



Oral cholera vaccines in mass immunization campaigns

GUIDANCE FOR PLANNING AND USE



**World Health
Organization**

Oral cholera vaccines in mass immunization campaigns

GUIDANCE FOR
PLANNING AND USE



World Health
Organization

WHO Library Cataloguing-in-Publication Data

Oral cholera vaccines in mass immunization campaigns:
guidance for planning and use.

1.Cholera – immunology. 2.Cholera vaccines. 3.Mass immunization.
I.World Health Organization.

ISBN 978 92 4 150043 2

(NLM classification: WC 262)

For further information, please contact the
Global Task Force on Cholera Control **cholera@who.int**
or visit our web site at **www.who.int/cholera**.

For a real life experience of a cholera mass vaccination campaign
please view the WHO video “Oral cholera vaccines: a mass vaccination
campaign, Zanzibar, United Republic of Tanzania, 2009” at **http://
www.who.int/cholera/technical/prevention/vaccines/en/index.
html**

© World Health Organization 2010

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Designed by minimum graphics
Printed in France

Contents

1. Background	1
1.1 Introduction	1
1.2 The disease: causative agent, clinical manifestations, prevention	2
1.3 Risk factors, seasonality and vulnerable groups	3
1.4 Usually-recommended prevention and control measures other than vaccines	4
2. Cholera vaccines: general considerations	6
2.1 Internationally-licensed vaccines: specifications	6
2.1.1 Dukoral (WC/rBS)	6
2.1.2 Shanchol	7
2.1.3 Characteristics of currently available vaccines	8
2.2 When should OCV be used: surveillance, assessment tool and decision-making process	8
2.2.1 Surveillance, endemicity and seasonality	9
2.2.2 WHO decision-making tool for OCV use in complex emergencies	9
2.3 WHO recommendations on the use of OCV	10
2.3.1 Recommendations on the use of OCV in complex emergency settings	10
2.3.2 Recommendations on the use of OCV to control cholera outbreaks	11
2.3.3 Recommendations on the use of OCV in endemic settings	11
3. Organizing and implementing a mass vaccination campaign	14
3.1 Registration of the vaccine	15
3.2 Macroplanning – national level	15
3.2.1 Planning and supervision	15
3.2.2 Summary of activities at national level	16
3.2.3 Information, communication and social mobilization	19
3.2.4 Human resources	20

3.2.5 Logistics	23
3.2.6 Budget	31
3.3 Microplanning – district level	32
3.3.1 Planning and activities	32
3.3.2 Immunization session	37
3.4 Common errors that may diminish campaign effectiveness	41
3.5 Mass vaccination campaigns linked to research studies	42
Annexes	45
Annex 1 Decision-making tool for the use of oral cholera vaccine (OCV) in complex emergencies	47
Annex 2 Checklist for immunization campaign activities at national level	55
Annex 3 Staff required and relevant job descriptions	57
Annex 4 Social mobilization and health education messages	62
Annex 5 Forms 1–5: tally sheets and summary tables	65
Annex 6 Team composition in different settings	72
Annex 7 Flowchart	74
Annex 8 Explanation and flow chart for control forms	75
References	82

1. Background

1.1 Introduction

About 1.8–2.8 million people die of diarrhoea every year, representing 3.7% of the 56 million deaths recorded globally. For children under the age of 5, the percentage of deaths due to diarrhoea reaches 15–19%. In low- and middle-income countries, diarrhoea is the second killer among communicable diseases after lower respiratory infections, the seventh when considering all causes of death. DALY calculation shows that diarrhoea ranks sixth among the causes of burden of disease, third among communicable diseases.

Epidemiological trends indicate that epidemic-prone diarrhoeal diseases have been rising in recent years. Massive outbreaks of cholera, a disease representing roughly 4.2% of all epidemic diarrhoea, now affect countries that had been free of the disease for decades. Cholera remains an important public health problem for many countries, and it is estimated that the disease kills between 75 000 and 120 000 people every year. Usually-recommended prevention and control measures are efficient, and WHO recommendations in this regard have not changed. However, they often cannot be put in place with sufficient timeliness and sustainability, which is why WHO is now considering the use of new tools that may contribute to lowering the effect of cholera on at-risk populations. Among them, safe and effective oral cholera vaccines (OCV) are now available, and WHO recommendations regulating their use have recently been issued and a 3-step decision-making tool developed for crisis situations, to guide policy-makers in their decision on whether to use OCV during complex emergencies (1,2).

In this context, the Global Task Force on Cholera Control decided to issue practical information on the preparation and implementation of mass vaccination using OCV, intended for all (governments, institutions or NGOs) that might be involved in any phase of a mass vaccination campaign using OCV. This document aims to help organizers to prepare and implement campaigns in order to maximize benefits for the population.

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

Information given here is essentially drawn from WHO’s direct experience in the use of OCV.

1.2 The disease: causative agent, clinical manifestations, prevention

Cholera is an acute enteric infection caused by the ingestion of the bacteria *Vibrio cholerae* O1 or O139.¹ Transmission of the disease occurs through direct faecal-oral contamination or through ingestion of contaminated water or food. It is characterized in its most severe form by a sudden onset of acute watery diarrhoea with or without vomiting that may lead to death in a few hours as a result of severe dehydration, acidosis, circulatory collapse, hypoglycaemia in children and renal failure. Both children and adults may be affected. The extremely short incubation period – two hours to five days – enhances the potentially explosive pattern of outbreaks, so that the number of cases rises very quickly.

The infectious agent *V. cholerae* O1 is of two biotypes – classical and El Tor – that include three serotypes (Inaba, Ogawa and, rarely, Hikojima). However, the classical biotype has not been identified since the early 1990s. *V. cholerae* O139, first identified in Bangladesh in 1992 and currently present in various areas in South Asia, possesses the same virulence factors as O1, and creates a similar clinical picture. Reservoirs are human beings and environmental pockets – brackish water and estuaries – in association with copepods and zooplankton.

During the 19th century, cholera spread repeatedly from its original reservoir in the Ganges delta to the rest of the world, before receding back to South Asia. Six pandemics were recorded, killing millions of people across Europe, Africa and the Americas. The seventh pandemic, still ongoing, started in 1961 in South Asia, reached Africa in 1971 and the Americas in 1991. It is now considered that the disease is endemic in many countries, and that the pathogen causing cholera remains in the environment. It must therefore be controlled in order to limit its impact on populations.

About 75% of cholera cases are asymptomatic. Among those presenting symptoms, 80–90% develop acute watery diarrhoea, and 10–20% of these cases develop severe watery diarrhoea with vomiting. If untreated, the case-fatality rate may reach up to 40%; with proper treatment, it should remain below 1%.

The WHO standard case definition states that cholera should be suspected when:

.....

¹ *V. cholerae* non-O1 non-O139 can cause mild diarrhoea but do not generate outbreaks.

1. In an area where the disease is not known to be present, a patient aged 5 years or more¹ develops severe dehydration or dies from acute watery diarrhoea.
2. In an area where there is a cholera epidemic, a patient aged 5 years or more develops acute watery diarrhoea, with or without vomiting.

Diagnosis is confirmed by isolating *V. cholerae* O1 or O139 from faeces through laboratory testing. To ensure the quality of samples, Cary Blair transport medium should be used for transport and storage of rectal swabs. Laboratory testing is also required to determine antimicrobial resistance and should be performed regularly on a selected number of patients in the course of an outbreak to detect any change in antimicrobial susceptibility patterns.

1.3 Risk factors, seasonality and vulnerable groups

Cholera, a waterborne disease, is closely linked to inadequate environmental management. The absence or shortage of safe water and sufficient sanitation and, generally, poor environmental status are the main causes of spread of the disease. These factors are present in many places in the developing world, and even more acutely in overcrowded settings. Typical at-risk areas are periurban slums, where basic infrastructures are not available, as well as camps for internally displaced persons or refugees, where the minimum requirements² of clean water and sanitation are not met. The populations most affected are therefore those living in insalubrious conditions, where environmental safety is not ensured.

In the context of complex emergencies, it is important to stress that beliefs regarding cholera epidemics caused by dead bodies after disasters, whether natural or man-made, have been dismissed based on evidence (3,4) but uncontrolled rumours and panics are often rife. However, the consequence of a disaster – disruption of water and sanitation systems, massive displacement of populations to inadequate and overcrowded camps, etc. – may increase the risk of transmission, should the pathogen be present or introduced.

Cholera is now present in many countries. The occurrence, spread and extent of outbreaks remain extremely difficult to predict. They depend on a multiplicity of well-known factors, including local endemicity, living

.....

¹ Children < 5 years of age are excluded from the standard case definition as, at an early age, several pathogens may cause similar symptomatology that, without proper testing, cannot be distinguished one from another. It does not mean that young children cannot be affected by cholera.

² According to SPHERE standards: at least 15 litres/person/day; latrines: maximum 20 persons per latrine (<http://www.sphereproject.org>).

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

conditions, forced or voluntary population movements, as well as environmental and cultural factors. Therefore, an efficient surveillance system aiming to collect reliable baseline data can help significantly to identify epidemiological patterns. This is especially true in endemic settings where cholera appears regularly, sometimes linked to specific climatic and cultural conditions. If seasonal recrudescence could be anticipated, prevention and control would be enhanced. The availability of good epidemiological data is paramount to ensure the efficient implementation of any prevention and control measure put in place, especially if the use of OCV is envisaged.

Cholera is extremely virulent and, unlike other enteric diseases, may kill healthy adults and children within hours. In addition, particular groups among populations at risk appear even more vulnerable to severe and fatal forms of the disease. For example, field observations of AIDS and cholera comorbidity tend to indicate that HIV-positive persons suffer from more severe diarrhoea in repeated and longer episodes, their immunodeficient system being unable to produce natural immunity. Specific studies have yet to be conducted, but this issue merits attention, since many countries endemic for cholera also report very high levels of HIV seroprevalence. Other weakened individuals, such as malnourished children, are also at greater risk of death if infected by cholera.

1.4 Usually-recommended prevention and control measures other than vaccines

Measures for preventing cholera have not varied significantly in recent decades, and are based mainly on the provision of clean water and proper sanitation to populations potentially affected. Information and health education designed for community leaders and the general public, which should lead to behaviour change, are equally important.

Once an outbreak is detected, the usual intervention strategy aims to reduce mortality – ideally below 1% – by ensuring access to treatment and controlling the spread of disease by implementing hygiene and disinfection measures. To achieve this, all partners involved should be properly coordinated and the water and sanitation sector must be included in the response strategy.

The majority of patients with cholera may be treated through the administration of oral rehydration salts (ORS); very severe cases only are treated through the administration of intravenous fluids, preferably Ringer lactate. Appropriate antibiotics may be given to severe cases to diminish the duration of diarrhoea, reduce the volume of rehydration fluids needed and shorten the duration of *vibrio* excretion. Antimicrobial resistance should

be monitored throughout the outbreak. Oral rehydration corners (ORC) and cholera treatment centres (CTC) should be set up in affected areas to provide easily accessible and timely treatment. In addition, specific training should be given to health-care staff, and sufficient medical supplies should be available. Coordinated information and communication strategies should also be implemented.

Detailed information on other recommended prevention and control measures may be found in three key WHO technical guidelines that describe case management and outbreak assessment precisely, and are designed for health-care staff and professionals involved in cholera control activities (5).

1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

3.1 OCV Registration

3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies

2. Cholera vaccines: general considerations

Two types of oral cholera vaccines are available, of which only one is currently prequalified by WHO. Both vaccines are safe and procure a protection of > 50%, lasting for 2 years in endemic populations. They require cold-chain conditions and are given in 2 doses, between a minimum of 1 and a maximum of 6 weeks apart.

A number of other cholera vaccines – oral and parenteral, killed and live – are under development. Other vaccines are being produced in certain countries, such as China or Viet Nam, but cannot be internationally marketed or prequalified by WHO owing to general regulatory issues. They will therefore not be described here.

The previously licensed oral single-dose vaccine consisting of an attenuated live and genetically modified *V. cholerae* O1 strain (CVD 103-HgR) is no longer manufactured and is thus not available.

The use of the early parenteral cholera vaccine has been almost abandoned, owing to its low protective efficacy and the high occurrence of severe adverse reactions. WHO has never recommended the use of this vaccine.

2.1 Internationally-licensed vaccines: specifications

2.1.1 Dukoral (WC/rBS)

The only internationally available vaccine, currently produced in Sweden by Crucell Biotechs under the commercial name Dukoral®, was granted WHO prequalification and has been licensed in more than 60 countries. It consists of killed whole-cell *Vibrio cholerae* O1 with purified recombinant B-subunit of cholera toxin (WC/rBS).¹ The vaccine is supplied in 3 ml 1-dose vials, each with a sachet of sodium bicarbonate buffer, and is administered in 2 doses, between a minimum of 1 and a maximum of 6 weeks apart.

.....
¹ Each dose consists of 1 mg recombinant cholera-toxin B-subunit and approximately 10¹¹ inactivated whole cells of the classic and El Tor biotypes of *V. cholerae* O1, serotypes Inaba and Ogawa.

Each dose of the vaccine should be administered in 150 ml of water (75 ml for children aged 2–6 years) mixed with the buffer. Due to the large volume of liquid associated with the vaccine, it cannot be administered to children aged < 2 years. The protection starts approximately 1 week after ingestion of the second dose, and gives a demonstrated protection of 85–90% at 6 months in all age groups, and of 62% at 1 year among adults (6). Vaccinees must be informed of the necessity to fast for 1 hour before and 1 hour after ingesting the dose.

Dukoral is prequalified to be stored between + 2 °C and + 8 °C, and is stable for 1 month at 37 °C. Nevertheless, this vaccine should be kept under a strict cold chain, except during the day of vaccination where cold-chain conditions can be less stringent for vaccines that are being used the same day in the field. The volume of a single dose of OCV is almost 15 times the volume of other vaccines used in mass vaccination (e.g. measles vaccine).

