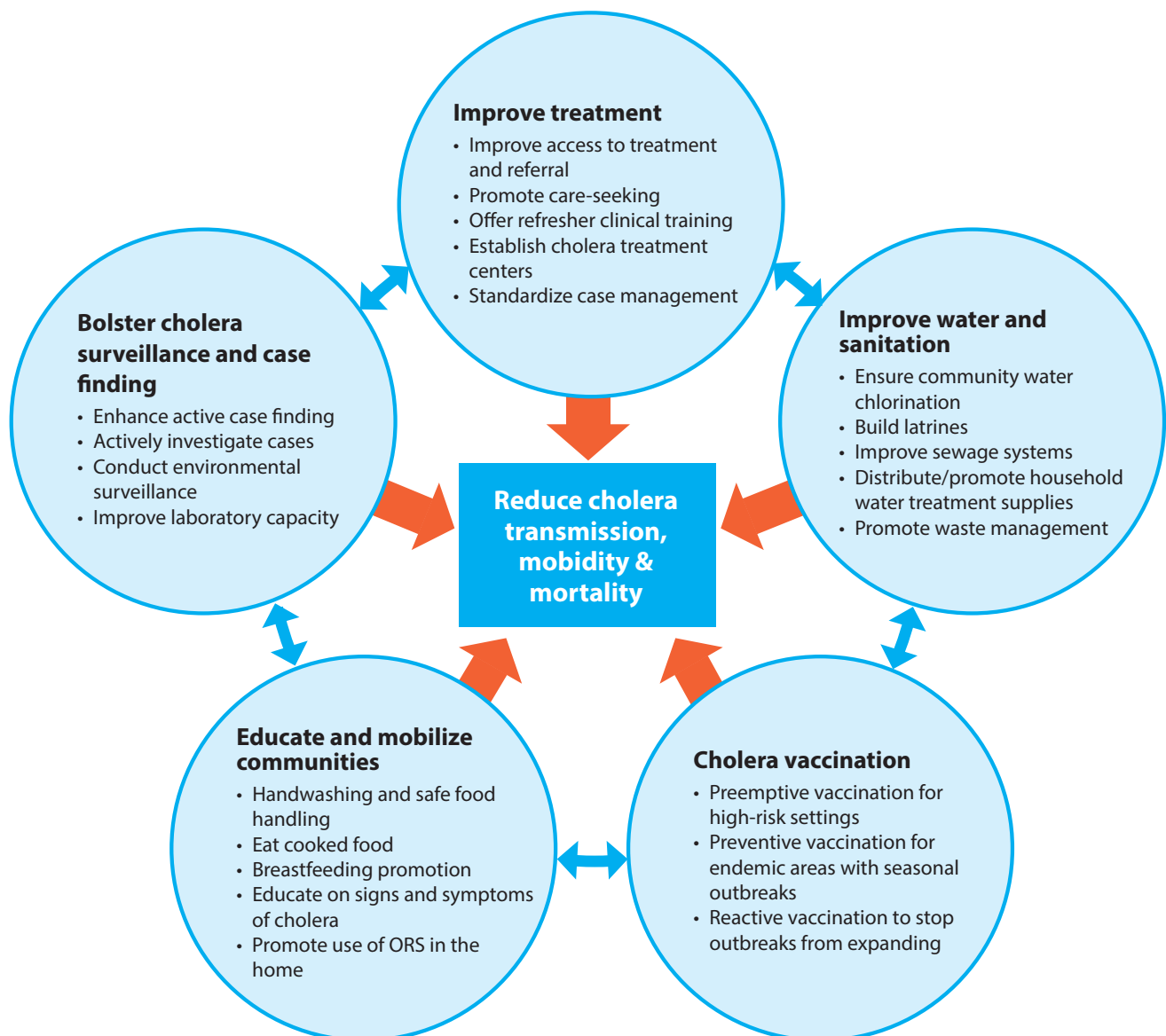
5. Integrating cholera vaccination with other interventions

This section contains some practical tips and examples of how cholera vaccination can be administered in coordination with other cholera control measures, even when there is limited time to organize a campaign and human and financial resources are also limited.

5.1 Combining vaccination with other cholera prevention and control strategies

An integrated approach for preventing and controlling cholera is shown in Figure 7. WHO recommends that cholera immunization "should be used in conjunction with other prevention and control strategies in areas where the disease is endemic ... or those at risk for outbreaks"[24]. Integrating vaccination with other control measures such as efforts to improve water, sanitation and hygiene (WASH) is often talked about but not always practiced. This is especially true when a cholera vaccination campaign is organized quickly, such as during an outbreak or a humanitarian crisis.

Figure 7. An integrated approach leads to synergistic cholera prevention and control

Improve treatment
- Improve access to treatment and referral
- Promote care-seeking
- Offer refresher clinical training
- Establish cholera treatment centers
- Standardize case management

Bolster cholera surveillance and case finding
- Enhance active case finding
- Actively investigate cases
- Conduct environmental surveillance
- Improve laboratory capacity

Improve water and sanitation
- Ensure community water chlorination
- Build latrines
- Improve sewage systems
- Distribute/promote household water treatment supplies
- Promote waste management

Reduce cholera transmission, mobidity & mortality

Educate and mobilize communities
- Handwashing and safe food handling
- Eat cooked food
- Breastfeeding promotion
- Educate on signs and symptoms of cholera
- Promote use of ORS in the home

Cholera vaccination
- Preemptive vaccination for high-risk settings
- Preventive vaccination for endemic areas with seasonal outbreaks
- Reactive vaccination to stop outbreaks from expanding

Why is an integrated approach for cholera control so important?

There are three main reasons why an integrated approach to cholera is important. First, vaccination alone does not provide a community with complete protection from cholera. This is because the current vaccines are not 100% effective and protection is not life-long. In addition, not everyone in a community will be vaccinated; past OCV campaigns have not been able to achieve coverage rates greater than 70–80%. Infants younger than 1 year of age and sometimes pregnant women will not receive the vaccine.

Second, other control measures such as water and sanitation improvements increase the effectiveness of cholera vaccination and vice versa. Thus vaccination and these other measures act synergistically. On the one hand, improvements in sanitation and hygiene will reduce the amount of *V. cholerae* that people ingest through contaminated water or food, making it more likely that a vaccinated person's immune system can fight the pathogen and avoid severe disease. On the other hand, vaccination means fewer people will excrete trillions of *Vibrio* bacteria (*V. cholerae*) and contaminate water sources. The fewer pathogens that are removed from the chain of transmission, the more successful WASH activities will be.

Finally, it is difficult to convince policymakers and the public to accept a campaign of vaccination if people continue to use the same contaminated water sources and practice unhygienic behaviors. Proposing an integrated strategy strengthens the case for vaccination.

Credit: Andreea Campeanu, Médecins Sans Frontières, 2014

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Box 11. Strategies and useful tips for integrating cholera interventions

- Include people from different sectors, such as health educators, teachers, and water and sanitation engineers to plan and organize the vaccination campaign and inform the public. These other professionals will have ideas on how to take advantage of a cholera vaccination campaign to promote good WASH practices, distribute point-of-use materials to reduce household water contamination and so forth. They can also be useful in obtaining funds or in-kind contributions (volunteers and supplies) from government or private sources.

- Encourage all health care workers (e.g., in hospitals and cholera treatment centers) to inform patients and their families about OCV and the upcoming vaccination campaign.

- Always try to include information on hygiene, safe water, and proper food handling practices and other ways to prevent cholera in all communications leading up to and during the vaccination campaign. For example:

  - Include messages on handwashing and other hygiene/safe water practices in all broadcast or printed announcements about the vaccination campaign.

  - Hold health education talks during vaccination sessions.

  - Include health education (see Figure 8) messages on materials distributed to vaccines, such as on vaccination cards, leaflets, and T-shirts.

- Distribute materials to improve hygiene and water quality such as hand soap or chlorine tablets to all vaccine recipients and their families during the vaccination sessions.

Box 12. Integrating oral cholera vaccination with other prevention and control strategies: real-life examples from the field

- In Kalemie (2014) in the Democratic Republic of Congo, cholera vaccination was included as a component of a large multisectoral effort to control cholera. The effort also involved making improvements to the water delivery system and the establishment of a cholera treatment center and strong case management.

- In refugee camps in South Sudan (2014), OCV was provided as part of a package of interventions to reduce the risk of cholera and other epidemic-prone diseases that included health education; distribution of soap, chlorinated water and albendazole (a deworming medicine); and vaccination against measles and meningitis.

- In Haiti during a rural OCV pilot project (2012)[28], vaccination teams were encouraged to share key messages about cholera prevention and treatment with everyone they met before and during the vaccination campaign. Messages were disseminated through radio shows, sound trucks, town criers, local television, T-shirts and posters. Educational information was provided to at least one member of all enumerated households. The education campaign reportedly led to significant improvements in knowledge about cholera and practices related to waterborne diseases.