No adverse event was noted in pregnant women taking the vaccine, a fact biologically logical since OCV is not absorbed in the bloodstream but stays in the gut. However, no study was conducted on pregnant women to prove this assumption scientifically. Women should therefore be informed and the choice of taking the vaccine or not should be left to them alone. The same may be said for HIV-positive persons. As the vaccine does not enter the bloodstream, the risk of causing an infection is minimal. However, the risk might be higher for advanced immunocompromised HIV patients.

2.1.2 *Shanchol*

Shanchol is the second type of vaccine, licensed in India in 2009. It is the result of a modification of an initial North-South technology transfer of Dukoral to Viet Nam via India and the Republic of Korea. This vaccine is currently undergoing WHO prequalification. It is a bivalent vaccine protecting both against *V. cholerae* O1 and O139. Unlike Dukoral, this vaccine does not contain the bacterial toxin B-subunit and thus does not require any buffer for administration. Shanchol is administered in 2 doses, 2 weeks apart, and is provided in single-dose vials.

The shelf-life is 2 years at a temperature of +2 and +8 °C; stability data at room temperature are still being collected. An interim analysis of an ongoing phase III clinical trial has shown 67% protection against culture-confirmed cholera among all age groups of those who received 2 doses, and no decline of protection was observed during the second year of follow-up.

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control

This document concentrates on the WHO-prequalified 2-dose vaccine (Dukoral), while recognizing that this guidance for use is also valid for the second type of vaccine (Shanchol) except for the aspects related to the logistics of water, as this latter vaccine does not require any buffer. Since the specifications of the various vaccines under development might vary significantly from those of OCV available today, guidelines will be updated once these new vaccines are on the market, and once their public health use in mass immunization has been demonstrated.

2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

2.1.3 Characteristics of currently available vaccines

COMMERCIAL NAME	Dukoral® (WC/rBS)	Shanchol ® (variant WC)
Protection against	<i>V. cholerae</i> O1 for > 50% for 2 years	<i>V. cholerae</i> O1 and O139 for > 50% for 2 years
Exclusion criteria	Children < 2 years	Children < 1 year
Presentation	Oral suspension (vaccine) and effervescent granules (buffer)	Oral suspension (vaccine)
Shelf-life	3 years	2 years
Storage	Cold chain (+2 – +8 °C)	Cold chain (+2 – +8 °C)
Stability at ambient temperature	1 month at 37 °C	Stability tests ongoing
Administration course	2 doses min. 1 to max. 6 weeks apart	2 doses 2 weeks apart
Amount of drinking-water needed/dose	150 ml for adults and children > 6 years 75 ml for children aged 2–6 years	None
Current price (Dec. 2010)	~ € 3.5 per dose	~US\$ 1.5 per dose
WHO prequalified	Yes	Not yet

2.2 When should OCV be used: surveillance, assessment tool and decision-making process

Practical considerations should be taken into account when deciding upon implementing a mass vaccination campaign using OCV. Vaccination, when used, should not disrupt other priority health interventions. While vaccines provide a short-term effect as an immediate intervention to a potential cholera outbreak, expanding access to improved drinking-water sources and sanitation constitutes a longer-term solution for most water-borne diseases. Since 2000, several public health interventions using OCV

have taken place with the technical support of WHO. Experience gained highlights major challenges remaining, including the need to improve risk assessment, the difficulty in defining the target population, as well as the logistic challenges of delivering a multidose vaccine through a mass vaccination campaign (7).

2.2.1 Surveillance, endemicity and seasonality

Sensitive surveillance using the WHO standard case definition and frank reporting aim at collecting reliable baseline data. When analysed, these data help to identify trends over time as well as vulnerable populations living in high-risk areas. Recently, endemic cholera has been defined as “the occurrence of faecal culture-confirmed cholera diarrhoea in a population in at least 3 of the past 5 years” (8).

An analysis of existing data (seasonality, baseline data, etc.) needs to be conducted to determine the best timing for vaccination in order to enhance the protection of the population. Past experience has shown that a 2-dose vaccine cannot be used once an outbreak has started in a given population, except to protect other well-defined but not-yet-affected population groups at risk of contamination.

Prevaccination surveillance should be maintained and reinforced once the target population has been identified, in order to monitor the impact of vaccination programmes (e.g. among particular age groups and spatial clusters).

2.2.2 WHO decision-making tool for OCV use in complex emergencies

The WHO decision-making tool assists governments and other agencies in determining the relevance of cholera vaccination in a given setting.¹ A three-step process is proposed to assess:

- the risk of a cholera outbreak (this assessment should be undertaken first);
- whether key public health priorities are or can be implemented in a timely manner together with an analysis of the capacity to respond to a possible cholera outbreak;
- the feasibility of an immunization campaign.

.....
⁵ See Annex 1.

1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

3.1 OCV Registration

3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies

2.3 WHO recommendations on the use of OCV

In view of recent major prolonged outbreaks as well as new emerging strains that seem to be more virulent, WHO has issued a new position paper on cholera vaccine use (7). WHO recommends that current available cholera vaccines be used as complements to traditional control and preventive measures in areas where the disease is endemic and should be considered in areas at risk for outbreaks. Vaccination should not disrupt the provision of other high priority health interventions to control or prevent cholera outbreaks (8).

WHO’s recommendations on the use of OCV during complex emergencies (2) elaborated by a group of experts in Cairo, Egypt, on 14–16 December 2005, specify the use of a multidisciplinary approach when OCV is administered during emergencies, as well as the need to consider its use within broader public health priorities.

2.3.1 Recommendations on the use of OCV in complex emergency settings

WHO specifies the following concerning relevance and a multidisciplinary approach when considering using OCV during a complex emergency situation (2).

- The relevance of oral cholera vaccination should be examined in the light of other public health priorities. Among the top 10 priorities in emergencies is the control of communicable diseases, which should always include a risk assessment for cholera.
- The WHO risk-assessment tool and the 3-step decision-making tool (2)¹ should guide health authorities in their decision on whether to use OCV during complex emergencies.
- If a cholera vaccination campaign is deemed necessary after assessment of epidemic risk and public health priorities, water and sanitation programmes should be implemented before or concurrently with the vaccination campaign. The existing surveillance system should be maintained and reinforced.
- A high-level commitment by all stakeholders and national authorities is critical.

Exclusion criteria for OCV use (2):

- Vaccination with the current internationally available WHO-prequalified vaccine is not recommended once a cholera outbreak has started,

.....
⁵ See Annex 1.

unless a ring-vaccination can be envisaged to limit the spread to well-defined not-yet-affected population groups.

- An OCV campaign that would interfere with other critical public health interventions should not be carried out.
- Other exclusion criteria include: very high mortality from a range of causes; basic needs (food, shelter) not covered; an ongoing outbreak of another disease; an untenable security situation.

2.3.2 Recommendations on the use of OCV to control cholera outbreaks

During outbreaks, key priority control measures should be sustained. They include timely and proper case management of cholera patients, expanding access to improved sources of drinking-water and sanitation, and working with communities to encourage behavioural change to diminish the risk of infection.

Reactive vaccination (8) might be considered in view of limiting the extent of large prolonged outbreaks, provided the local infrastructure allows it, and an in-depth analysis of past cholera data and identification of a defined target area have been performed.

Preventing the occurrence of potential outbreaks, based on risk assessment and epidemiological data, should be considered through pre-emptive vaccination (8) in addition to usually-recommended control measures. Pre-emptive vaccination may also be considered to limit the spread of outbreaks to new areas at risk. However, challenges in assessing the risk for outbreaks are huge, as the trigger responsible for cholera outbreaks has not yet been identified.

Ideally pre-emptive and reactive vaccination should cover as many people as possible who are eligible, and should occur as quickly as possible.

2.3.3 Recommendations on the use of OCV in endemic settings

When using OCV in endemic settings (8) it is important to target the population identified as being most at risk. This should be done based on a thorough analysis of past cholera data in the area concerned. Vaccine use must be complementary to existing strategies for cholera control, such as safe water and sanitation, case management, and health education of the community.

Target population

The target population for cholera immunization varies extensively from that for other vaccines, e.g. meningitis or measles, that exclusively target

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

children and teenagers under the age of 15 years. In the case of cholera, the entire population aged > 2 years¹ is considered. Infants < 2 years are not included owing to the large amount of liquid (75–150 ml) required to absorb each dose of vaccine. Pregnant women should be given the choice to take the vaccine or not after having been informed of the characteristics of the vaccine; no adverse effect has been noted in pregnant women but no scientific study has been conducted on this issue.

At-risk populations are those living without acceptable access to safe water and proper sanitation. They comprise inhabitants of impoverished periurban areas, certain rural areas or refugee camps. Other vulnerable settings, such as detention centres, might also benefit from such immunization. Areas targeted for mass immunization may therefore be very diverse, and only a prior situation analysis can help determine who needs to be vaccinated. Nonetheless, given the high price of the vaccine, the difficulty of dealing with a 2-dose product and the fact that all age groups should be immunized, cost-effectiveness and feasibility aspects should be included in the determination of the target population.

Vaccination strategies and sustainability

In the context of complex emergencies, the sustainability of vaccination strategies is not the main concern, and actions are directed to short-term prevention of further damage. The objective is to gain time to be able to repair infrastructures and resume the provision of basic services.

The situation in endemic countries is rather different. In endemic areas, when it is decided to use OCV in mass vaccination, vaccination strategies should be clearly defined, and sustainability ensured. If this is not the case, there is a high risk associated with engaging in a one-shot action that, in the mid- and long-term, may prove to be inefficient or even counterproductive. Countries envisaging the introduction of OCV should establish a strategy allowing sustainability and acceptance by the population. Surveillance data should be available in order to decide on the timing and areas to be targeted.

Furthermore, the concept of herd protection should be taken into account, since it may play a major role in increasing the impact of vaccination and reducing the cost and burden of cholera. A recent study has established the existence of an additional indirect protective effect among both vaccinated and non-vaccinated individuals when a high proportion of the population was vaccinated, and a possible reduction of the incidence of cholera in all age groups (9). More evidence needs to be gained on

.....
¹ > 1 year for Shanchol.

the effect of herd protection in various settings to ascertain the threshold level of vaccination needed to achieve an acceptable level of protection in a community.

Each situation is special, and it is impossible to determine one strategy valid for all. But common elements should be examined:

- OCV vaccination usually targets all people > 2 years¹ of age within a particular high-risk area.
- OCV must be administered in 2 doses, between a minimum of 1 and a maximum of 6 weeks apart.
- Revaccination should be scheduled to occur 2 years after initial immunization, unless longer-term efficacy of the vaccine becomes available.
- Covaccination should be avoided in order not to diminish the effect of other vaccines, or there should be one day at least before the administration of another vaccine.

Periodic mass vaccination campaigns are probably the best vaccine delivery strategy. Community settings such as schools, health-care centres and religious institutions may be appropriate venues for the campaigns. Another option may be incorporating OCV in routine vaccination, particularly for young children between campaigns.

Timing

The epidemiological pattern and anticipated occurrence of cholera is extremely difficult to establish with any certainty, especially in the numerous countries worldwide where surveillance data are lacking. However, in endemic settings seasonal characteristics – drought, floods or rainy season – tend to increase the risk of transmission. In addition, many elements may influence the decision to vaccinate and the timing to be adopted. For instance, the risk of spread of an outbreak from a neighbouring region or country may lead to such a decision, as may massive displacements of populations from or into an endemic area. Only a careful examination of specific surveillance, population, meteorological, geographical and cultural data are able to provide valuable information that will allow those responsible to make a decision.

.....

¹ > 1 year for Shanchol.

1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

3.1 OCV Registration

3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies

3. Organizing and implementing a mass vaccination campaign

Experience shows that a mass vaccination campaign involving more than 50 000 people may be implemented in as little as 3 weeks, provided that the campaign has been well planned, that all elements are in place, that security is ensured, and that the population is well defined, not mobile, well organized and willing to support the campaign. Conversely, campaigns are likely to extend over several months when planning and implementation are complicated by internal and external factors. The duration therefore depends on realistic practical considerations based mainly on resources and logistic issues. It is in any case crucial that the 2 doses of vaccine are administered strictly between a minimum of 1 and a maximum of 6 weeks apart.¹ Not respecting this timing jeopardizes the protective efficacy of the vaccine.

Experience has shown that the majority of people come for vaccination during the first 2 days, weekends (adult males) and the last day. It is therefore preferable to plan vaccination rounds not exceeding 6 days to maintain interest and good dynamics among the target population and staff performing the vaccination.

Only people having received the 1st dose during the 1st round session are authorized to receive the 2nd dose of vaccine during the 2nd round session. Authorizing people to get their 1st dose during the 2nd round session will oblige, for ethical reasons, to organize a 3rd round session within 6 weeks to permit these people and those who had missed the 2nd round to receive their 2nd dose.

Annex 5 contains key control forms including tally sheets and summary tables to ease follow-up and monitoring of the mass vaccination campaign. For further explanations and a flow chart on the use of these forms, see *Annex 8*.

.....
¹ 2 weeks apart for Shancol.

3.1 Registration of the vaccine

Before any campaign is planned, the vaccine should be officially registered by the national regulatory authorities of the country where the campaign will take place. Import authorizations and customs clearance should be negotiated and obtained well before the start of the project to avoid any delay in its implementation. Those responsible for the project should be aware that this process may be time-consuming, especially if the OCV is not already licensed in the country.

3.2 Macroplanning – national level

Once a vaccination campaign has been decided, planning should start immediately. Experience shows that mobilizing the support of authorities and partners is the basis of success. National authorities, including the ministry of health, should be fully involved in the vaccination project from the earliest stage.

High-level political commitment is essential; all sectors involved should be in agreement and a memorandum of understanding describing tasks and responsibilities should be signed by the different parties involved. Coordination should be functioning, and an intersectoral coordinating committee should be established, with the participation of the different departments involved at the level of the ministry of health, other ministries, implementing partners (NGOs), etc. Appropriate thematic subcommittees and a plan of action should also be established, to cover the five following sectors of intervention:¹

1. planning and supervision (including target population identification and schedule);
2. information, communication, social mobilization, community involvement and health education;
3. human resources;
4. logistics;
5. budget and finance.

3.2.1 Planning and supervision

Selection of target areas

The results of a thorough risk assessment for cholera outbreaks, performed during the decision-making process, should be analysed to define areas most at risk whose inhabitants will clearly benefit from vaccination. A cost-effectiveness analysis should also be performed.

.....

¹ See Annex 2.

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

Target population

An estimate as precise as possible of the target population is a prerequisite. As all age groups – except children < 2 years¹ of age – should be given the vaccine, an assessment and mapping of the target population should be conducted well in advance. The larger the target population, the more difficult the campaign will be, in terms of practical, financial and logistic factors.

Population data should be obtained, if possible, from an official source and everyone involved in the planning should use the same figures. If several estimates are available, the highest figures should be privileged in order not to face a shortage of materials and vaccines.

If disaggregated figures are not available, a percentage representing the proportion of children < 2 years should be deducted. Usually, 4–8% of a population is aged < 2 years. However, particular circumstances may impact on this percentage (e.g. massive displacement of children and mothers may increase the percentage, or certain types of disasters, as in Indonesia, where only few children escaped the tsunami, may lower it). The latest updates should be used when the target population is highly mobile.

EXAMPLE
Target population for a target area of 20 000 inhabitants

The age-range population data are not available; the average figure of 4% of children < 2 years is therefore taken as a basis for calculation. The target population includes all except children < 2 years.

20 000 – (4% x 20 000) = 20 000 – 800 = 19 200 persons.

3.2.2 Summary of activities at national level

A table summarizing planned activities, schedule, responsible person/ institution and budget is an extremely useful tool. The example below is indicative and should be adapted to local circumstances.

.....
¹ < 1 year for Shanchol.

PLANNING AND PREPARATION

PHASE 1

Macroplanning

- Ensure that the vaccine is registered by the national regulatory authorities
- Establish intersectoral coordinating committee and thematic subcommittees
- Analyse epidemiological data to define target areas
- Determine target areas
- Assess as precisely as possible figures of target population
- Define responsibilities and task-sharing
- Define and disseminate schedule of activities
- Define budget
- Place order for vaccines
- Assess storage, cold-chain and waste-disposal facilities
- Meet district leaders and health officials
- Establish local responsibilities
- Develop plan for social mobilization
- Define the number of immunization points and assess feasibility at field level
- Assess needs in staff
- Assess training needs
- Define logistic forms
- Request logistic material
- Identify waste-disposal measures
- Start activities to address gaps
- Finalize the budget for all components of the campaign
- Develop and field-test guidelines and checklists
- Develop and field-test social mobilization and advocacy material

PHASE 2

Microplanning

- Reconcile macroplanning and microplanning data, information and outcomes
- Revise budget if necessary
- Print and distribute field guidelines to districts
- Receive all cold-chain and immunization supplies; review storage and logistic situation
- Develop and print supervisory checklists
- Develop and print tally sheets and summary forms
- Prepare training on running an immunization session
- Develop radio and television announcements and press articles
- Print social mobilization and advocacy material
- Develop evaluation plans

PHASE 3

Final phase of preparation

- Conduct training for immunization staff
- Prepare launching ceremony
- Verify availability of transport for materials and staff
- Finalize logistic spreadsheets and ensure consistency of calculations at all levels
- Reassess the different immunization points
- Receive vaccines to be stored in cold rooms
- Make supervisory visits to problematic districts
- Prepare supervisory teams
- Confirm preparation for opening ceremony

1. Background	Planning and preparation (continued)	
1.1 Introduction	— Intensify all community social promotion activities — Begin newspaper, radio and television announcements — Dispatch vaccines to districts according to storage availability	
1.2 Disease		
1.3 Risk factors	IMPLEMENTATION	
1.4 Prevention and control	1 day before	— Visit and supervise vaccination posts to assess level of preparedness — Send the estimated amount of vaccines for 1 day to all vaccination points — Conduct press briefing — Prepare site for opening ceremony
2. Cholera vaccines	Day 1	— Conduct opening ceremony — Supervise immunization posts
2.1 Licensed OCV	Daily during 1st dose	— Organize a daily meeting to revise field events and outcome of activities at all levels — Collect daily reports (data + logistic report) — Report estimated coverage on a daily basis and main logistic issues
2.2 When to use	Between two rounds	— Review logistics (waste management, cold chain, etc.) at all levels — Review vaccination rate and fine-tune for improvement — Conduct social mobilization to remind that it takes 2 doses to be vaccinated — Train staff on 2nd dose immunization session
2.3 WHO recommendations	Daily during 2nd dose	— Meet once a day (morning or evening) to revise field events and outcome of activities at all levels — Review supervisory checklists at all levels on a daily basis — Review logistic records/logistic issues on a daily basis
3. Mass vaccination campaign	POST-VACCINATION	
3.1 OCV Registration	2–3 days after	— Estimate immunization coverage — Check AEFI (adverse events following immunization) reporting system — Check waste management/recycling — Give preliminary feedback to communities/public on campaign results to date — Decide on use of remaining vaccines (who and where)
3.2 Macro-planning	2 weeks after	— Meet all district and national coordinators to review campaign
3.3 Microplanning	1 month after	— Calculate expenditure — Compile and submit technical report
3.4 Common errors		
3.5 Research studies		

3.2.3 Information, communication and social mobilization

Before beginning the immunization campaign, information on the objectives of the campaign and on selected target populations should be communicated to all stakeholders and local authorities. Information will continue throughout the campaign and, at the end, results must be communicated. The usual preventive measures should be recalled and the fact that vaccination comes in addition to, and not in replacement of these, should be highlighted.

Social mobilization

Before and during the immunization campaign, social mobilization activities should be intensified; all information on the campaign (target population, target area, immunization points and dates) should be disseminated. Key messages for cholera prevention should also be widely disseminated.¹ Several media may be used, such as radio, TV, newspapers, mobile teams equipped with loudspeakers, posters, leaflets, etc. Enrolling prominent figures from the community (schoolteachers, religious leaders, but also singers or actors) can help disseminate the message. In addition, social mobilization may also be conducted in places where people tend to wait without having much to do, and are therefore available to listen to specific messages. Hairdressers' salons, bus stops or other such places can be targets. The success of social mobilization strategies depends largely on local and cultural specificities and how well they are understood and integrated into strategy and message development. Special care should be taken to avoid cultural misunderstandings that might jeopardize the success of the vaccination campaign. Campaign organizers should also be attentive to negative messages spread by opponents to the campaign. Specific strategies should be developed and attempts to enter into dialogue with potential opponents should be undertaken.

It is very important that the population understand that the immunization campaign is a preventive measure additional to the usual ones, and that safe drinking-water, safe food, good personal hygiene and adequate sanitation should be maintained or reinforced. Specific social mobilization and communication messages and the best ways to disseminate them should be determined in coordination with communication professionals, media and public health specialists. Special attention should be paid to local customs, sociocultural determinants, literacy rates and languages.

Social mobilization should start at least two weeks before the beginning

.....
¹ See *Annex 4*.

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

of the vaccination session. The campaign itself should be launched with an opening ceremony in which high-ranking officials should participate.

3.2.4 Human resources

Staff for immunization posts

The success of mass campaigns depends largely on having a sufficient number of vaccination teams. A team usually comprises vaccinators and volunteers, preferably chosen among the population to be vaccinated. Qualified health workers should be drawn carefully from hospitals and/or health facilities to ensure the least possible disruption of essential services, including routine EPI activities. The fact that OCV is administered orally, and not injected, means that only a minimum number of medically trained people need to be involved, therefore not disturbing excessively other medical tasks. In addition, oral vaccines do not usually trigger severe adverse events. However, proper training must be provided to all vaccination team members, and it is advisable that each team comprises a medically-trained person.

A vaccination team consists of a *minimum* of four people:

Person 1: responsible for screening for eligibility and filling out the immunization card;
 Person 2: responsible for buffer-solution¹ preparation and pouring the correct amount of buffer solution into the cup;
 Person 3: vaccinator, responsible for mixing the vaccine with the buffer solution and checking the full ingestion of the vaccine;
 Person 4: responsible for filling in tally sheets and stamping (or signing) the immunization card.

A fifth person may be added:
 Person 5: communicates health education messages.

Depending on the setting, an additional person may be needed to control the crowd. The composition of vaccination teams may also vary depending on the registration system. For a mass vaccination campaign linked to research studies, the number of team members should be increased (see *Table 1* below).

To optimize the number of persons vaccinated per hour per team, the following should be ensured:

- circulation in vaccination post perfectly planned;
- no bottleneck in screening area;
- no shortage of materials;
- adequate number of staff;
- effective social mobilization.

Proposed vaccination team composition^a

Type of vaccination	Vaccination in emergencies		Planned mass vaccination						Planned mass vaccination related to a study	
Type of record	Marking and tally sheet only		Vaccination card (marking and tally sheet)		Vaccination card (marking and tally sheet)		Tally sheet, vaccination card and registry logbook (marking optional)		Tally sheet, vaccination card and registry logbook (marking optional)	
Team member/ description of task	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose
Total number of persons per team	6	6	6	6	11	10	14	13	17	13
Number of persons vaccinated per team per hour	50–70	50–70	40–60	50–60	80–100	90–110	70–90	70–90	60–90	60–90

^a Detailed job descriptions can be found in *Annex 3*.

The number of vaccination teams to be mobilized should be estimated taking into account the duration of the campaign (each round) and the size of the target population. It will also depend directly on the number of staff available.

Staff at district and national level

Whenever possible, EPI staff should be in charge of preparing and implementing the OCV campaign and should follow the plan of action.

Supervision and monitoring

Supervision is necessary to ensure the quality of planning and implementation. The success of a campaign largely depends on the work of motivated supervisors who assist in preparation, support training and are able to identify and solve problems before referring issues to the next management level.

Supervisors at central level should visit all districts five weeks before the

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

start of the campaign and revisit selected districts with particular difficulties or organizational questions (logistics, social mobilization, etc.) three weeks before the start of the campaign.

Supervisors at district level should meet all team leaders and visit vaccination posts two weeks before the start of the campaign, and revisit problematic places one week beforehand. Visits are also paramount between the two rounds. Several households in the neighbourhood should be visited between two and five days before the OCV campaign (1st and 2nd round) in order to verify whether the population is aware of the campaign, dates, target population and location of the nearest vaccination post. If the survey indicates that social mobilization is inadequate or ineffective, efforts should be intensified and effective messaging to the population reinforced.

Sector supervisors should verify that, during immunization sessions, teams follow set procedures, collect tally sheets and fill in daily summary reports.¹ They are also in charge of quality control.²

Staff in charge of logistics

- At national level, one person should be responsible for:
- purchase, reception and storage of vaccines and materials;
 - dispatch of vaccines and materials to the selected areas.

At each level, one staff member should be responsible for logistic issues and should closely coordinate with logisticians at the next level. Other staff include, at each level, those in charge of stocks and transport of materials (drivers, storekeepers, stock managers, etc.).

Training

Training of trainers should be conducted at central level. This training should include supervisors and team leaders, who will be in charge of the training of immunization staff. Training material should be adapted from the material proposed in this document. This training must include refreshment on cholera treatment and all other preventive measures, epidemiological data and training on the OCV campaign itself. It is recommended to divide training into two parts: a theoretical part followed by a practical one during which trainees have to set up an immunization post themselves.

.....

¹ See terms of reference in *Annex 3*.
² See *Annex 2*.

3.2.5 Logistics

Vaccines

■ *Estimation of vaccine requirements*

Taking into account that:

- the target population amounts to all persons except children < 2 years¹ (4% when local population data are not available);
- two doses are mandatory to ensure protection;
- experience has shown that wastage is < 1% (the vials are made of strong glass and do not break easily);
- owing to the inevitable drop-out of vaccinees between the two rounds, a reserve stock is not needed.

The amount of vaccines needed is equal to (target population – population < 2 years) x 2.

EXAMPLE

Vaccine requirements for a population of 20 000 for which age-range population data are not available

Target population = all persons except children < 2 years:

$$20\,000 - (4\% \times 20\,000) = 20\,000 - 800 = 19\,200 \text{ persons.}$$

$$\text{Number of doses required} = \text{target population} \times 2 \text{ doses} = 19\,200 \times 2 = 38\,400 \text{ doses.}$$

No revolving stock mechanism is currently in place, therefore negotiations should be conducted on an ad hoc basis. In addition, the WHO-prequalified product is still relatively new on the public health scene and national licensing may be needed.

The shelf-life of vaccines and buffers² should be identical, and last for at least one year after importation. Packing requirements (insulated boxes, weight and volume to be decided according to air-cargo capacity), quantity, batch numbers and expiry dates of buffers should be identical to those of vaccines. Plastic cups with a measuring mark may be obtained from the manufacturer.

Experience has shown that it is extremely difficult to reach a vaccination rate > 85% at first dose; furthermore, the drop-out rate between the two rounds is about 10–15%. Therefore, about 15–20% of doses usually remain unused, and plans for storing and using them should be made ahead of vaccination.

.....

¹ < 1 year for Shanchol.

² No buffer required for Shanchol.