- In Forecariah, Guinea (2012)[29], women of reproductive age receiving an OCV also received soap and chlorine tablets and specific information on the importance of using the products to prevent cholera.

5.2 Combining cholera vaccination with other vaccinations or child health activities

Local program managers may wish to combine cholera vaccination with other health care activities such as routine immunization programs or distribution of bed nets to protect against malaria. Cholera vaccination can be added to supplemental immunization activities for polio, measles, meningitis A or yellow fever. Combining OCV campaigns with other health care activities can also save time, effort, and money, but they can also make the delivery of routine child health challenging:

- OCV is generally given to all persons older than age 1 or 2 years, including adults, whereas other vaccine campaigns focus mainly on children. Thus implementers need to find ways to attract older children and adults to the joint vaccination campaigns.
- The optimal timing for OCV campaigns, such as during an outbreak or before the cholera season begins, may not coincide with the planned schedule of other vaccination campaigns.
- Many vaccines require a single dose, whereas OCV requires a second dose approximately 2 weeks after the first dose.

KEY MESSAGES

- An integrated approach to cholera control and prevention increases the effectiveness of cholera vaccination and other control measures.
- Add other health activities or interventions to cholera vaccination campaigns when possible.
- Each vaccination interaction is an opportunity to tell people about ways to prevent cholera and when and where to seek treatment.
- Teams providing WASH interventions should reinforce the opportunities for obtaining OCV if such a campaign is imminent. Both OCV and WASH teams should reinforce the messages of the other team.

6. Educating and mobilizing a community for a vaccination campaign

This section contains an overview of the importance of communicating with communities that will be receiving the vaccine. People must feel they understand what will be happening and why. Program managers who plan OCV campaigns should work in partnership with communities because a lack of proper communication leads to the risk of misunderstandings and the spread of rumors.

6.1 Importance of social mobilization and communication for the campaign

The goal of social mobilization and communication for an OCV campaign is to ensure that people age 1 year and older in the target area are vaccinated. Building social support within a community, especially its leaders, is key to mobilizing acceptance of vaccination. To achieve this, people need to know:

- Who should get the vaccine
- Why they should get the vaccine
- What the vaccine does
- When and where to get vaccinated

Health care workers, specifically health promotion staff, volunteers, and clinical staff, play a key role in informing the community about the vaccination campaign and in ensuring that the campaign is well attended by the target population. IEC activities that are part of a social mobilization effort are important both before and during a vaccination campaign to maintain high coverage. Vaccine campaign managers should review the daily coverage figures by geographic area and focus on the IEC activities of health care workers where coverage is low. The communication activities and messages should also reinforce messages about how to prevent cholera (Figure 8) and where and when to seek treatment (Box 13).

In addition to preventive messages, the vaccine program should also alert the population about what to do in case a cholera outbreak should occur in the community, and promote health care-seeking (Box 13).

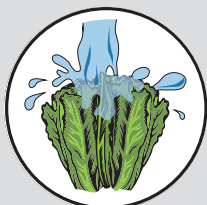### Box 13. Key messages to promote health care-seeking during an outbreak

Cholera can cause death, but it is easy to treat:

1. In case of acute, watery diarrhea (three or more liquid stools in 24 hours), go to the nearest health center to seek care. This is especially important for pregnant women and those suffering from other medical conditions because they are at highest risk for severe cholera.

2. At the onset of watery diarrhea, start taking ORS. For adults, take a large cup (250 ml) of ORS every time after using the toilet.

3. If you don't have ready-to-use ORS available, use clean water and add 6 teaspoons of sugar and 1/2 teaspoon of salt for each liter of water. However, it is best to use ready-to-use ORS.

Figure 8. Key messages for cholera prevention to appear on posters, leaflets and other Information, education and communication (IEC) materials

Drink and use safe water. Safe water is water that is bottled with an unbroken seal, has been boiled, or has been treated with a chlorine product.

Wash food with safe water and either peel food or cook it well, eat it hot, and keep it covered.

Wash hands often with soap and safe water (after using the toilet, before eating or cooking, after eating, after cleaning baby's feces). If no soap is available, brush hands often with ash or sand and rinse with safe water.

Use latrines or bury your feces. Do not defecate in any body of water.

Keep latrines clean.

6.2 Target audiences for an information and social mobilization campaign

OCV campaigns have several different target audiences that may require the use of specific social mobilization and IEC activities and materials (Box 14). The content, tone and language are generally different for each audience, and social mobilization and IEC activities should be tailored to those needs. For instance, the medical community will need more technical information about the vaccine's efficacy, duration of protection and safety than the general public. In general, the more audiences receive accurate, timely and appealing information, the better the campaign will be.

Box 14. Target audiences for communicating about OCV campaigns

- Household members to be vaccinated, including mothers
- Community leaders and influencers (e.g., religious, political and traditional leaders)
- Frontline health care workers and volunteers
- Journalists and media representatives (print, broadcast and Internet)
- The medical community, including providers from the private sector, nongovernmental organizations, and faith-based organizations

Box 15. Tips for developing social mobilization activities for cholera vaccination campaigns

- Messages should address key concerns, beliefs, and misperceptions of the population. Beliefs and concerns can be discerned by, for example, interviewing health workers and holding focus group discussions with community members in the target areas.
- Form a technical committee to plan and organize the IEC campaign. The committee should include community leaders, medical professionals, educators, women's association members and other key members of the community.
- Organize meetings such as a press conference and/or interviews with media representatives because they can play a vital role in raising awareness about cholera, educating about the vaccine, informing the public about the vaccination campaign, dispelling rumors and correcting misinformation.
- Try to have a prominent political or community leader launch the campaign and take the vaccine in a public location. Additionally, ensure that broadcast and print media cover the launch.
- During the first vaccination session, give the vaccine recipient written and verbal reminders about the need to obtain a second dose.

6.3   Ways to spread the word

Information about the vaccine and the vaccination campaign can be disseminated in various ways; for example:

- Radio and TV programs, or public service announcements
- Printed materials such as leaflets, flyers or posters
- Face-to-face communication by health professionals, volunteers, community leaders, and others via community meetings, house-to-house visits, announcements at religious gatherings, booths set up at markets, during clinic visits, etc.
- Engaging journalists who can report on the campaign and interview health care professionals

It is good practice to use multiple channels for communication. The choice of channel and media will depend on the local culture and customs, timing, available funding and involvement of various sectors of society. Civil society organizations, religious groups, women's organizations, and schools may need to be involved. Good communication campaigns do not necessarily have to take months to plan and implement or be very expensive to achieve good coverage (see the story about Guinea in Box 17). In an emergency setting, communication will have to be carried out quickly, whereas campaigns for endemic areas will likely take longer to plan and be more deliberate.

KEY MESSAGES

- Remember that local community members such as leaders and volunteers are often most effective and efficient at mobilizing a community for a vaccination campaign.

Box 17. How a simple communication program successfully spread the word about a reactive cholera vaccination campaign in Guinea[29,23]

A cholera outbreak began in February 2012 in two remote districts of Guinea. By early April, in an effort to prevent a major epidemic the Ministry of Health decided to hold a mass vaccination campaign in those two districts. The first round of vaccinations was scheduled to begin just 2 weeks after the decision had been made, giving little time to prepare a social mobilization/communication campaign. Local radio, TV nor SMS were available in the districts, nor was there time to develop and distribute printed materials about the vaccination campaign.

Despite these challenges, immunization coverage during the first round of vaccinations was nearly 90% in each district. How was this achieved?

First, people in the districts already knew about cholera and were aware of the outbreak, so they were motivated to protect themselves against the disease. Second, medical professionals, traditional leaders and local government officials were all informed about the campaign in advance.

Third, and most important, traditional communication and local community leaders were asked to get the word out. Two days before the vaccination day, a health promoter visited each community to help village leaders and town criers gather people together and provide simple information about the vaccination campaign, including eligibility for the vaccine, and when and where the campaign would take place. In more populated areas, local outreach workers went door-to-door to provide this information. Preexisting print materials on how to recognize and control cholera were also distributed. In addition, the vaccination sessions were used to provide additional information on cholera prevention to those receiving the vaccination.

7 Preparing for and conducting cholera vaccination campaigns

This section contains information on carrying out an OCV campaign.

7.1 Identifying vaccination sites and scheduling campaigns

Locations in which to hold OCV campaigns should be easily accessible with adequate space for crowds. Examples of suitable places to set up vaccination sites are:

- Health facilities
- Schools
- Community centers
- Places where local public events are held
- Outreach sites located in a clean environment
- Open spaces

Work sites such as factories or places that employ many workers can also be considered to make vaccination of these workers as convenient as possible.

The day and time of the vaccination campaign in each location should be as convenient as possible for those eligible to receive the vaccine (Box 18).

Box 18. Setting convenient days and times to achieve high cholera vaccination coverage

Several previous OCV campaigns have had trouble achieving high vaccination coverage among adult men who often are away at work during days when OCV campaigns are normally held. A key strategy to increase vaccination rates can be to extend the vaccination sessions to include evening or early morning hours, depending on the local culture and economy. Holding some sessions on the weekend might also be considered.

7.2 Organizing the vaccination sites and forming the vaccination team

Only simple furniture and a limited number of supplies are needed at vaccination sites (Box 19).

Depending on the season, plastic sheeting, umbrellas or shelters should be used to provide coverage for those waiting outside to be vaccinated. If possible, the vaccination sites should also be close to public toilets.

The sites should be organized to avoid excess crowding and long queues, and to ensure an efficient flow of people. It is important to ensure crowd control. The site must have a designated entry and exit with a one-way flow to prevent backtracking through the crowd. The diagram in Figure 9 illustrates the set-up, personnel and one-way flow of a vaccination site.

Box 19. Furniture and supplies needed

Furniture:

- Two tables (one for the registrar and one for the vaccinator)
- Three chairs
- Additional seating (e.g., benches, mats to be used by caretakers/children, pregnant women and elderly people)

Supplies:

- Banner/posters to identify the site on the outside
- Vaccine carriers
- Forceps or pliers to open the vials
- Safety boxes for disposal of used vaccine vials
- Trash bags or bins for other waste
- Forms: vaccination cards and tally sheets
- Pens/pencils
- Health education materials such as wall posters and leaflets on cholera prevention
- Any incentives or commodities such as soap or chlorine tablets, as available, to give to vaccine recipients
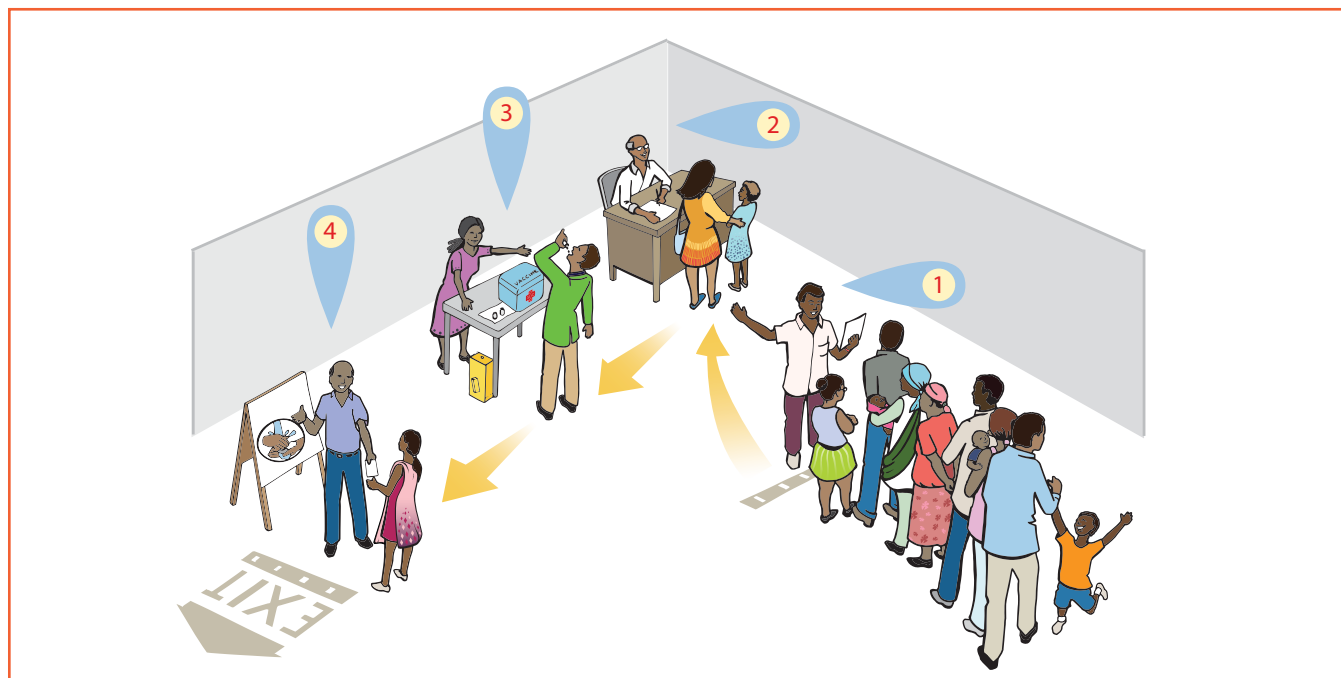
Credit: Leonora Baumann, Médecins Sans Frontières, 2015.

Credit: Médecins Sans Frontières, 2014

Figure 9. Diagram of the vaccination site and personnel

1) Crowd controller, 2) registrar, 3) vaccinator, 4) an additional person to provide health education messages and materials, as available, and to be alert to anyone experiencing an adverse event that might occur soon after vaccination.

The numbers and types of people working at the vaccination sites will vary depending on the size of the population to be vaccinated and the level of attendance. Vaccination program managers should also adjust the numbers and composition of the team during the campaign as needed. Normally, however, at least three people are needed at each site: a crowd controller, a registrar and a vaccinator. A suggested composition of the team is as follows:

Role	Responsibility
Crowd controller	Greets people coming for the vaccination, shows them where to go, controls the crowd, and ensures that the site is well organized.
Recorder or registrar	Screens people for eligibility (e.g., age of infants), fills out the vaccination card and vaccine register (if used) and tally sheet. Often the registration process takes the most time and creates the biggest backup, preventing people from quickly getting the vaccine and moving along. Managers may therefore want to adjust the team to have two registrars at each vaccination session.
Vaccinator	Double checks the eligibility of the individual, prepares and provides the vaccine, ensures that the cold chain is maintained, and disposes empty vaccine vials into safety boxes.
Educator/Adverse Event Focal Point	Provides health education and cholera-prevention messages, gives out commodities (e.g., soap, chlorine tablets), reminds individuals about the need to obtain the second dose and explains where and when the second round will take place. This person should also be alert to any adverse events that might occur soon after the vaccine is administered. These should be recorded if they occur.
Supervisor	Monitors and advises staff, ensures that enough vaccine and supplies are in place and forms are completed, and troubleshoots any problems. A supervisor should oversee each vaccination site; however, one supervisor can supervise several vaccination sites. This person will need to be able to travel between the sites being supervised.

Box 20. Adjusting the vaccination teams to improve efficiency and save costs in Guinea

It may be difficult to judge the number of people needed to conduct a successful vaccination campaign, especially the first time. One reason is because it is difficult to estimate attendance, and this can be affected by the adequacy of the social mobilization campaign and cultural beliefs. It can also be difficult to estimate how long it will take health workers to complete some of the tasks (e.g., check the vial and vaccine vial monitor, open the vial, etc.), especially for people with no previous experience administering OCVs. That is why it is important to be flexible and adjust the setup of the vaccination sites and team composition based on initial experience with the campaign.

This was the case in Guinea in 2012, where the first mass campaign of distributing Shanchol in Africa was organized. The organizers expected two lines to form at each site to accommodate the crowds, and had two people for each major task (two crowd controllers, two registrars, two vaccinators) at the vaccination sessions in Boffa district. This turned out to be unnecessary, and after revising the performance and workload of the vaccination teams, the organizers decided to reduce the number of people per vaccination team from nine people to five in the next campaign that was scheduled to occur in Forecariah district.

Monitoring and evaluation data showed that the five-person teams were able to vaccinate as many people per day as the nine-person teams. This change significantly reduced the cost per vaccinated person.

7.3   Storing and transporting the vaccine

According to the package inserts, OCVs, including Shanchol, should be kept at 2–8°C at all times, including when in transport, storage, and when used at a vaccination session. A basic cold chain consists of the following:

- Storage: refrigerators, freezers and cold rooms
- Transport: cold boxes, vaccine carriers and icepacks
- Cold chain monitoring: thermometers, temperature log tags and freeze watch monitors

Before the vaccination campaign, it is important to verify the cold chain equipment inventory, including the number and working status of freezers, refrigerators, vaccine carriers and icepacks in all locations (district stores, health facilities, etc.) to keep the vaccine cold until it is used. WHO has developed a Microsoft Excel-based tool included in the Annexes to OCV IGC Request Form[30] that provides an estimate of the cold chain capacity required to store and transport OCVs. Additional information on the cold chain, including preparation of insulated containers for vaccine transport, can be found in the supplies and logistics, cold chain support package[31] by UNICEF.