1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

3.1 OCV Registration

3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies

Transport and storage of vaccines

Import authorizations and clearance procedures should be examined well in advance. OCV is prequalified to be stored between + 2 °C and + 8 °C and should be maintained under a strict cold chain.¹

OCV is supplied in single-dose vials, plus a sachet of sodium bicarbonate buffer.² Vials and buffer sachets are generally shipped in separate boxes, as vials require a cold chain but buffer sachets do not. The volume issue is extremely important and a careful assessment of cold-chain facilities at all levels and of transportation capacities should be conducted prior to ordering the vaccine. A refrigerator with a storage volume of 196 litres is able to hold only 8000 doses. By comparison, the volume needed to vaccinate 500 people against measles is 1.5 litre (including waste and reserve) whereas, to vaccinate 500 people against cholera using OCV, the volume amounts to 25 litres, more than 16 times the volume required for measles vaccine.³

EXAMPLE International shipment of OCV Dukoral® in Aceh, Indonesia		
	Advantages	Disadvantages
Small insulated boxes were requested in order to be carried by hand	Insulated boxes = cold boxes at field level	Large volume and weight for transport and storage
57 288 vaccine vials = 44 styrofoam boxes (1302 vials/each) Weight: 44 x 24 kg = 1056 kg Volume: 44 x (64 x 44 x 34 cm) = 4.2 m ³	Insulated boxes could be reused for vaccine shipment elsewhere in the country or given to population	Shipment more expensive

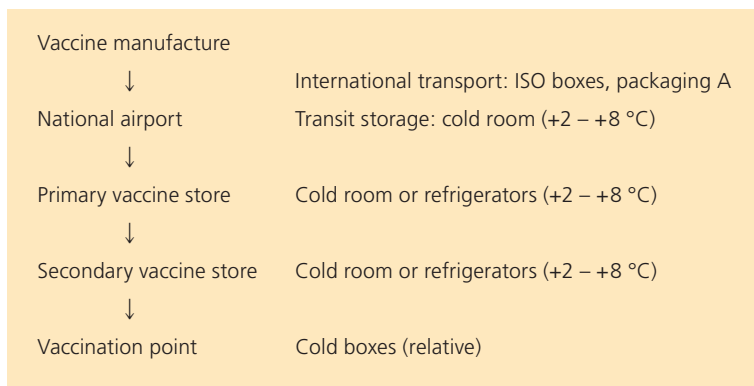
.....

¹ Provided that the campaign is well managed, cold-chain conditions on the day of vaccination for vaccines being sent to the field may be less stringent in view of existing stability data.

² No buffer required for Shanchol.

³ Volume requirement to vaccinate 20 000 people (40 000 doses), taking into account that vials are of 18 ml (for a content of 3 ml): 720 litres + 35% = 972 litres.

■ Steps from central to peripheral level: cold-chain requirements



Transportation between the different levels also requires a strict cold chain. Cold boxes or insulated shipment boxes with ice packs may be used. To ensure a permanent cold chain, the following should be strictly respected:

- Shipment packing should be known in advance (weight, volume, type of insulated boxes) in order to plan and organize transport and cold-chain facilities.
- A backup generator is essential to be able to maintain a functioning cold chain (cold room, refrigerated container or refrigerators) in case of power cut.
- Strict temperature control is necessary at all steps. Sufficient control material (thermometers, temperature monitors, etc.) should be available and staff should be trained accordingly.
- Vaccine vial monitors should be inserted in the vaccine boxes.
- Vaccines should be kept as long as possible in secured cold-chain conditions (cold room or refrigerator with back-up generator).
- Vaccines should be sent to the field at the very last moment and only in required amounts (supplies for the 2nd round will be determined according to the number of vaccines used during the 1st round).
- A strict cold chain should be ensured at all steps, using cold boxes with sufficient ice packs.¹
- Freezing and turnover of ice packs should be anticipated.

.....

¹ Provided that the campaign is well managed, cold-chain conditions on the day of vaccination for vaccines being sent to the field may be less stringent in view of existing stability data.

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

- Sufficient time and material should be foreseen to repack vaccines when moving between different locations.

Materials other than vaccines

■ Water

OCV is mixed with a large amount of water,¹ and planners should ensure that sufficient quantities of safe water are available on site or brought from an external source. Each dose of vaccine needs to be diluted in 150 ml of water¹ (75 ml for children aged 2–6 years). By experience, the volume of water needed is about 150 ml per vaccine dose including waste. To vac-cinate 5000 individuals, 1500 litres of safe water are therefore needed.

If bottled water is used, 1.5 litre bottles (or multiples of 1.5 litre) should be preferred, as this corresponds to the needs for the administration of 10 doses of vaccine.

Comparison of different sources of water

Place	Water source	Advantage	Disadvantage
Aceh (Indonesia); Darfur (Sudan)	1.5 litre bottled water	Hygienic Easy to use Easy to measure quantity of water when preparing the buffer solution ~10% saving	Transport constraints if not available on site High cost
Mozambique	Tap water (chlorinated)	Low cost	Supply procedure to be implemented Need strict hygiene procedure (water and carrier) Assess for adequate free chlorine residual Water carriers needed for transport Measuring tools needed (1.5 l)
Zanzibar (United Republic of Tanzania)	1.5 litre bottled water	Hygienic Easy to use Easy to measure quantity of water when preparing the buffer solution ~10% saving Purchased on site	

¹ Not required for Shanchol.

■ *Cups*

The vaccine should be administered in 150 ml cups.¹ For hygienic reasons, disposable cups should be used. For ecological reasons, and to ease waste management, it is preferable to use paper cups rather than plastic cups; 2% waste should be foreseen when ordering paper cups. Paper cups may be difficult to purchase locally in large amounts, and suppliers often need to order them out of the country. As the delivery time may reach up to 6 months, the order should be placed well in advance.

Comparison of different cups

Place	Type and number of cups	Advantage	Disadvantage
Aceh (Indonesia); Darfur (Sudan)	Plastic cups single use 10 200 cups for 5000 people (10 000 doses)	– Safe – Hygienic – Easy to use	Waste management needed, if cups are not given to vaccinees Important volume High cost Not always available on site
Zanzibar (United Republic of Tanzania)	Paper cups single use		
Mozambique	Reusable ~30–50 cups per team	– Low volume – Low cost	Need strong hygiene procedure and control Human resources and time needed in cleaning Need cleaning tools and product Large amount of safe water required

■ *Measuring cups*

To pour the correct amount of buffer solution into paper cups, plastic cups with measuring marks (0.75 ml; 150 ml) are necessary. To create measuring cups easily, take two strong plastic cups of different colours, one for 75 ml and the other for 150 ml measurement. Pour in the cup the quantity of water needed (e.g. 150 ml), put a mark on the plastic cup; cut a piece 4 cm wide above the mark. Thus the cup cannot be filled with more liquid than counted.

■ *Water container*

To prepare oral cholera vaccine, each vaccine dose should be mixed with a buffer solution.² This buffer solution is prepared mixing 1 buffer sachet with 150 ml drinking-water. For a mass campaign each team should prepare the buffer solution in bulk on a daily basis, in a water container. For

¹ Not required for Shanchol.

² No buffer required for Shanchol.

1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

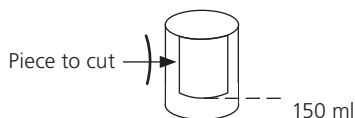
3.1 OCV Registration

3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies



reasons of hygiene, the water container must be covered and have a tap in order to fill cups. The volume of the water container depends on the vaccination strategy (mobile or fixed team), and the number of people targeted to be reached daily by the team.

■ Scissors

One pair of scissors per team is required to open the buffer sachets.

Registration materials

Identification of those who have received one dose of vaccine is important for two reasons:

- vaccinees should receive only one dose of vaccine per round;
- only those who have received the 1st dose are eligible for the 2nd dose.

Two methods exist for identifying individuals that have received the vaccine:

- mark a specific finger (with permanent ink);
- give a vaccination card.

The two methods may be used separately or combined.

■ Marking

Marking fingernails (right for the 1st dose and left for the 2nd) is important and may be combined with issuing vaccination cards if necessary. However, finger marking is not culturally accepted in all countries. If not possible, alternative solutions should be found to trace vaccinees, for instance by issuing vaccination cards or replacing finger marking by plastic bracelets, etc.

If the finger mark only is used to identify those eligible for the 2nd round/dose, particular attention should be paid to the duration of visibility of the mark, which should exceed the total duration of the campaign which includes the 1st and the 2nd rounds (marking required for at least 6 weeks).¹

.....
¹ See page 14. *Organizing and implementing a mass vaccination campaign.*

■ *Vaccination cards*

At the 1st dose session, an individual vaccination card is given to each person receiving the vaccine. The following information is required: full name, age, sex, address and/or location, date of 1st dose of vaccine, date of 2nd dose. In order to protect the vaccination card from deterioration, a transparent plastic pocket may be issued to vaccinees. After the participant receives the vaccine, the vaccination card (for the 1st and 2nd dose) should be stamped or signed by a member of the team. The following materials are required:

- vaccination card: one per vaccinated person, to be given only at the 1st round;
- pens for each person responsible for filling out the vaccination card;
- transparent plastic pockets (if issued): one per vaccination card;
- stamps or pens for those signing the card.

■ *Tally sheet*¹

A tally sheet should be used for recording the number of people immunized per day (by age group and by sex) in each vaccination post and per team. It enables the control and evaluation of the vaccination as well as the estimation of vaccine coverage and waste. Details of the vaccine received and vaccine returned (used and unused) should be recorded on a daily basis on the tally sheet. The following materials are required:

- tally sheet: a minimum of one tally sheet per day and per vaccinator is necessary throughout the campaign (1st and 2nd dose). A tally sheet is sufficient for an average of 200–300 people;
- pens for each counter;
- clipboards for each counter.

■ *Registration logbook*

In some countries, national guidelines require that all vaccinated people are recorded. Registration is a rather heavy process and is not mandatory for all mass campaigns. The registration logbook should record all the information written on the vaccination card. If the vaccination card is given a number, the same number should be reported on the logbook. Two registration logbooks per team are required, one for the first-dose and one other for the second-dose session. The following materials are required:

- registration logbook for the first-dose session: sheet or book;
- registration logbook for the second-dose session: sheet or book;

.....

¹ See Annex 5.

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

- pens for each recorder;
- clipboards for each recorder in case sheets are used rather than a book.

■ **Reporting tools**

Information from the tally sheets should be reported to the higher level. At the end of each day, each team leader should fill a daily summary report by compiling data from tally sheets and send it to supervisors.

During microplanning it is important to include the costs of materials not directly related to vaccination. These include:

- materials for immunization-post installation such as ropes, poles, plastic sheeting, etc.;
- materials for logistic organization such as envelopes, rubber bands, staples, paperclips, etc.;
- cleaning materials for the immunization point: soap, buckets, mops, etc.

Transport and storage of materials other than vaccines

The total volume of materials should be carefully evaluated. The vaccine itself is extremely voluminous and heavy; other materials and water should also be counted, even if they do not need to be stored in cold-chain conditions. Appropriate secure storage should be planned at all levels, from central to peripheral.

EXAMPLE

Material required to vaccinate 20 000 individuals

Item	Number of boxes	Volume	Weight
40 000 buffer sachets ^a	50 boxes of 810 units	50 x (27x23x22 cm) = 50 x 0.014 m ³ = 0.7 m ³	50 x 6 kg = 300 kg
40 000 disposable paper/plastic cups ^b	40 boxes of 1000 units	40 x (36x30x40 cm) = 40 x 0.043 = 1.7 m ³	40 x 1 kg = 40 kg
4000 bottles of water (1.5 l) ^c	334 boxes of 12 units	334 (35x28x35 cm) = 334 x 0.035 m ³ = 11.7 m ³	334 x 20 kg = 6680 kg
Materials: water containers, cleaning kit, scissors, pens, forms, etc.			

^a No buffer required for Shanchol.

^b Not required for Shanchol.

^c Not required for Shanchol, but safe water may nevertheless be required by certain persons to swallow the vaccine.

■ *Transport*

Transport is needed for:

- transportation of vaccine, cold-chain equipment such as cold boxes, ice packs, vaccine carriers and other supplies (cups, water, water containers, etc.) from the central to the peripheral levels;
- distribution of social mobilization and monitoring materials;
- transportation of personnel involved in monitoring and supervision of the vaccination campaign, planning, training and implementation.

The large volume of the materials has a direct impact on transport costs.

■ *Waste management*

A strategy for waste collection and recycling should be planned at the beginning of the vaccination campaign. Waste should be sorted out by type:

- Glass: empty OCV vials. In all countries, glass recycling factories should be found.
- Plastic: cups if in plastic; OCV vial caps and rubber; empty buffer sachets.
- Paper: cups if in paper.

Paper cups may be burnt in an incinerator. It is preferable to burn plastic in an appropriate incinerator, as toxic pollution may ensue. Plastic bottles should be given to the team members or the community if needed; disposable paper cups are preferable to plastic cups. Materials required:

- plastic rubbish bags in order to recover waste and rubbish at vaccination posts;
- containers or large boxes at peripheral and central levels in order to dispose of waste appropriately.

3.2.6 Budget

All the information to define the budget is described above.

■ *Budget lines:*

1. Planning and supervision.
2. Social mobilization and communication campaign.
3. Human resources:
 - Per diem (including night allowances where applicable).
 - Training costs.
4. Logistics
 - Vaccines.

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

- International transport of vaccines (international freight, insurance, customs clearance, etc.).
- Other material (water, cups, water containers, forms, stationery etc.).
- Internal transport of vaccines and materials (boats, trucks, motor-cycles, bicycles, animals, etc.).
- Storage (cold room, cold-chain material, material storage, logistic personnel, etc.).
- Other materials including IEC material and those needed to set up the immunization post.