Often, the boxes containing the vaccine are transported by truck (lorry) to health facilities in large boxes that are able to maintain a cold temperature. The boxes are then placed in a refrigerator. Originally, the recommendation was to keep the vaccine cold until it was administered. This required the vaccine to be placed in small vaccine carriers with preconditioned icepacks (Box 21) for delivery to the vaccination sites. More recently, the vaccine was found to be stable when kept at ambient temperatures, at least for the day it is taken to a field site. This simplifies OCV administration procedures because the strict cold chain does not need to be maintained during the day of vaccination. It is important to ensure that enough vaccine is available at campaign sites to avoid running out but also having too much leftover vaccine. Any unused vials remaining at the end of the day should be placed back into cold storage, and those vials should be used first the following day.

Amount of storage needed

Shanchol is currently packaged in boxes of 35 single-dose vials. The box size is 14 x 10.5 x 4 cm. This corresponds to 0.6 liter per box.

- A typical large vaccine carrier will hold around 100 vials of vaccine.
- Vaccinating 1,000 people per session will require 29 boxes (of 35 vials each) and 10 vaccine carriers.

Preparing the vaccine carriers and preconditioning the icepacks

OCV should never be frozen. A common mistake that results in freezing vaccines is to place the vaccine carrier directly on top of icepacks that have just come out of the freezer. The icepacks typically come out of a freezer at a temperature of around −20°C and are therefore frozen solid. Thus it is important to prepare the vaccine carriers by prechilling them, and to precondition the icepacks by leaving them out at room temperature for some time to soften. The steps to prepare a vaccine carrier are detailed in Box 21.

Box 21. Preparing vaccine carriers and icepacks for transporting OCV

1. Prechill the insulated container by placing icepacks inside the closed insulated container for at least 1 hour. After an hour, remove all icepacks.
2. Precondition the icepacks so the vaccine vials will not freeze. This means keeping the icepacks at room temperature for a period of time to allow the core of the icepack to rise to 0°C (this may take 30 minutes or more if the room is cold). An icepack is adequately conditioned as soon as beads of water cover its surface. Check to determine whether the icepacks have been conditioned by shaking them and listening for water.
3. Fill the vaccine carrier with the conditioned icepacks.
4. Take the vaccine vials out of the refrigerator and place them in the vaccine carrier.

Making sure the vaccine is not frozen

Any frozen OCV vials must be discarded, and any vials suspected of having been frozen during transport or storage must also be discarded. Freeze-watch monitors can be used to detect periods of freezing. Note that the "shake test" used for some vaccines, such as pneumococcal conjugate vaccine, does not work for OCV.

7.4 Checking and administering the vaccine

The vaccinator must take several steps to prepare and administer an OCV (Box 22).

Checking the vaccine

The vaccine is likely to arrive at the vaccination site in a vaccine carrier. Vaccines should be used in the order in which they arrive. The vaccinator or another team member should check the expiration date on the vial. If the date has passed, the vial should be discarded.

The vaccinator should also check the vaccine vial monitor (VVM) on the label of the vaccine vial (Box 23). If the VVM is in Stage 3 or Stage 4—indicated by the box in the center being as dark or darker than the outer circle—the vial has been exposed to too much heat and should not be used. Vials at Stage 2—indicated by the box being a little dark but still lighter than the outer circle—can still be used, and should be used before other vials.

Box 22. Steps taken by the vaccinator to prepare and administer whole-cell only oral cholera vaccines (e.g., Shanchol)

1. Remove a few vaccine vials from the vaccine carrier.
2. Screen the person to be vaccinated and ensure they meet eligibility criteria (e.g., at least 1 year old).
3. Check the expiration date of the vial.
4. Check the VVM on the vial and discard any vials with a VVM at Stage 3 or Stage 4.
5. Check to make sure that the vaccine is not frozen.
6. Shake the vial vigorously to mix the contents well.
7. Remove the aluminum cap of the vial with forceps or pliers (Figure 10).
8. Before removing the plastic lid, shake the vial again carefully to be sure that sediment has not formed at the bottom, but be sure not to spill out the contents.
9. Give the vial to the recipient and make sure they drink and swallow the entire contents. For children 12 and younger, give the vial to their caregiver to administer to the child.
10. Mention key measures individuals should take to prevent cholera and remind them about the timing of the second dose (if a health educator or someone else does not do this).
11. Discard empty vials in a safety box and safely dispose the aluminum cap and plastic lids.
12. Keep track of the number of vials used and complete the Daily Logistic Supply and Return form (A) at the end of the day.
13. Record the age and sex of each subject on a Tally Sheet.

Box 23. What is a VVM and how is it interpreted?

The vaccine vial monitor (VVM) is the color dot on the label on all vaccines supplied through UNICEF. It is a time- and temperature-sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level (e.g., a VVM-14 will change color when the vaccine has been exposed to a cumulative heat equivalent to 14 days at 37°C).

Interpreting the VVM is simple. Focus on the central square. Its color will change progressively. As long as the color of this square is lighter than the color of the ring, the vaccine can be used. As soon as the color of the central square is the same color as the ring or darker than the ring, the vial should be discarded. The legend below explains the different stages of the VVM based on the color of the central square, and what action should be taken for each stage. A vial with a VVM in Stage 3 or Stage 4 should be discarded.

Stage 1: Inner square lighter than outer circle
If the expiry date has been passed, USE the vaccine.

Stage 2: At a later time, inner square still lighter than outer circle.
If the expiry date has not been passed, USE the vaccine.

Discard Point

Stage 3: Inner square matches colour of outer circle.
Do not use the vaccine. Inform your supervisor.

Beyond Discard Point

Stage 4: Inner square darker than outer circle.
Do not use the vaccine. Inform your supervisor.

KEY MESSAGES

- OCV should not be frozen. If vials appear frozen or the freeze-watch monitors indicate they might have been frozen, they should be properly discarded.
- It is important to consider the amount of vaccine expected to be used during the immunization session. Secure enough vaccine to use during the campaign to avoid running out, but avoid having excessive amounts of leftover vaccine.
- Be sure to check the VVM of each vial before administering it to an individual.

7.5 Screening the vaccinees

The registrar and vaccinator need to make sure that each person is eligible to receive the vaccine:

- Children must be 1 year or older to receive Shanchol or Euvichol.

- Depending on the country's policy, pregnant women may or may not be eligible. Some countries may decide that pregnant women are not be eligible to receive the vaccine because of a lack of data on its safety during pregnancy. However, killed vaccines should not pose a risk to the fetus. In fact, WHO recommends the use of OCV for pregnant women in high-risk areas[24].

- The vaccine should not be given to people who are acutely ill, such as with gastrointestinal illness, high fever or too ill to leave their bed. However, people with a minor illness such as a mild upper respiratory tract infection may receive the vaccine.

- Countries may have different policies on who is eligible to receive the vaccine during the second vaccination round. Most will allow people who did not receive the vaccine in the Round 1 to receive it in Round 2. Other countries will only allow vaccine to be administered during Round 2 to those who received it during Round 1. If a first dose if given during the second round, arrangements will need to be made to provide a second dose to those people 2 to 4 weeks later. On the other hand, if the policy is to administer the second dose of the vaccine only to those who received the first dose in Round 1, then those individuals will need to have a vaccine card documenting receipt of the first dose. This policy obviously complicates identifying those who are eligible.

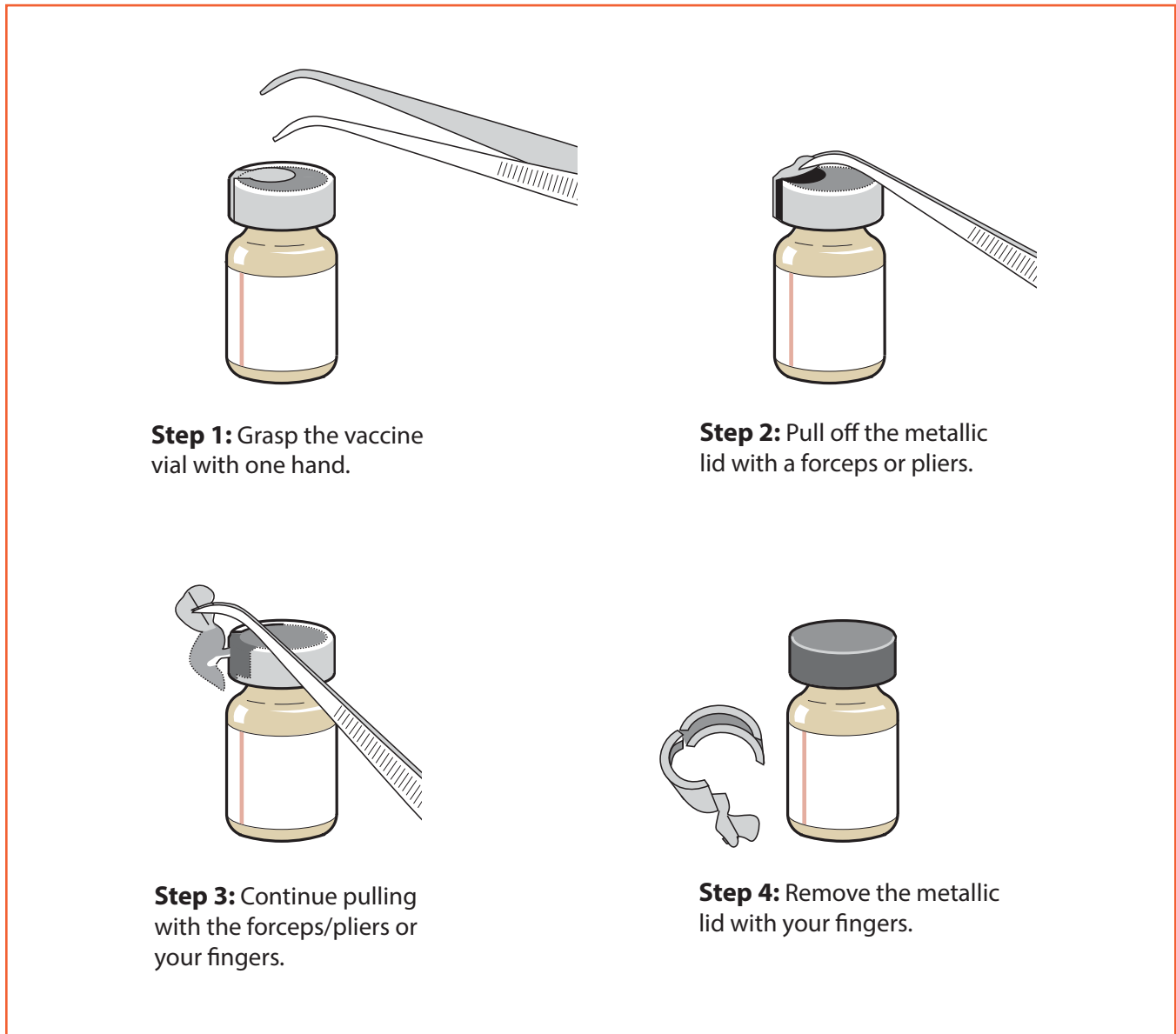### KEY MESSAGES

Vaccinators or other team members should:

- Ask the age of young children (should be ≥1 year old).

- Follow the country policy regarding exclusion criteria:
  - If the policy is not to vaccinate pregnant women with OCV, ask women if they are or think they may be pregnant.
  - If the policy is not to provide a first dose during a second-round campaign, ask participants for their vaccination card.

- Ask whether the person feels sick and to what degree.

Credit: Corentin Fohlen, Médecins Sans Frontières, 2014

Administering the vaccine

Shake the vial vigorously to make sure that it is well mixed. Open the vial by removing the aluminum cap with forceps or pliers (Figure 10). Shake it again carefully just before removing the plastic lid.

Figure 10. How to open the Shanchol vaccine vial

Step 1: Grasp the vaccine vial with one hand.

Step 2: Pull off the metallic lid with a forceps or pliers.

Step 3: Continue pulling with the forceps/pliers or your fingers.

Step 4: Remove the metallic lid with your fingers.

Note: This procedure is for the Shanchol vial; Euvichol vials are easily opened using the plastic lid on the vial.

OCV is easy to administer because it is given orally and there is only one dose in each vial. Advise people older than 12 years of age to administer the vaccine themselves. Children 12 and younger should obtain help from their parent or caregiver.

The vaccinator should make sure that the person has swallowed the entire contents (1.5 ml) of the vial, especially young children. It is not necessary to provide water when administering the vaccine, although if safe water is available, it can be provided to facilitate drinking the vaccine. Some like to drink water after the vaccine because of its unpleasant taste.

KEY MESSAGES

- Shanchol and other OCVs should only be administered orally. They should *never* be given with a needle parenterally (intramuscularly, subcutaneously or intravenously).

Place empty vaccine vials in safety boxes without the cap or lid (Figure 11). The caps, lids and water cups, if used, should be disposed of in appropriate waste bins.

Figure 11. Safety box for safe vial disposal

7.5 Recording the vaccination

After each vaccination, the registrar should complete the following steps:

- Fill out the *Vaccination* Card (Annex A) and give it to the vaccinated individual or caregiver. If this is the first dose, either the registrar or the vaccinator should fill in the date of the second vaccination and tell the individual to bring their vaccination card with them for the second round.

- Record the vaccination on the *Tally Sheet* (Annex B). There should be one Tally Sheet for each vaccination session. Figure 12 shows an example tally sheet. In this example, when a person takes a dose of vaccine, the vaccination is recorded by filling in the circle that corresponds to the person's age group and sex. If vaccination campaigns occur on more than one day, then a new Tally Sheet should be used each day.

- Complete the *Daily Logistic Supply and Return form* (Annex C). Either the vaccinator or the registrar may complete these, but they should be collected and verified by the site supervisor. This information should be shared with the rest of the team in review meetings (see below for more details on the supervisor role).

Figure 12. Filling out the Tally Sheet, Example
(See Annex B for a tallysheet template that can be printed)

	Male				Female			
≥ 1yr - 4 yr	●●○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	●●●○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total 1 - 4 yr	7							
≥ 5 - 14 yr	●●●●○ ○○○○○	●○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	●●●●○ ○○○○○	●●○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total 5 - 14 yr	14							
≥ 15 yr	●●●●● ○○○○○	●●●●● ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	●●●○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total ≥15 yr	13							
Grand total	34							

At the end of each vaccination session, the registrar should:

- Count the number of circles filled in on the Tally Sheet to determine the number of people vaccinated (in total and by age and sex group) during that session.

- Count the number of vaccine vials that have not been used and write down the amount in the Daily Logistic Supply and Return form.

- Complete the Tally Sheet with information about the number of doses received, the number used, the number remaining, and information about any vials with VVMs that have changed color.

Box 24. Forms to use (see Annexes)

- **Vaccination Card**: Filled out by the registrar and given to the vaccinated person or their caregiver for them to bring to the second round.
- **Tally Sheet**: Completed by the registrar, an easy way to count the number of people vaccinated at each session.
- **Daily Logistic Supply and Return form**: Completed by the registrar, contains a summary of the number of the supplies received and the number returned to the site supervisor.

7. 6 Communicating with those attending a vaccination session

Vaccination sessions present an important opportunity to inform attendees about the need for a second dose, when that will occur, and to reinforce key messages about cholera prevention and treatment. The registrar should remind people about the second dose and the date of the second round when giving them the vaccination card. Health education messages regarding cholera prevention, signs and symptoms of the disease, and when and where to seek treatment can be promoted through wall posters, leaflets and verbal messages by the vaccinator or health educator. A simple way to impart cholera prevention messages is to print key messages (Figure 8) on the back of the vaccination card. Remember that vaccine is a part of an integrated strategy for cholera control.

Box 25. Information for every vaccine recipient and caregiver

- The importance of returning for a second dose

- When and where the second dose will be administered

- Adverse events following immunization with oral cholera vaccine are unusual, but if they occur they usually consist of mild and short-lived intestinal discomfort (e.g., diarrhea, nausea, vomiting or stomach ache)

- Seek health care if a person becomes seriously ill following vaccination

- Key ways to prevent cholera (refer to other sections of this manual for these messages)

- Signs and symptoms of cholera and what to do if you suspect that you or a family member has the disease; this is especially important if the vaccination is organized in response to an outbreak

7.7   Handling vaccines and waste after the vaccination session

- **Waste disposal.** The empty cholera vaccine vials should be disposed of in safety boxes without the caps. The aluminum caps should be discarded along with the empty vaccine boxes in trash bins or bags and incinerated. The safety boxes must be transported to facilities identified and designated for proper and safe disposal.

- **Leftover vaccines.** Vials remaining from each vaccination site should be returned to the storage facility from which they came and returned to the refrigerator. If vaccines have been out of the cold chain during the day, those vials should be the first to be used the next day. Vaccine vials with VVMs at Stage 2 should also be used first.

8. Supervision and monitoring

This section emphasizes the importance of an excellent supervisor and a system for monitoring campaign activities.

8.1 Supervision

Good supervision is required to conduct a successful vaccination campaign. Supervisors should be well informed on all aspects of vaccination campaigns and procedures, and they must monitor key aspects of the campaign and solve problems as they arise. Often, one supervisor is responsible for monitoring several vaccination sites.

A supervisor checklist is shown in Annex D. Their key roles and tasks are as follows:

- **Serve as facilitators during health worker training sessions.** Supervisors must be sure that all team members understand the vaccination procedures and how to fill out all vaccination forms. Simulation exercises or role playing are good ways to make everyone familiar with vaccination campaign procedures. It is important to create a good atmosphere with the team so that no one is afraid or embarrassed to ask questions.