3.3 Microplanning – district level

Microplanning should be managed at district level. The following information should be collected in each target area:

- target population;
- district maps, showing administrative areas and main roads;
- percentages of population in rural and urban zones;
- identification of vaccination points;
- a detailed cold-chain inventory showing functional and non-functional equipment, comprising: number of facilities available, locations and possible back-up options (private sector, NGOs, etc.);
- distance between vaccine stocks and vaccination posts;
- difficult-to-reach areas and suggested transport and storage solutions.

3.3.1 Planning of activities

National- and district-level activities are very similar, but the latter contain more operational elements. In addition, district-level activities include planning, coordinating and supervising microplanning activities conducted at local level. Guidelines should be sent well in advance to participants in the microplanning workshop in order to set up planning.

Training

Training should be ensured by the persons trained during the training of trainers. The training is divided into two parts: one general presentation and a workshop in subgroups according to the role within the vaccination team. Training should emphasize the four elements that differ significantly from other mass vaccination campaigns:

- large target population (all population > 2 years);¹

.....

¹ > 1 year for Shanchol.

- oral vaccine to be administered with a large amount of water;¹
- 2-dose vaccine;
- need to fast 1 hour before and 1 hour after ingestion of the vaccine.

Training at each level should include standardized information, such as:

- General information about the campaign:
 - Objectives of the vaccination campaign
 - Dates of the vaccination campaign (1st and 2nd rounds)
 - Target age groups
 - Map of catchment areas.
- Social mobilization and response to community and media concerns about the campaign.
- Immunization session:
 - Preparation and management of a vaccination post, detailing position of and minimum spacing between tables, and area design
 - Cold-chain management
 - Preparation of the vaccine (buffer solution preparation)²
 - Registration of vaccinees (tally sheet, marking and/or completing immunization card).
- Daily summary report:
 - Compiling data and logistic reports.
- Waste management and collection.
- Hygiene.
- Supervision.

At least one full day of training should be foreseen, to allow sufficient time for questions. Vaccination team members should have practised several times their assigned tasks (buffer preparation,² vaccine preparation, registration, etc.). The training should explain the difference between the 1st and 2nd dose round, as screening and team organization are different. A refresher training course should take place between the 1st and 2nd dose in order to adapt implementation strategies according to the lessons learnt during the 1st dose.

Monitoring and supervision

The success of a campaign largely depends on the quality of supervision. To ensure and encourage implementation of best practices, a standard checklist should be used.³ Supervisors should be thorough and systematic when

..... •

¹ Not required for Shanchol.

² No buffer required for Shanchol.

³ See *Annex 3*.

1. Background	
1.1 Introduction	
1.2 Disease	
1.3 Risk factors	
1.4 Prevention and control	
2. Cholera vaccines	
2.1 Licensed OCV	
2.2 When to use	
2.3 WHO recommendations	
3. Mass vaccination campaign	
3.1 OCV Registration	
3.2 Macro-planning	
3.3 Microplanning	
3.4 Common errors	
3.5 Research studies	
PLANNING AND PREPARATION	
Activities at district level	
Phase 1	— Prepare for initial planning meeting: census data, maps, list of communities, inventory of cold-chain equipment in district — Attend national meeting — Undertake a situation assessment of cholera surveillance system — Assess waste-disposal possibilities — Establish district vaccination coordinating meeting — Define the number of immunization points and assess feasibility at field level in collaboration with the national level — Start filling in logistic forms — Organize national-level meeting to complete logistic forms — Establish a district social mobilization subcommittee — Identify staff — Assess training needs
Phase 2	— Receive logistic materials — Meet subdistrict and local vaccination coordinators — Distribute schedule and task lists — Distribute vaccination guides to subdistrict and local coordinators — Verify accuracy of district calculations
Final phase of preparation	— Train immunization teams — Ensure immunization and other waste-disposal measures have all been completed
2 weeks before implementation	— Receive vaccines from central level according to storage availability — Transfer forms and materials to immunization post teams — Organize supervisory visits to post coordinators, solve local problems — Initiate activities for difficult-to-reach areas and special populations — Intensify social mobilization activities at community level
1 week before implementation	— Visit and support selected subdistricts and post coordinators — Make supervisory visits to all team coordination posts and assess preparation
IMPLEMENTATION	
1 day before	— Transfer the vaccines to all immunization points
Day 1	— Conduct opening ceremonies
Daily during 1st dose	— Daily meeting to revise field events and outcome of activities at all levels — Daily collection of summary reports (data + logistics) and analysis

Implementation (continued)

- Between 2 rounds** — Meeting between supervisors and team leaders to:
- review logistic setting (waste management, cold chain, etc.) at all levels
 - review vaccination coverage and fine-tune
 - prepare the 2nd round
- Maintain vaccine in strict cold chain
- Maintain social mobilization to recall that 2 doses are needed to be vaccinated

-
- Daily during 2nd dose** — Daily meeting to revise field events and outcome of activities at all levels
- Daily collection of summary reports (data + logistics) and analysis

POST-VACCINATION

- 2–3 days after** — Send vaccine back to central level in the appropriate cold chain
- Meet all subdistrict coordinators in districts
- Implement national recommendations for waste management

-
- 1 week after** — Estimate vaccination coverage and waste in districts
- Review supervision checklists
- Attend national-level review meeting
- Submit campaign results
-

performing quality-control checks, ensuring that all aspects of field activities are being implemented as well as possible. They should note whether:

- plans are adequate and estimates are correct;
- maps of the area to be supervised, listing posts and communities in the related catchment area, are available and being used;
- vaccine is stored in the proper way (maintaining an uninterrupted cold chain) and is well administered (correct mixture for buffer solution¹ and correct amount of buffer solution liquid with respect to the age range);
- waste is collected.

During their visits, supervisors should monitor implementation of activities by:

- completing a supervisory checklist;
- verifying that logistic forms are complete and updating significant changes;
- verifying that vaccination staff at various levels understand their tasks correctly;

.....
¹ See Annex 4.

1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

3.1 OCV Registration

3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies

- enquiring whether transport needs are being met (i.e. transportation of vaccine and personnel for supervision and social mobilization activities);
- identifying any constraints and working with vaccination campaign committee members as well as with communities in order to overcome them.

During the vaccination campaign, supervisors at all levels should visit immunization points in order to monitor, assist with and solve any problems or task issues, and report to the next management level.

Health education and social mobilization

Before and during the immunization campaign, social mobilization activities should be intensified. All information on the immunization campaign (target population, target areas, immunization points) should be clearly communicated. At the same time, all key messages for cholera prevention should be repeated.¹ The involvement of community leaders is a milestone of the social mobilization campaign; meetings before, during and after the immunization session should be carried out.

Logistics

The distribution of vaccines and other materials should take place at the planned time, from central to district level, from district to subdistrict level and finally to vaccination posts. The distribution plan should account for:

- the distance (back and forth) that has to be covered to distribute vaccines and materials;
- the mode of transport and the corresponding fuel costs;
- staff required (drivers, technicians for cold-chain final checks and maintenance);
- the time required for distribution.

A perfect knowledge of the volume and weight of supplies is necessary in order to plan distribution correctly.

¹ See annex 4.

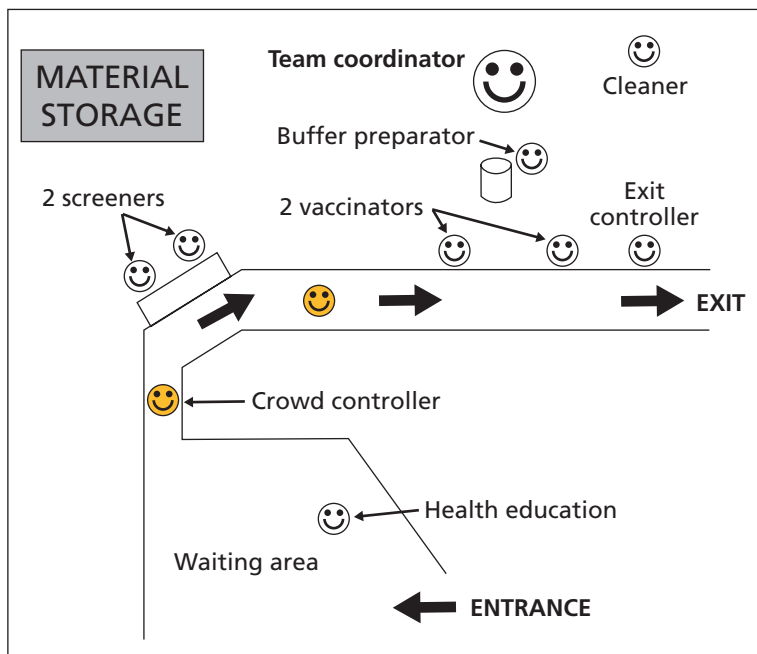
3.3.2 Immunization session

Organization of vaccination posts

A well-functioning vaccination post should ensure a comfortable and efficient flow. An orderly one-way flow of traffic should be designed in order to prevent backtracking and confusion. Ropes and cables should indicate the circulation path. A minimum space should be maintained between each step in the immunization post. Bottlenecks occur most often during screening, and two screeners are needed to avoid them. A friendly atmosphere should be created at vaccination posts.

Depending on the season (rainy or hot season), plastic sheeting, umbrellas or shelters should be provided for staff members and people waiting to be vaccinated. If possible, the vaccination post should be close to public toilets.

Model for 1st dose session



1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

3.1 OCV Registration

3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies

To maximize the number of people to be vaccinated, the following should be implemented:

- circulation in vaccination post perfectly planned;
- no bottleneck in the screening area;
- no shortage of materials;
- correct number of vaccination team members;
- constant daily flow of persons all along the day;
- social mobilization very effective (schedule of vaccination clearly communicated to the community and their leaders).

The following materials are required, per team, at each vaccination post:

- one vaccine carrier per vaccinator and frozen ice packs for each immunization day;¹
- the correct number of vaccine vials, buffer sachets, cups and water to meet the daily target;
- one water container to prepare the buffer solution² (water and buffer sachets);
- one pair of scissors to open buffer sachets;
- a sufficient number of markers or gentian violet ink for finger marking (if used);
- a sufficient number of tally sheets to meet the daily target of the post;
- a sufficient number of pens and clipboards;
- AEFI³ case investigation forms;
- means of identifying vaccination post (poster, banner, flag) and staff (caps, t-shirts or armbands);
- bins for waste collection (one for vials, one for the rest including vial caps, rubber, paper cups and buffer sachets);
- hygiene material (soap and cleaning material);
- tables and chairs borrowed from the local community;
- ropes and poles in order to indicate circulation at the vaccination site;
- plastic sheeting or umbrellas;
- and, depending on the registration chosen:
 - a sufficient number of vaccination cards and plastic pockets to meet the daily target;
 - stamp and ink in order to stamp vaccination cards.

.....
¹ Provided that the campaign is well managed, cold-chain conditions on the day of vaccination for vaccines being sent to the field may be less stringent in view of existing stability data.

² Not required for Shanchol.

³ Adverse event following immunization.

Staff: immunization team

A vaccination team consists of a *minimum* of four people:

Person 1: Responsible for screening for eligibility and filling out the immunization card.

Person 2: Responsible for buffer solution¹ preparation and pouring the correct amount of buffer solution into the cup.

Person 3: Vaccinator, responsible for mixing the vaccine with buffer solution and checking the full ingestion of the vaccine.

Person 4: Responsible for filling in tally sheets and stamping (or signing) the immunization card.

A fifth person may be added:

Person 5: Communicates health education messages.

Depending on the setting, an additional person is needed to control the crowd. The composition of the vaccination team may vary according to the registration mode.

Activities at the vaccination post

■ Health education messages

One person (generally a volunteer from the community) responsible for giving the population waiting to be immunized:

- health education messages on cholera and preventive measures;²
- information about the vaccination (fasting, 2-dose vaccine, age, etc.).

■ Screening

The population must be screened to control their eligibility before receiving the vaccine (they have fasted for 1 hour; they are > 2 years old,³ they are not pregnant). For the 1st round:

- Screener controls that people have fasted for 1 hour and that they are in the age target.
- Screener fills in the vaccination card (if vaccination card issued).

For the 2nd round:

- Screener controls that people are eligible (they have fasted for 1 hour; they have received the 1st dose; control that they have the finger mark and/or the vaccination card).

.....

¹ No buffer required for Shanchol.

² See *Annex 4*.

³ > 1 year for Shanchol.

1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

3.1 OCV Registration

3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies

■ Preparation and administration of the vaccine

Preparation of the buffer solution:¹ The buffer solution is prepared in bulk, 150 ml of safe water per buffer sachet, in water containers with taps. The buffer solution is then poured from the containers into the cups:

- 150 ml of buffer solution for people > 6 years;
- 75 ml only of buffer solution for children 2–6 years of age.

It takes about 10 minutes to prepare 100 doses of buffer solution (= 15 litres). Additional amounts of buffer solution should be prepared during the day according to needs. Buffer solution must be ingested the same day as it was prepared. At the end of the immunization day, remaining buffer solution should be discarded.

Vaccine preparation: just before ingestion, the content of the vaccine vial should be poured in the right amount of buffer solution (75 ml for children aged 2–6 and 150 ml for those aged > 6).

Vaccine ingestion: ingestion of the vaccine must be carefully monitored, particularly for children.

■ Marking and/or immunization cards, tally sheets

A person having ingested the vaccine should be:

- recorded on the tally sheet (according to age range and sex);
- marked (with permanent marker on the little finger) and/or should be given a stamped (or signed) immunization card when applicable.