- **Monitor the organization and procedures of the vaccination sessions.** Supervisors should visually inspect all vaccination sites and sessions under their supervision to make sure that sufficient vaccines and supplies are available. They should verify that good clinical practices are followed; that is, that expired, heat-exposed or frozen vaccine is not being used; that people are being appropriately screened; that the full content of the vaccine is administered; and that adverse events are properly recorded. They should also check that vaccinators are properly disposing waste; that people are being given the correct information about the disease, the vaccine, and the need for a second dose and the where and when to show up for it; and that vaccination cards and tally sheets are being used correctly.

- **Communicate with the community.** Supervisors should interact with community members before and during the campaign to anticipate possible problems, learn about and mitigate any rumors or misinformation about the vaccine, and hear what people have to say about the campaign.

- **Check and complete monitoring and evaluation forms.** Check the Tally Sheets and Daily Logistic Supply and Return forms against the number of vaccine vials remaining, complete the Daily Reporting Form (Annex E) and Supervisor Checklist (Annex D).

- **Help the vaccination team.** Supervisors should provide feedback to the team during and after each vaccination session on a daily basis to help them understand the main barriers, find timely solutions, and motivate them to implement a successful campaign.

8.2 Adverse events following immunization

What is an adverse event and what causes it?

An adverse event following immunization is defined as a "medical occurrence (unfavorable or unintended sign, abnormal laboratory finding, symptom or disease) which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine"[32].

In general, adverse events may be due to:

- A reaction to the vaccine itself–most being mild or short-term
- An error in how the vaccine is administered (e.g., an injection causing an abscess)
- Anxiety on the part of the vaccine recipient
- Something other than the vaccination (that is, a "coincident event")

In most cases, it is difficult to determine with certainty that the event is actually due to the vaccination.

OCVs have a strong safety profile; only about 1 in 50 people taking the vaccine report any side effects, and these are mainly gastrointestinal upset. OCV side effects are generally mild, last only a few hours, and do not require treatment.

In addition, because cholera vaccine is given orally, there are no adverse events caused by injection, such as using an unsterile needle or injecting in the wrong site, which can be a major cause of side effects with injectable vaccines.

> **Box 26. Most common complaints after taking OCV**
>
> - Upset stomach
> - Diarrhea
> - Vomiting
> - Nausea

Nevertheless, as with any vaccine, even those with a long history of safety, a surveillance system should be in place to monitor possible adverse events. During mass immunization campaigns there is often an increase in adverse events—either real or perceived—being reported. This increase may be due to the large number of vaccinations performed in a short period of time, resulting in a concentration of events. Thus it may be helpful to establish a system for detecting such events. Even though the vaccine has been found to be safe in the past, the system to detect adverse events, should they occur, is reassuring to the individuals being vaccinated and to health officials alike.

Monitoring and reporting an adverse event during a cholera vaccination campaign

In a passive surveillance system, a person with signs or symptoms of illness seeks medical attention and thus reports the event. In an active surveillance system, a team member serves as an adverse event focal point to record the number of adverse events being reported. An adverse event focal point should be identified for each vaccination site. Often the team supervisor or health educator plays this role. Adverse event surveillance normally starts when the first vaccinations are given and lasts for several days (e.g., 14 days) following the campaign.

During the vaccination session, the vaccinator or health educator should tell everyone receiving the vaccination:

- That an adverse event is possible.
- Common adverse events include stomach upset, diarrhea, nausea and vomiting but that these are almost always mild and do not last very long.
- Where to seek care in case they experience an adverse event that is severe or persistent.

The team member whose responsibility is collect information on adverse events (i.e., the adverse event focal point) should use a reporting form to collect information about each event. A sample adverse event reporting form used by the WHO can be found in the working copy of Monitoring and Evaluation of AEFI during OCV Mass Vaccination Campaigns[33]. The form should be used to report the following information for each individual reporting an adverse event: age, sex, pregnancy status, history of allergies, vaccination date, consultation date, date of symptom onset, type of symptoms and clinical outcome (recovery, transfer to another health facility, or death). More information about adverse events following immunization and an eLearning course on the subject can be found in the WHO vaccine safety basics e-learning course[34].

8.3 Estimating vaccination coverage from administrative data

Estimating the vaccination coverage rate is a useful indicator of the performance of the vaccination campaign both while the campaign is occurring and after it is finished. The coverage rate can be calculated daily during the campaign to determine what percent of the target population is being vaccinated and to make necessary changes. For example, if the percentage of people seeking the vaccination is smaller than what had been anticipated, supervisors may decide to add more hours or days to the vaccination sessions, conduct additional social mobilization, or even have the vaccination teams go door-to-door to provide the vaccine or have a mop-up round. On the other hand, if the coverage is higher than expected in a given area, managers may need to order more vaccine to avoid a stock-out.

The immunization coverage rate is simply the number of people vaccinated as a percentage of all the people eligible for the vaccine in the target areas. In most cases, the denominator is all persons age 1 year and older in the targeted area (if pregnant women are not eligible for vaccination, they should be excluded from the denominator). The formula is:

$$\textbf{Administrative coverage (\%)} = \frac{\textbf{Number of persons vaccinated}}{\textbf{Number of persons age} \geq \textbf{1 year in targeted area}} \times \textbf{100}$$

Vaccination coverage should be calculated for each round to determine the percent of people who received a single dose and of those who received two doses. The number of people vaccinated in each round also calculates the dropout rate:

$$\textbf{Administrative coverage (\%)} = \frac{\substack{\textbf{Number persons vaccinated in} \\ \textbf{Round 2 with two doses} - \textbf{Number of} \\ \textbf{persons vaccinated in Round 1}}}{\substack{\textbf{Number of persons vaccinated in} \\ \textbf{Round 1}}} \times \textbf{100}$$

If the dropout rate between the two rounds is high, supervisors may wish to undertake efforts such as those mentioned above to increase participation in the second round.

The tally sheets and count of vaccine vials should provide an accurate number of the persons vaccinated each day in each vaccination site (the numerator).

The more difficult challenge is to obtain an accurate number of people in the target population (the denominator). This can be especially difficult due to population movement, inaccurate census data or projections, or multiple sources of population data, all with different estimates.

It may therefore be necessary to obtain a new estimate of the target population before starting the vaccination campaign. This could mean:

- Carrying out a new, rapid census of the population in the target areas.
- Using surveys to calculate the density of the population and extrapolate these figures to the area covered by the campaign.
- Using satellite images to estimate population figures.

The most accurate way of obtaining vaccination coverage is by conducting a vaccine coverage survey after the vaccination campaign. Instead of using administrative data, a survey involves selecting a representative sample of households in the target area and asking them about their participation in the campaign, and checking vaccination cards as confirmation.

9. Conclusion

This manual is meant to enable vaccine program managers to carry out OCV campaigns of their own and to develop their own materials for training others to do so. Vaccine program managers with previous experience implementing vaccination programs may have found much of the information to be a simple review of the concepts already in use. For others, however, implementing an OCV campaign is a new challenge. We trust the information contained herein outlines the essential steps in implementing a successful campaign, and helps trainers develop their own training materials and training sessions for members of OCV teams. Additional information about oral cholera vaccine can be found at StopCholera.org. For comments or additions, please contact the authors at info@stopcholera.org.

Credit: Luca Sola, Médecins Sans Frontières, 2015

References

1. Oral cholera vaccines in mass immunization campaigns, guidance for planning and use. WHO, 2010. (Accessed 12.23.2015, at: http://apps.who.int/iris/bitstream/10665/44448/1/9789241500432_eng.pdf.)

2. Addendum to "Oral cholera vaccines in mass immunization campaigns, guidance for planning and use." WHO. (Accessed 12.23.2015, at: http://www.who.int/cholera/vaccines/AddendumGuideVaccinationForShanchol050913.pdf.)

3. Guidance on how to access the oral cholera vaccine (OCV) from the ICG emergency stockpile. International Coordinating Group (ICG), 2013. (Accessed 12.23.2015, at: http://www.who.int/cholera/vaccines/Guidance_accessing_OCV_stockpile.pdf.)

4. Oral cholera vaccine stockpile. WHO, 2016. (Accessed 12.23.2015, at: http://www.who.int/cholera/vaccines/ocv_stockpile_2013/en/.)

5. Framework for developing an integrated communication strategy for the introduction of oral cholera vaccine in cholera prevention and control programmes. UNICEF, 2014. (Accessed 12.23.2015, at: http://www.unicef.org/cbsc/files/Cholera-FrameworkBookV2.pdf.)

6. Guidance note on the use of oral cholera vaccines for UNICEF. UNICEF, 2012. (Accessed 12.23.2015, at: http://www.unicef.org/immunization/files/UNICEF_OCV_Guidance_20_July2012_final.pdf.)

7. Vaccination in acute humanitarian emergencies: a framework for decision making. Who, 2013. (Accessed 12.23.2015, at: http://apps.who.int/iris/bitstream/10665/92462/1/WHO_IVB_13.07_eng.pdf.)