■ Registration logbook record

A registration logbook record should be made only in countries where the registration of vaccinees (name, age, sex, etc.) is required. This registration logbook should record all information found on the vaccination card, including the card number. Experience shows that it is impossible to use the same register book for the 2nd dose session, trying to match vaccination card number to identify those who have received the 1st dose. Therefore, a separate register book by round and by team is required.

■ Monitoring

At the end of the immunization day, team leaders should compile data from tally sheets and fill in the daily summary report, to be used to estimate the vaccination rate, comparing the number of people vaccinated with the number targeted for the area. The strategy should be adapted if

.....
¹ No buffer required for Shanchol.

needed (i.e. adapt vaccination-post opening hours in order to catch age range not caught).

Team leaders should check that:

- remaining buffer solution is discarded and the water container is cleaned;
- vaccines are kept in a strict cold chain;
- all waste is collected and equipment and other supplies are stored in a secure area;
- the vaccination post and its immediate vicinity are clean.

At the end of the first round, team leaders should:

- send summary forms related to each implementation level to the higher level;
- send the list of materials and supplies remaining, and order material and supplies needed for the 2nd round;
- send back to the central level unused supplies that are not needed for the next round (i.e. vaccination cards and pockets);
- store vaccines in a strict cold chain;
- store all equipment and unused supplies in a secure area.

At the end of the 2nd dose round, team leaders should:

- send summary forms related to each implementation level to the higher level;
- send back to the central level unused supplies with a packing list;
- send back to the central level remaining vaccine vials in a proper cold chain;
- inform if vaccines were not stored in an appropriate cold chain (+2 – +8 °C);
- ensure proper waste disposal of glass, plastic and paper.

3.4 Common errors that may diminish campaign effectiveness

The most common avoidable errors that may diminish the effectiveness of a mass campaign are:

- Preparation beginning too late.
- Vaccine registration not completed on time.
- Vaccine ordered too late.
- Paper cups ordered too late.
- Inadequate supplies ordered.
- Unclear attribution of responsibilities.
- Inadequate training.

1. Background
1.1 Introduction
1.2 Disease
1.3 Risk factors
1.4 Prevention and control
2. Cholera vaccines
2.1 Licensed OCV
2.2 When to use
2.3 WHO recommendations
3. Mass vaccination campaign
3.1 OCV Registration
3.2 Macro-planning
3.3 Microplanning
3.4 Common errors
3.5 Research studies

- Inadequate social mobilization.
- Inadequate involvement of other sectors.
- Inadequate distribution of supplies to vaccination teams.
- Inadequate transportation (vaccine, materials, staff and supervision).
- Inaccessibility of posts to workers, especially in urban and periurban areas. To reach a maximum of people, vaccination should be available outside working hours.
- Campaign rounds too long, leading to weak dynamics among teams and communities, and the loss of details.
- Insufficient cold-chain facilities.
- Deficiency in cold-chain management (not enough ice packs, interruption of the cold chain, cold room not in good condition, etc.).

3.5 Mass vaccination campaigns linked to research studies

When data collected during the campaign are used within the framework of a research study, it is mandatory to check with the relevant ethical committees what kind of consent is needed (written or oral). Details of the study, of the campaign organization, data management, confidentiality and consent forms must be spelt out in the study protocol and approved by relevant ethical review committees. Major organizational elements that differ from a vaccination campaign not linked to a study are described below.

Organization of vaccination posts

Two specific activities are added to the normal activities of an OCV campaign: consent and complete registration of vaccinees. In order to link 1st dose data with 2nd dose data, each individual must be registered under a unique identifier. The easiest way to ensure consistency is to issue vaccination cards that vaccinees must produce before receiving their 2nd dose of vaccine. Each card should have a unique identifier or serial number.

To ensure an optimal flow at the vaccination post, the site should be well chosen and prepared, with organized circulation comprising a single entry and a single exit point. The waiting area as well as the vaccination point should be indicated by ropes and cables. A separate area large enough for about 20 people, ensuring quietness and privacy, should be foreseen to explain to participants the aims of the study and the rights of participants, and to receive their consent. It is very important to explain that consent is not given for receiving the vaccine or not, but to allow or not the use of personal data.

Staff

Teams for mass vaccination campaigns linked to research studies should be composed of the following:

Staff	Task	No. staff 1st dose	No. staff 2nd dose
Screener	Check eligibility (1st dose: age, fasting; 2nd dose: if 1st dose received, fasting)	2	1
In charge of registration	Fill vaccination card (name, age, address, etc.)		
Health educator for consent	Give information on vaccination and related study and ask for consent	2	
In charge of preparing buffer solution	Prepare buffer solution by mixing safe water with buffer sachets	1	1
Vaccinator	Mix vaccine and buffer, and control vaccine ingestion	2	2
Tally sheet recorder	Fill in tally sheets		
Finger marker (optional)	Mark the finger of vaccinated persons	1	1
In charge of stamping vaccination card	Stamp or sign the vaccination card	2	2
Registry recorder	Fill in logbook registry		
Exit controller	Control that people leaving the site are fully registered and remind of the necessity to come for the 2nd dose	1	1
Crowd controller	Control the flow and crowd movements	4	3
Cleaner	Keep the immunization post (table, materials, etc.) and immediate vicinity clean	1	1
Team leader	Supervise the team	1	1
Health educator	Respond to questions and give health education messages (in the waiting area)	1	1
Total persons in one team		18 (17)	14 (16)
Average number of vaccinated people per team per hour		60–90	70–90

.....
¹ No required for Shanchol.

1. Background

1.1 Introduction

1.2 Disease

1.3 Risk factors

1.4 Prevention and control

2. Cholera vaccines

2.1 Licensed OCV

2.2 When to use

2.3 WHO recommendations

3. Mass vaccination campaign

3.1 OCV Registration

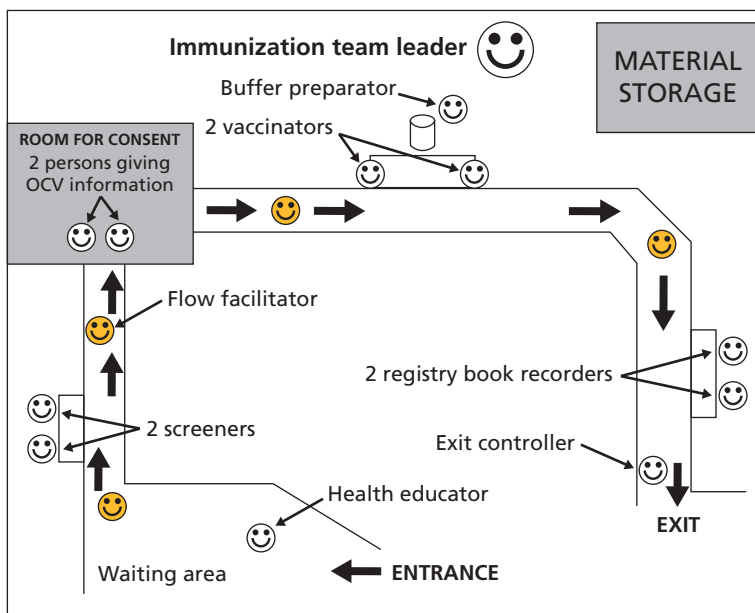
3.2 Macro-planning

3.3 Microplanning

3.4 Common errors

3.5 Research studies

Model for 1st dose session/study



Annexes

Annex 1	Decision-making tool for the use of oral cholera vaccine (OCV) in complex emergencies	47
Annex 2	Checklist for immunization campaign activities at national level	55
Annex 3	Staff required and relevant job descriptions	57
Annex 4	Social mobilization and health education messages	62
Annex 5	Forms 1–5: tally sheets and summary tables	65
Annex 6	Team composition in different settings	72
Annex 7	Flowchart	74
Annex 8	Explanation and flow chart for control forms	75

Annex 1

Decision-making tool for the use of oral cholera vaccine (OCV) in complex emergencies (2)

Introduction

The aim of the decision-making tool described in this annex is to help determine the relevance of OCV use for mass immunization campaigns in the context of complex emergencies. For this purpose, complex emergencies are defined as situations in which:

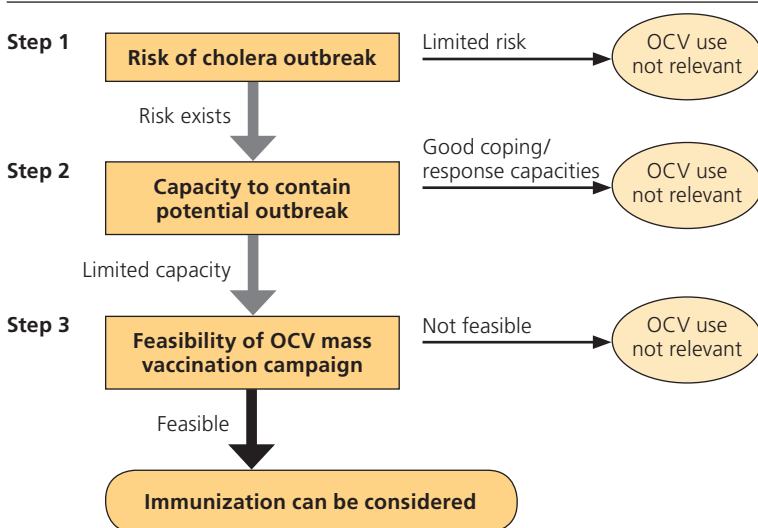
- a large part of the population is affected, leading to potential massive population movements;
- the coping capacities of local and national authorities are overwhelmed by the magnitude of the man-made or natural disaster;
- numerous national and international actors may participate in the relief effort.

While this tool may be used in other crisis situations, WHO plans to produce another document – to be published shortly – on the use of OCV in endemic settings.

The decision-making process follows a three-step approach (see *Fig. 1*), with the relevance of OCV use being examined at each step:

1. A risk assessment for a cholera outbreak, which should be undertaken first.
2. An assessment of whether key public health priorities are or can be implemented in a timely manner, combined with an analysis of the capacity to contain a possible outbreak.
3. An assessment of the feasibility of an immunization campaign using OCV.

Decision-making tree for OCV use in complex emergencies



Relevance of OCV use

During the course of a complex emergency, the following public health aspects should be taken into account when examining the relevance of the potential use of OCV:

- The top 10 public health priorities in emergencies¹ include the control of communicable diseases: a risk assessment for cholera should always be part of the initial assessment.
- Regardless of whether or not OCV is used, access to sufficient safe water and adequate sanitation should be ensured.
- Priority should be given to other health priorities when:
 - mortality is very high (above the emergency threshold of 1/10 000 per day);
 - basic needs (food, shelter, basic health services and security) are not met;
 - an outbreak of another disease is ongoing.
- With the currently available internationally prequalified two dose vaccine,²

¹ See <http://www.who.int/mediacentre/factsheets/fs090/en/> for details.

² Whole-cell killed *V. cholerae* O1 with purified recombinant B-subunit of cholera toxin (WC/rBS), administered in two doses, between a minimum of 1 and a maximum of 6 weeks apart, in 150 ml of water mixed with a buffer.

vaccination is not recommended in an area where an outbreak has already started.

The relevance of oral cholera vaccination should therefore be examined in the light of all public health priorities identified.

Remarks

Each step of the decision-making process should be assessed carefully and each element linked with the next, as shown in the decision-making tree (*Fig. 1*). The Global Task Force on Cholera Control, at WHO headquarters, will provide expertise and guidance whenever necessary. Decision-makers should not hesitate to contact the Task Force with any doubts or questions.

A high level of political commitment by all stakeholders and national authorities is critical.

If a decision is made to conduct a cholera vaccination campaign, water and sanitation programmes should be implemented before (or at least concurrently with) vaccination. A surveillance system – including laboratory capacity to diagnose cholera and basic health education for communities – should also be implemented before a mass cholera vaccination campaign is started.

1. Assessment of the risk of a cholera outbreak

Criteria	Factors to be considered	Examples
Epidemiology	1. Endemicity 2. Risk of introduction 3. Seasonality	1. Natural immunity, e.g. have any cases been detected within the previous 5 years? 2. Displacement, population movements from an endemic area. 3. Beginning/end of peak season.
Water supply	1. Current access to sufficient quantity of safe water 2. Capacity and timing to reach and maintain standards	1. According to Sphere standards, 20 l/person per day, quantity and quality of the water. Chlorination, water trucks, waterpipes, wells, etc. Risk of water supply becoming contaminated with <i>V. cholerae</i>. 2. Poor disinfection practices, poor water-handling practices. Low likelihood of protecting water supplies and reaching high level of disinfection before outbreak.
Sanitation	1. Current access and use 2. Capacity and timing to reach and maintain standards	1. According to Sphere standards, number of persons/latrine, waste management, etc. 2. Latrines "turnover", space to build new latrines.
Hygiene	1. Levels of personal and food hygiene	1. Lack of adequate quantities of water for washing. Availability of soap for handwashing. Poor food hygiene practices.
Population/ demography	1. Density 2. Vulnerability 3. Closed/open settings	1. Square metres per person according to Sphere standards. Number of people per household, and average household size. 2. Disrupted living conditions, specific vulnerable groups, long period of flight from conflict, leading to stress and malnutrition. 3. Closed settings such as detention centres or refugee camps, with control of population movements.
Community	1. Sociocultural behaviours	1. Level of education, hygiene practices, funeral practices, seasonal social and religious gatherings.