8. Principles and considerations for adding a vaccine to a national immunization programme, from decision to implementation and monitoring. WHO, 2014. (Accessed 12.23.2015, at: http://www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/.)

9. Sack DA, Sack RB, Nair GB, Siddique AK. Cholera. *Lancet* 2004;363:223-33.

10. Ali M, Nelson AR, Lopez AL, Sack DA. Updated global burden of cholera in endemic countries. *PLoS Negl Trop Dis* 2015;9:e0003832.

11. UNICEF cholera toolkit. UNICEF, 2013. (Accessed 12.23.2015, at: http://www.unicef.org/cholera/index_71222.html.)

12. StopCholera toolkit. DOVE StopCholera, 2016. (Accessed 12.23.2015, at: https://www.stopcholera.org/toolkits/stopcholera-toolkit.)

13. Kanungo S, Desai SN, Nandy RK, et al. Flexibility of oral cholera vaccine dosing-a randomized controlled trial measuring immune responses following alternative vaccination schedules in a cholera hyper-endemic zone. *PLoS Negl Trop Dis* 2015;9:e0003574.

14. Bhattacharya SK, Sur D, Ali M, et al. 5 year efficacy of a bivalent killed whole-cell oral cholera vaccine in Kolkata, India: a cluster-randomised, double-blind, placebo-controlled trial. *Lancet Infect Dis* 2013;13:1050-6.

15. Ali M, Emch M, Yunus M, et al. Vaccine protection of Bangladeshi infants and young children against cholera: implications for vaccine deployment and person-to-person transmission. *Pediatr Infect Dis J* 2008;27:33-7.

16. Longini IM Jr, Nizam A, Ali M, Yunus M, Shenvi N, Clemens JD. Controlling endemic cholera with oral vaccines. *PLoS Med* 2007;4:e336.

17. Anh DD, Canh do G, Lopez AL, et al. Safety and immunogenicity of a reformulated Vietnamese bivalent killed, whole-cell, oral cholera vaccine in adults. *Vaccine* 2007;25:1149-55.

18. Mahalanabis D, Lopez AL, Sur D, et al. A randomized, placebo-controlled trial of the bivalent killed, whole-cell, oral cholera vaccine in adults and children in a cholera endemic area in Kolkata, India. *PLoS One* 2008;3:e2323.

19. Sur D, Lopez AL, Kanungo S, et al. Efficacy and safety of a modified killed-whole-cell oral cholera vaccine in India: an interim analysis of a cluster-randomised, double-blind, placebo-controlled trial. *Lancet* 2009;374:1694-702.

20. Saha A, Chowdhury MI, Khanam F, et al. Safety and immunogenicity study of a killed bivalent (O1 and O139) whole-cell oral cholera vaccine Shanchol, in Bangladeshi adults and children as young as 1 year of age. *Vaccine* 2011;29:8285-92.

21. Hashim R, Khatib AM, Enwere G, et al. Safety of the recombinant cholera toxin B subunit, killed whole-cell (rBS-WC) oral cholera vaccine in pregnancy. *PLoS Negl Trop Dis* 2012;6:e1743.

22. Ciglenecki I, Bichet M, Tena J, et al. Cholera in pregnancy: outcomes from a specialized cholera treatment unit for pregnant women in Leogane, Haiti. *PLoS Negl Trop Dis* 2013;7:e2368.

23. Luquero FJ, Grout L, Ciglenecki I, et al. First outbreak response using an oral cholera vaccine in Africa: vaccine coverage, acceptability and surveillance of adverse events, Guinea, 2012. *PLoS Negl Trop Dis* 2013;7:e2465.

24. Cholera vaccines: WHO position paper. *Wkly Epidemiol Rec* 2010;85:117-28.

25. In Brief: Cholera and the use of oral cholera vaccines in pregnant women. DOVE StopCholera, 2016. (Accessed 12.23.2015, at: https://www.stopcholera.org/sites/cholera/files/2_3_cholera_and_pregnancy.pdf.)

26. Grout LM-P, Luquero FJ, Grais RF. Suivi de la campagne de vaccination de masse avec Shanchol®: Surveillance des issues de la grossesse. Ministry of Health, Guinea. : Epicentre, Médecins Sans Frontières; 2014 March 2014.

27. Azman AS, Luquero FJ, Ciglenecki I, Grais RF, Sack DA, Lessler J. The impact of a one-dose versus two-dose oral cholera vaccine regimen in outbreak settings: a modeling study. *PLoS Med* 2015;12:e1001867.

28. Ivers LC, Farmer PE, Pape WJ. Oral cholera vaccine and integrated cholera control in Haiti. *Lancet* 2012;379:2026-8.

29. Ciglenecki 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:e1001512.

30. Annex to the OCV ICG request form. (Accessed 12.23.2015, at: http://www.who.int/entity/cholera/vaccines/Annexes_OCV_ICG_Requestv9Oct2013.xls?ua=1.)

31. Supplies and logistics, cold chain support package. UNICEF, 2015. (Accessed 12.23.2015, at: http://www.unicef.org/supply/index_68367.html.)

32. Causality Assessment of an Adverse Event Following Immunization, User Manual for the Revised WHO Classification. WHO, 2013. (Accessed 12.23.2015, at http://www.who.int/vaccine_safety/publications/aevi_manual.pdf.)

33. Monitoring and evaluation of AEFI during OCV mass vaccination campaigns, "Working Copy". Working group on Monitoring & Evaluation, 2014. (Accessed 12.23.2015, at: http://www.who.int/cholera/vaccines/ocv_aefi_protocol.pdf.)

34. Vaccine safety basics e-learning course. WHO, 2016. (Accessed 12.23.2015, at: http://vaccine-safety-training.org/home.html.)

Annexes

Annex A: OCV Vaccination Card

Front of card

Oral Cholera Vaccine -- Vaccination
Card Ministry of Health

OCV Vaccination Serial Number:

Name: _____   Age (yr): _____

District: _____   Village: _____

Site Name: _____

Oral Cholera Vaccine Dose	Lot no/Entry date	Vaccination date	Date of next vaccination
1st dose			
2nd dose			

Back of card

Key messages for cholera prevention

Drink and use safe water. Safe water is water that is bottled with an unbroken seal, has been boiled, or has been treated with a chlorine product.

Wash food with safe water and either peel food or cook it well, eat it hot, and keep it covered.

Wash hands often with soap and safe water (after using the toilet, before eating or cooking, after eating, after cleaning baby's feces). If no soap is available, brush hands often with ash or sand and rinse with safe water.

Use latrines or bury your feces. Do not defecate in any body of water.

Keep latrines clean.

Annex A Vaccin anticholérique oral - Carte de vaccination

Recto de la carte

Vaccin anticholérique oral --
Carte de vaccination Ministère de la Santé

Numéro de série:

Name: _____   Âge (ans): _____

District: _____   Village: _____

Nom du site: _____

Dose du vaccin anticholérique oral	Lot No/Date d'expiration	Date de la vaccination	Date de la prochaine vaccination
1ere dose			
2eme dose			

Verso de la carte

Messages clés pour la prévention du choléra

Buvez et utilisez l'eau potable. L'eau potable est une eau en bouteille fermée, ou une eau qui a été bouillie ou traitée avec un produit chloré.

Laver la nourriture avec l'eau potable et soit peler soit bien cuire la nourriture, manger chaud, et garder couvert.

Se laver les mains souvent avec de l'eau potable et du savon (après avoir utilisé les toilettes, avant de faire la cuisine, avant ou après avoir mangé, après avoir nettoyé les fesses de bébé). S'il n'y a pas de savon, se frotter les mains souvent avec de la cendre ou du sable et rincer à l'eau potable.

Utiliser des latrines ou enterrer les matières fécales. Ne pas déféquer dans un plan d'eau.

Garder les latrines propres.

Cholera Vaccination Tally Sheet

Sheet N°:………………

Team:…………………………….. District:…………………………………..

Date:……………………………… Health Zone:…………………………………….…

Health Area:………………………………… Neighborhood:………………………………………

Number of vaccine vials used:

Utilization rate= $\dfrac{\text{Number of people vaccinated} \times 100}{\text{Number of doses used}}$ Utilization rate ┌────────────────┐ %

≥ 1yr - 4 yr	(tally circles grid)	
Total 1 - 4 yr		
≥ 5 - 14 yr	(tally circles grid)	
Total 5 - 14 yr		
≥ 15 yr	(tally circles grid)	
Total ≥15 ry		
Grand total		

Check a circle for a given dose (1 person vaccinated)   1 square = 100 doses administered

Utilization	Number of doses received	Extra number of doses received	Total received	Number of remaining doses	Number of doses used
Vaccine doses					

Visial vial monitor

Reading	☐	☐	☐	■
Interpretation		Can be used		Can not be used
Number of VVMs with changed color				

Cholera Vaccination Tally Sheet by Sex

Sheet N°:………………

Team:……………………………….   District:…………………………………..

Date:…………………………………   Health Zone:………………………………………..

Health Area:…………………………………   Neighborhood:…………………………………………

Number of vaccine vials used:

Utilization rate= $\dfrac{\text{Number of people vaccinated} \times 100}{\text{Number of doses used}}$ Utilization rate |_____| %

	Male				Female			
≥ 1yr - 4 yr	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO
Total 1 - 4 yr								
≥ 5 - 14 yr	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO
Total 5 - 14 yr								
≥ 15 yr	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO	OOOOO OOOOO
Total ≥15 ry								
Grand total								

Check a circle for a given dose (1 person vaccinated)   1 square = 100 doses administered

Utilization	Number of doses received	Extra number of doses received	Total received	Number of remaining doses	Number of doses used
Vaccine doses					

Visial vial monitor

Reading		□	□	□	■
Interpretation		Can be used		Can not be used	
Number of VVMs with changed color					

Cholera Vaccination Tally Sheet by Dose

Sheet N°:………………

Team:…………………………………..

Date:……………………………………

Health Area:…………………………………

District:…………………………………..

Health Zone:………………………………………..

Neighborhood:……………………………………

Number of vaccine vials used:

Utilization rate= Number of people vaccinated ×100

Number of doses used

Utilization rate ☐ %

	Vaccine							
	Dose 1				Dose 2			
≥ 1yr - 4 yr	⬤	⬤	⬤	⬤	⬤	⬤	⬤	⬤
Total 1 - 4 yr								
≥ 5 - 14 yr	⬤	⬤	⬤	⬤	⬤	⬤	⬤	⬤
Total 5 - 14 yr								
≥ 15 yr	⬤	⬤	⬤	⬤	⬤	⬤	⬤	⬤
Total ≥15 ry								
Grand total								
	Check a circle for a given dose (1 person vaccinated)				1 square = 100 doses administered			

Utilization	Number of doses received	Extra number of doses received	Total received	Number of remaining doses	Number of doses used
Vaccine doses					

Visial vial monitor

Reading	☐	☐	☐	■
Interpretation	Can be used		Can not be used	
Number of VVMs with changed color				

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Annex B: Feuille de pointage vaccination choléra

Feuille de pointage vaccination choléra

Feuille N°:..................

Equipe:..............................	District:.............................
Date:.............................	ZS: ....
AS:	Avenue/quartier:.............................

Nombre de flacon de shanchol utilisé::

Utilization rate= $\dfrac{\text{Nombre de personnes vaccinées} \times 100}{\text{Nombre de doses utilisés}}$ 　Taux d'utilisation du Schancho 　[　　　　　　　　] %

≥ 1an - 4 ans	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total 1 - 4 ans								
≥ 5 - 14 ans	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total 5 - 14 ans								
≥ 15 ans	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total ≥15 ans								
Grand total								

Cocher un rond pour une dose donné (1 personne vaccinée)　1 Carré = 100 doses données

Consommation	Nombre de flacon recu	Extra reçu durant la journée	Total reçu	Nombre restant	Nombre utilisé
Vaccin Shancho					

Pastille de contrôle

Lecture	▫	▫	▫	■
Interpretation	Utilisé		Non utilis	
Nombre de pastille qui change de couleur				

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Feuille de pointage vaccination choléra - sexe

Feuille N°:.................

Equipe:....................................... District:...

Date:.. ZS: ………………………………………..

AS: ………………………………… Avenue/quartier:..

Nombre de flacon de shanchol utilisé::

Utilization rate= $\dfrac{\text{Nombre de personnes vaccinées} \times 100}{\text{Nombre de doses utilisés}}$ Taux d'utilisation du Schancho [%]

	Homme				Femme			
≥ 1an - 4 ans	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo
Total 1 - 4 ans								
≥ 5 - 14 ans	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo
Total 5 - 14 ans								
≥ 15 ans	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo	ooooo ooooo
Total ≥15 ans								
Grand total								

Cocher un rond pour une dose donné (1 personne vaccinée)   1 Carré = 100 doses données

Consommation	Nombre de flacon recu	Extra reçu durant la journée	Total reçu	Nombre restant	Nombre utilisé
Vaccin Shancho					

Pastille de contrôle

Lecture		▢	▢	▢	■
Interpretation		Utilisé		Non utilis	
Nombre de pastille qui change de couleur					

Feuille de pointage vaccination choléra - dose

Feuille N°:.................

Equipe:...   District:...

Date:...   ZS: ……………………………………………..

AS: ……………………………………   Avenue/quartier:..

Nombre de flacon de shanchol utilisé::

Utilization rate= $\dfrac{\text{Nombre de personnes vaccinées} \times 100}{\text{Nombre de doses utilisés}}$ Taux d'utilisation du Schancho   [%]

	Vaccine							
	Dose 1				Dose 2			
≥ 1an - 4 ans	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total 1 - 4 ans								
≥ 5 - 14 ans	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total 5 - 14 ans								
≥ 15 ans	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○	○○○○○ ○○○○○
Total ≥15 ans								
Grand total								

Cocher un rond pour une dose donné (1 personne vaccinée)   1 Carré = 100 doses données

Consommation	Nombre de flacon recu	Extra reçu durant la journée	Total reçu	Nombre restant	Nombre utilisé
Vaccin Shancho					

Pastille de contrôle

Lecture	☐	☐	☐	■
Interpretation	Utilisé		Non utilis	
Nombre de pastille qui change de couleur				

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Annex C: Daily Logistic Supply and Return Form

District: _____   Health facility: _____

Name of site: _____   Type of site: _____

Vaccination date: _____

	Cholera Vaccine Vials	Cold Box	Vaccine carrier	Waste Bag	Sharps container	Forceps	Marker	Pen	Table	Chair	Banner
No. Supply received											
No. Used											
No. Returned											

Signature of vaccinator: _____

Annex C: Formulaire d'Approvisionnement Logistique et de Retour de Matérielle

District: _____   Centre de santé: _____

Nom du site: _____   Type of site: _____

Date de la vaccination : _____

	Flacon de vaccine contra le cholera	Boite au froid	Porte vaccine	Sac pour les déchets	Récipient pour les objets pointus	Forceps	Marqueur	Stylo	Table	Chaise	Poster
No. Supply received											
No. Used											
No. Returned											

Signature du vaccinateur : _____

Annex D: Supervisor Checklist

<div align="center">

Annex D: Supervisior Checklist

This form is intended to assist supervisors when they visit the different vaccination sites. Most spaces can be answered with a "yes" or "no" or "concern."   If there is a concern with an item, write a short explanation. You may use additional pages to explain these concerns.

</div>

	1st site	2nd site	3rd site	4th site	5th site
Site name					
Community participation					
Are people are gathered at the site?					
Hve local leaders are informed about the vaccination?					
Site Organization					
Has the site identified by a banner?					
Is the full vaccination team present at the site?					
Is sufficient vaccine supply available?					
Is one-way crowd flow established?					
Are Individuals screened for eligibility?					
Vaccinators verify the expiration date of vaccines?					
Do vaccinators check the VVM before opening?					
Do vaccinators shake the vial before opening?					
Do vaccinators observe participants take the whole dose?					
Do vaccinators inform about the date of the second dose?					
Are tally sheets available?					
Are tally sheets used?					
Are the OCV registration cards well completed?					
Cold Chain					
Is the functioning cold chain available (refrigerator/cold box/vaccine carrier)?					
Are the vaccine vials being kept in cold box/refrigerator/vaccine carriers, keeping correct cold chain?					
Are vaccines beging kept so they aer not frozen?					
Waste Management					
Are the metallic lids properly discarded into waste bag after opening the vial?					
Are vaccine vials discarded in the waste bag after administration?					
Are other wastes collected in separate bag?					
AEFI					
Are AEFI forms available?					
Are vaccinees waiting after vaccination?					
Does the vaccinator have adequate knowledge of AEFI?					
Site name	1st site	2nd site	3rd site	4th site	5th site
Remarks					

Supervisor's Name_____

Signature_____

Date_____

Annex E: Daily Reporting Form

Round: _____

Health facility name	Vaccination site name	Date	Fixed site	Mobile team	Additional use	Number of children and adults vaccinated			Cholera vaccine used	
						Target	Total vaccinated	%	Number of vials used	Wastage rate

Supervisor name: _____ Signature: _____ Date: _____

Annex E: Formulaire de notification journalier

Tour: _____

Nom du centre de santé	Nom du site de vaccination	Date	Site fixe	Equipe mobile	Site additionnels	Nombre des enfants de plus de un an et adultes vaccinées			Vaccin contre le choléra	
						Cible	Total vaccinées	%	Nombre de flacons utilisé	Taux de perte

Nom du superviseur : _____ Signature: _____ Date: _____