2. Assessment of the capacity to contain a potential outbreak

Components of response	Factors to be considered	Examples
Magnitude of the outbreak	1. Size of affected area 2. Closed/open setting	1. Towns, open areas. 2. Refugee camps, detention centres.
Roads, communication routes	1. Potential for spread of outbreak along communication routes	1. Large outbreak affecting several locations. Closed refugee setting.
Health care	1. Infrastructure 2. Human resources 3. Accessibility 4. Supplies	1. Permanent, temporary, possibility to set up cholera treatment centres (CTC) and oral rehydration units (ORU), separate ward in the hospital. 2. Health-care staff, support staff, cleaners, cooks. 3. 24 hours/day or not, distance, remoteness. 4. Oral rehydration solution, infusion, Ringer's lactate, cholera cots, cleaning material, buckets, soap.
Health education	1. Human resources and social network 2. Accessibility 3. Supplies	1. NGOs, schools, associations, religious leaders, persons able to transmit the correct message. 2. Possibility to reach the population, transport, cultural acceptance. 3. Banners, leaflets, loudspeakers, etc.
Water and sanitation	Capacity to provide/improve/reinforce as needed in terms of quantity and quality 1. Human resources 2. Supplies 3. Technical component 4. Accessibility	Capacity to adequately disinfect drinking-water supplies, to reach minimal coverage with sanitary facilities, and to provide adequate water and soap for personal hygiene before outbreak. 1. Trained technical personnel, able to set up and maintain systems. 2. Ability to find rapidly on the local market materials such as cement, pipes, soap. 3. Ability to use appropriate technology according to locally available material, technical knowledge and cultural acceptability. 4. Distance to water source and to latrines, access 24 hours/day or not.

2. Assessment of the capacity to contain a potential outbreak (continued)

Components of response	Factors to be considered	Examples
Surveillance system	Capacity to ensure early detection and monitoring of outbreaks 1. Alert system within the community 2. Surveillance system 3. Diagnosis, laboratory confirmation	1. Reaction capacity, (tele) communications. 2. Trained human resources, data management. 3. Trained human resources, laboratory, supplies.
National and local authorities	1. Local governance systems 2. Management 3. Intersectoral coordination	1. Camp management, detaining authorities, local authorities. 2. At all levels of intervention. 3. Partnership, coordination meetings.

3. Assessment of the feasibility of an OCV campaign

Elements to be assessed	Factors to be considered	Examples
Vaccines (currently prequalified OCV) + buffer	1. Availability of good-quality products, shelf-life 2. Timing to arrive on site 3. Regulatory approval 4. Price	1. Possible production within a given time frame. 2. International and local transport. 3. In the importing country, customs regulations, etc. 4. Currently up to US\$ 5 per dose.
Vaccines (potential new vaccines)	1. Availability of good-quality products 2. Timing to arrive on site 3. Regulatory approval 4. Ease of use/ formulation 5. Price	1. Potential manufacturers. 2. International and local transport. 3. Prequalification process. 4. Single-dose, easy-to-use vaccine. 5. Inexpensive vaccine and related materials.
Access	1. Roads, airstrips 2. Security 3. Climatic conditions	1. Road conditions, distance. 2. Conflict, landmines, checkpoints, etc. 3. Rainy season, earthquakes, etc.

3. Assessment of the feasibility of an OCV campaign (continued)

Elements to be assessed	Factors to be considered	Examples
Population	1. Size 2. Target population 3. Stability 4. Acceptability 5. Strong social network	1. To be evaluated precisely. 2. Criteria for selection (subgroups, vulnerability, etc); percentage of the population to be reached; how to respect the targeting? 3. Guarantee to have the same people for the two doses (limited movements in and out), accessibility to the population. 4. No strong expressed opposition, cultural awareness, risk of social stigmatization? 5. To inform and mobilize the community.
Logistics (for 10 000 persons) ^a	1. Transport and storage capacity 2. Cold-chain capacity 3. Equipment and supplies 4. Telecommunications 5. Waste management	1. International and local transport of vaccines and related material by truck, aircraft, etc., up to vaccination posts. 2. To be assessed carefully; usually difficult to find sufficient space and volume. 3. Clean water in large quantity, paper, pens, cups, buckets, etc. 4. To maintain contact with and supervision of vaccination teams (telephone, radio, satellite telephones, e-mails, etc.). 5. Appropriate waste points, glass recycling facilities (usually difficult to find).
Resources	1. Human resources: number, training, training capacity 2. Financial resources 3. Partners and coordination	1. Vaccination teams, team leaders, supervisors. 2. Vaccines, transport, per diem payments, cold chain, supplies, etc. 3. Ministry of health, NGOs, local partners, community. Establish responsibilities and close monitoring throughout the implementation.

¹ For 10 000 persons: total weight and storage volume of vaccine vials, buffer, plastic cups and water are about: 4000 kg and 9 m³; without the water, weight is only 570 kg and volume 1.7 m³.

3. Assessment of the feasibility of an OCV campaign (continued)

Elements to be assessed	Factors to be considered	Examples
Outline of implementation plan	1. Well-defined target population 2. Detailed strategy, including realistic timing, and resources needed	1. People with less access to safe water; people with poor sanitation facilities; people with limited access to health care.
Monitoring capacity	1. Monitoring implementation 2. Monitoring outpost 3. Follow-up of epidemiological and biological surveillance	1. Strong monitoring and close supervision needed. 2. Vaccination coverage. 3. Case control, number of vaccinated vs non-vaccinated persons with confirmed cholera.

Annex 2

Checklist for immunization campaign activities at national level

1. Planning and supervision

- Selection of target population
- Selection of target area
- Definition and designation of roles and responsibilities of senior staff
- Resource mobilization
- Planning of activities
- Timing estimate (duration, best timing for immunization open days and hours, etc.)
- Security
- Overall practical information (geography, roads, etc.).

2. Communication, social mobilization, community involvement and health education

- Decision-makers, general public, community leaders, etc.
- Definition of communication means
- Advocacy campaign
- Identification of community leaders (religious leaders, political leader, women's groups, schoolteachers, etc.)
- Group meeting with leaders (acceptance, target population census, etc.)
- Definition of key messages for social mobilization
- Adaptation of health education message
- Definition of best timing (time of day/day of week, working and social habits, etc.)
- Production of social mobilization and health education material
- Recruitment of volunteers within the community.

3. Human resources

- Identify staff
- Recruit extra personnel

- Detail and designate the roles and responsibilities at different levels
- Adapt training materials/guidelines and other documents to the local context
- Carry out training of trainers
- Organize training at local level.

4. Logistics

- Procure vaccines and other supplies
- Arrange international transport
- Organize customs clearance
- Develop tally sheets and daily summary report
- Check availability of sufficient clean water on site
- Review warehousing facilities at all levels, including assessment of cold-chain facilities
- Assess waste management and recycling facilities
- Plan distribution of vaccine, supplies and other campaign materials to peripheral levels.

5. Budget

- Staff costs (salaries, per diem, etc.)
- Vaccines and other material costs
- Transport of vaccines, materials and logistic staff
- Warehousing
- Training
- Social mobilization and communication cost.

Annex 3

Staff required and relevant job descriptions

1. Screening and issuing vaccination cards

Skills. Ability to read and write.

Terms of reference

- Check that children are > 2 years¹ and that those about to receive vaccination have fasted during the past hour.
- Fill in the vaccination cards correctly.
- Explain the next steps of the vaccination session (consent, vaccination, registration).

2. Preparation of buffer solution

Skills. Ability to read, write and count.

Terms of reference

- Prepare the buffer solution according to the needs of each vaccinator.
- Mix the correct amount of buffer sachets according to the volume of water (10 sachets of buffer for 1.5 l of water).
- Ensure that enough buffer solution is available during the vaccination.
- Pour the correct amount of buffer solution into the cup (75 ml for children aged 2–6 and 150 ml for persons > 6 years).

3. Vaccinator

Skills. EPI (Expanded Programme on Immunization) staff or nurse.

Terms of reference

- Pour the vaccine in the correct amount of buffer preparation.
- Administer the vaccine.
- Check ingestion, particularly for young children, and report it on the vaccination card.
- Dispose of the vaccine vials and cups into the appropriate waste bin.

.....

¹ > 1 year for Shanchol.

- Remind people to come for the second dose on day X.
- Remind people that they must fast for the next hour.
- Fill in the tally sheet.

4. Marking and stamping vaccination card

Skills. Ability to read and write.

Terms of reference

- Stamp (or sign) the vaccination card of those who have just received the vaccine.
- Put the vaccination card in the plastic pocket (if issued).
- Mark (with permanent marker) the fingernail of those vaccinated.
- Remind people to come for the second dose.
- Remind people that they must fast for the next hour.

5. Regulation of the flux

Skills. Person from the community.

Terms of reference

- Maintain a regular flux between the different steps of the vaccination (entrance, after vaccination card deliverance, at the vaccination point).

6. Cleaner of the vaccination area

- Maintain the vaccination area and the immediate vicinity clean throughout the day.

7. Health educator

- Ensure that essential information about cholera vaccination is repeatedly communicated:
 - fasting for 1 hour before and 1 hour after taking the vaccine is compulsory;
 - vaccination is intended for people > 2 years¹ of age, with the exception of pregnant women (see section 2.1.1);
 - OCV vaccination requires the ingestion of two doses.
- Give the location of the different vaccination points.

.....
¹ > 1 year for Shanchol.

- Ensure that the three main messages about hygiene and cholera prevention are repeatedly communicated:
 - hand washing;
 - using latrines;
 - food hygiene (cook it, boil it, peel it or leave it).

8. Team leader

Skills. EPI staff.

Terms of reference

- Take overall responsibility for the smooth running of the vaccination post.
- Organize the vaccination post: no crowd inside the shelter, facilitate easy flow through the shelter (avoiding congestion inside the shelter).
- Number each tally sheet before distributing to the registration staff.
- Check that each member of the team is following respective terms of reference correctly.
- Ensure that hygiene standards are implemented at every step of the vaccination (from buffer preparation to delivery of the vaccine).
- Respect time schedules.
- Collect tally sheets at the end of the day and fill the summary before giving it to the sector supervisor.

9. Sector supervisor

Skills. EPI senior staff.

Terms of reference

- Supervise all vaccination points in the selected area.
- Ensure that all steps of the vaccination are performed correctly and that procedures are followed.
- Analyse and solve problems encountered by the staff during immunization.
- Participate in the vaccinators' training on health education and vaccination and ensure that it is conducted during the vaccination campaign.
- Collect all tally sheets and fill in the daily summary sheet for the sector every day, to be presented at the daily debriefing meeting.
- Coordinate with the sector supply officer the continuous availability of supplies.
- Assess the implementation of the vaccination campaign by evaluating each vaccination post using a standardized form.
- Report findings during the daily meeting.

10. Logistics at district and/or subdistrict levels

Skills. EPI senior staff.

Terms of reference

- Storage
 - Ensure a secure room to stock all materials.
 - Manage the stock of materials with stock cards and follow up all movements.
- Supply (vaccine and other materials)
 - Ensure the transport of materials:
 - before the beginning of the first-dose round;
 - before the second vaccination round;
 - at the end of the second round to return the materials.
 - Be aware of the volume and weight of materials to be transported.
 - Ensure that planning of distribution is adequate.
- Vaccine cold chain
 - Ensure a strict cold chain (+2–+8 °C) for vaccine, and ensure that temperature is controlled twice a day and recorded on the appropriate form.
 - Ensure that vaccines are in a secure cold chain (back-up generator in good condition).
 - Ensure that sufficient vaccine carriers and cold boxes are available for transportation of vaccine.
 - Ensure that a sufficient number of ice packs are available for transport and storage of vaccine.
 - Manage the stock of vaccine with stock cards and follow up all movements.
 - Sort out, store and distribute vaccine according to the different batch numbers.

11. Final registration (only if campaign is linked to a study)

Skills. Literacy.

Terms of reference

- Carefully fill in the register by copying all information written on the vaccination card.
- Stamp the vaccination card.
- Remind people to come for the second dose on day X.
- Remind people that they must fast for the next hour.

12. Exit controller (only when registration in logbook register is needed)

Skills. Literacy and ability to check whether the vaccination card has been properly filled in.

Terms of reference

- Check that the vaccination card has been stamped before participant leaves the post.
- Remind people to come for the second dose on day X.
- Remind people that they must fast for the next hour.

Annex 4

Social mobilization and health education messages

Vaccination teams should transmit the following core messages to the population.

Health education core messages

Focus on the three following main messages:

1. **Wash your hands** with soap (or ashes or lime, where soap is not available) after every defecation, before handling food (cooking, eating, also feeding children), after cleaning a patient, after defecation.
2. Use **latrine** for defecation.
3. Use **clean water and food**:
 - Boil the water before drinking (or use chlorinated water if possible), pour the water from water containers and do not dip a cup.
 - Food:
 - Cook raw food thoroughly
 - Eat cooked foods immediately
 - Store cooked food carefully in refrigerator
 - Reheat cooked food thoroughly
 - Avoid contact between raw food and cooked food
 - Eat fruit and vegetables you have peeled yourself
 - Keep all kitchen surfaces clean
 - Wash your cutting board especially well with soap and water
 - Wash your utensils and dishes with soap and water.

Information about cholera

Cholera is an acute watery diarrhoeal disease, which spreads very easily from one person to another if hygiene is not good. The patient could be quickly and severely dehydrated. The main treatment is to drink a lot or seek help at a primary health care unit. The first-line treatment is oral rehydration solution (ORS), and only for severe cases would intravenous fluids be given.

Information about the vaccine

- The vaccine helps to avoid the disease but good hygiene remains very important.
- The vaccine does not protect against other diarrhoeal diseases.
- One has to fast one hour before and one hour after taking the vaccine.
- The vaccine is only effective after the second dose.
- The vaccine can be given to anyone > 2 years¹ who is not acutely sick.
- During the implementation of the second-dose round of vaccination, persons who ask to be vaccinated without having had a first dose must be refused. The reasons are the following: administration of a second dose cannot be assured for them, and one dose alone does not have sufficient efficacy.

Food

Take home message: COOK IT – BOIL IT – PEEL IT – OR LEAVE IT.

Safe drinking-water

- Even if the water looks clear, it might contain *Vibrio cholerae* (or other pathogens).
- Boil water or add drops of chlorine solution to it before drinking.
- Keep drinking-water in a clean, covered pot or bucket or other container with a small opening and a cover. It should be used within 24 hours of collection.
- Pour the water from the container – do not dip a cup into the container.
- If dipping into the container cannot be avoided, use a cup or other utensil with a handle and keep it clean.

Wells

- Do not defecate or urinate in or near a source of drinking-water.
- Do not wash yourself, your clothes, or your pots and utensils in the source of drinking-water (stream, river or waterhole).
- Open wells must be covered when not in use to avoid contamination.
- The buckets used to collect water should be hung up when not in use – they should not be left on a dirty surface.

.....
> 1 year for Shanchol.

- The area surrounding a well or a handpump should be kept as clean as possible.
- Dispose of waste and standing water around a water source.

If a family member has diarrhoea:

- The greatest danger of cholera (and other diarrhoeal diseases) is loss of water from the body.
- Do not panic, but act quickly.
- Give a solution of oral rehydration salt (ORS) prepared with safe (boiled or chlorinated) water.
- Go immediately to the health centre. ***Continue drinking.***

Annex 5

Forms 1–5: tally sheets and summary tables¹

..... •

¹ Source: Valérie Perroud.

FORM 1

Oral Cholera Vaccine TALLY SHEET

Location											Date: / /										
Vaccination Post											Vaccinator:										
Age	Number of person receiving the oral cholera vaccine																				
	Male										Female										
2-6 yrs. old	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10	
	11	12	13	14	15	16	17	18	19	20	11	12	13	14	15	16	17	18	19	20	
	21	22	23	24	25	26	27	28	29	30	21	22	23	24	25	26	27	28	29	30	
	31	32	33	34	35	36	37	38	39	40	31	32	33	34	35	36	37	38	39	40	
	41	42	43	44	45	46	47	48	49	50	41	42	43	44	45	46	47	48	49	50	
	Total (a) =										Total (b) =										
6 to 15 yrs. old	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10	
	11	12	13	14	15	16	17	18	19	20	11	12	13	14	15	16	17	18	19	20	
	21	22	23	24	25	26	27	28	29	30	21	22	23	24	25	26	27	28	29	30	
	31	32	33	34	35	36	37	38	39	40	31	32	33	34	35	36	37	38	39	40	
	41	42	43	44	45	46	47	48	49	50	41	42	43	44	45	46	47	48	49	50	
	51	52	53	54	55	56	57	58	59	60	51	52	53	54	55	56	57	58	59	60	
	61	62	63	64	65	66	67	68	69	70	61	62	63	64	65	66	67	68	69	70	
	71	72	73	74	75	76	77	78	79	80	71	72	73	74	75	76	77	78	79	80	
Total (c) =										Total (d) =											
>15 yrs. old	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10	
	11	12	13	14	15	16	17	18	19	20	11	12	13	14	15	16	17	18	19	20	
	21	22	23	24	25	26	27	28	29	30	21	22	23	24	25	26	27	28	29	30	
	31	32	33	34	35	36	37	38	39	40	31	32	33	34	35	36	37	38	39	40	
	41	42	43	44	45	46	47	48	49	50	41	42	43	44	45	46	47	48	49	50	
	51	52	53	54	55	56	57	58	59	60	51	52	53	54	55	56	57	58	59	60	
	61	62	63	64	65	66	67	68	69	70	61	62	63	64	65	66	67	68	69	70	
	71	72	73	74	75	76	77	78	79	80	71	72	73	74	75	76	77	78	79	80	
	81	82	83	84	85	86	87	88	89	90	81	82	83	84	85	86	87	88	89	90	
	91	92	93	94	95	96	97	98	99	100	91	92	93	94	95	96	97	98	99	100	
	101	102	103	104	105	106	107	108	109	110	101	102	103	104	105	106	107	108	109	110	
	111	112	113	114	115	116	117	118	119	120	111	112	113	114	115	116	117	118	119	120	
121	122	123	124	125	126	127	128	129	130	121	122	123	124	125	126	127	128	129	130		
Total (e) =										Total (f) =											
Male Total (k) = (a+d+g) =										Female Total (l) = (b+e+h) =											
TOTAL OCV (k+l) = m										Signature											

FORM 2. Summary of tally sheets

☐ Dose 1 ☐ Dose 2

Vaccination Post: DATE: from to
Target population:
District: Province:
Doses of Cholera vaccine received: Doses of Cholera vaccine remaining:

Days	2–6 years old ^a			People vaccinated			Total vaccinee C + F = G	Logistic N° doses of vaccine used & wasted H	People not vaccinated	
	Male A	Female B	Total A+B = C	Male D	Female E	Total D+E = F			Refused I	Very sick J
Day 1	Daily									
	Cumulative									
Day 2	Daily									
	Cumulative									
Day 3	Daily									
	Cumulative									
Day 4	Daily									
	Cumulative									
Day 5	Daily									
	Cumulative									
Day 6	Daily									
	Cumulative									
TOTAL	K									

Name of the Post Leader:
Signature:
Date:

DON'T FORGET:
— Report data from column **G**, to “Data Summary sheet”
— Report data from row **K** to “Vaccination Round Summary”

^a
^a 1–6 years old for Shanchol.

68

☐ Dose 1 ☐ Dose 2

DATE: from to

Name of Health Centre (sub district, district, etc.):

Target population:

District:

Province:

Doses of Cholera vaccine received:

Doses of Cholera vaccine remaining:

[illegible]

Name of the Level Coordinator:

Signature:

Date:

70

DATE: from to

Target population:

Province:

Doses of Cholera vaccine remaining:

Name of the Level Coordinator:
Signature:
Date:

Annex 6

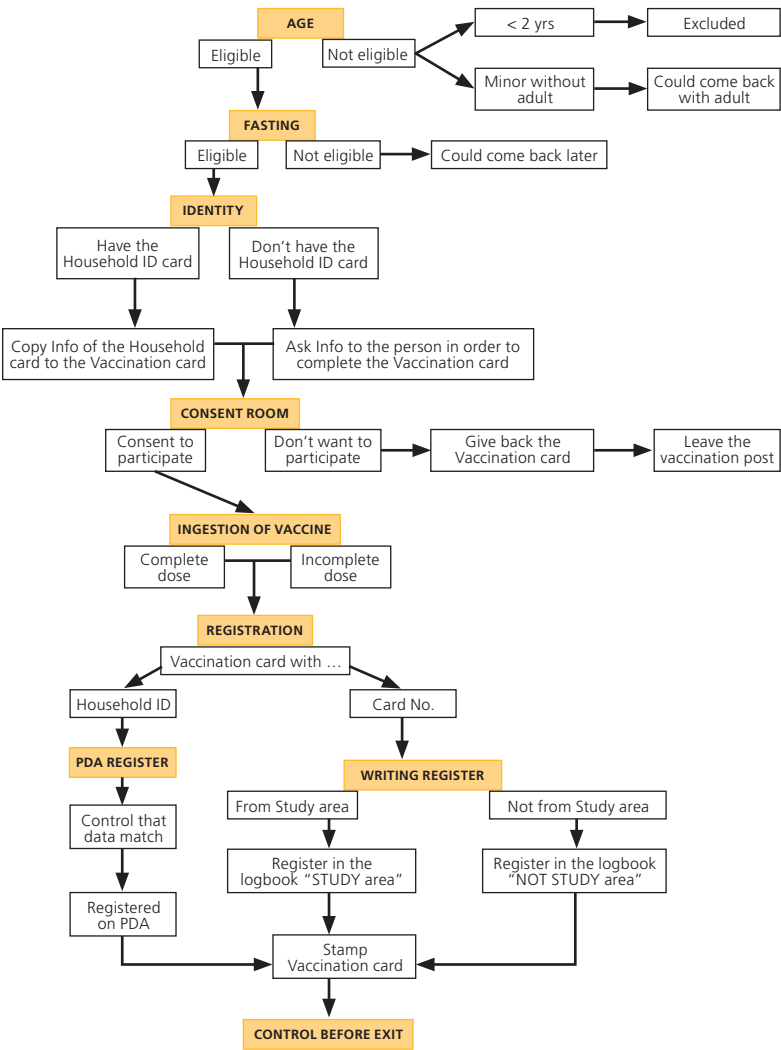
Team composition in different settings

Type of vaccination	Vaccination in emergency	Planned mass vaccination		Planned mass vaccination		Planned mass vaccination		Planned mass vaccination related to a study	
		1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose
Type of records	Marking & tally sheet only	Vaccination card, (marking) & tally sheet		Vaccination card, (marking) & tally sheet		Vaccination card, (marking) & tally sheet		Tally sheet, vaccination card & register logbook (marking optional)	
Team member	Description of task	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose
Screener	See if people are eligible (1st round: age, fasting / 2nd round: see if received 1st dose, fasting)	1	1	1	1	2	1	2	1
Registration	Fill vaccination card (name, address,								
Consent	Explanation on OCV campaign, and studies linked							2	
Buffer prepare solution	Prepare buffer solution mixing safe water with buffer sachets	1	1	1	1	1	1	1	1

Vaccinator	Mix vaccine and buffer & control vaccine ingestion	1	1	1	1	2	2	2	2	2	2
Tally sheet recorder	Fill the tally sheet										
Finger marker/ stamp	Mark the finger of vaccinated person and/ or stamp the vaccination card	1	1	1	1	1	1	2	2	2	2
Registry recorder	Fill the logbook register										
Exit	Control that person going out is well registered							1	1	1	
Crowd controller	Control the flux	1	1	1	1	2	2	3	3	4	3
Cleaner	Keep the local clean	Team members	Team members	Team members	1	1	1	1	1		
Team leader	Supervise the team	The vaccinator	The vaccinator	The vaccinator	1	1	1	1	1		
Health educator	Inform population and give health education message (waiting area)	1	1	1	1	1	1	1	1	1	
TOTAL PERSONS IN ONE TEAM		6	6	6	6	11	10	14	13	17	13
Vaccinated people per team per hour		50-70	50-70	40-60	50-60	80-100	90-110	70-90	70-90	60-90	70-90

Annex 7

Flowchart



Annex 8

Explanation and flow chart for control forms

1. VACCINATION POST LEVEL

Form 1: Tally sheet

How many?	2–3 sheets per day per vaccination post (1 sheet = average of ~80 people)
What for?	Record people (age range; sex) going forward to the vaccination post Record people refusing vaccine or sick Record vaccine doses received and used during the day
Who fills it in?	For people: the recorder in charge at vaccination post For vaccine: the vaccination post leader
When?	During the entire vaccination day
Why?	So that the vaccination post leader may complete Form 2, <i>Summary of tally sheets</i> So that the peripheral coordinator may complete Form 3, <i>Vaccination round summary</i>
To be sent where?	To the peripheral coordinator at the end of each dose session
Why?	So that the peripheral coordinator has a back-up

Form 2: Summary of tally sheets

How many?	2 sheets per vaccination post (1 per dose)
What for?	Summarize daily information coming from <i>Tally sheets</i> • Record number of people vaccinated (age range; sex) during the round (detailed per day) • Record vaccine use and waste during the round (detailed per day) • Record the number of people who refused the vaccine (refused; very sick)
Who fills it in?	The vaccination post leader

When?	Once a day, after recovering the <i>Tally sheets</i> of the day Each day, the vaccination post leader must give the data to the peripheral coordinator.
To be sent where?	Send a copy to the peripheral coordinator at the end of each dose session
Why?	So that the peripheral coordinator may complete: • the 1st dose daily summary (for round 1) • the 2nd dose daily summary (for round 2) • the vaccination-round summary

NOTES

In case there are several small vaccination posts, with teams moving every day from one to one other, for example, if one team vaccinates each day at a different village:

- use ONE *Summary of tally sheets* PER TEAM (and not per post)
- record at the beginning of each day the village vaccinated.

2. PERIPHERAL LEVEL

Form 3: Vaccination round summary

How many?	2 sheets per peripheral base (1 per dose)
What for?	Summarize information coming from <i>Tally sheets</i> and <i>Summary of tally sheets</i> given by each vaccination post leader • Record vaccine used and wasted during the round (detailed per vaccination post) • Record the number of people vaccinated (age range; sex) during the round (detailed per vaccination post) • Record the number of people who refused the vaccine (refused; very sick)
Who fills it in?	The peripheral coordinator
When?	1 x per dose session, after recovering <i>Tally sheets</i> and <i>Summary of tally sheets</i> from each vaccination post leader
To be sent where?	Send a copy to the regional coordinator at the end of each dose session
Why?	So that the regional coordinator may complete ONE <i>Vaccination round summary</i> sheet at his/her level

Form 4a: 1st Dose daily summary (to be used for round 1)

Form 4b: 2nd Dose daily summary (to be used for round 2)

How many?

1 sheet of each, per peripheral base

What for?

Summarize information coming from *Summary of tally sheets* given by each vaccination post leader

- Record vaccine used and wasted during the round (detailed per vaccination post and per day)
- Record the percentage of vaccine wastage during the round (detailed per vaccination post and per day)
- Record the number of people vaccinated during the round (detailed per vaccination post and per day)
- Record the coverage of the round (detailed per vaccination post and per day)
- Record the number of people who refused the vaccine (refused; very sick)

Who fills it in?

The peripheral coordinator

When?

Each day when recovering data from vaccination post leaders or 1 x per dose session, after recovering all *Summary of tally sheets* from all vaccination post leaders

Each day, the peripheral coordinator must give the data to the regional coordinator.

To be sent where?

Send a copy to the regional coordinator at the end of each dose session

Why?

So that the regional coordinator may complete:

- ONE Form 4a, at his/her level, at the end of the round 1
- ONE Form 4b, at his/her level, at the end of the round 2

Form 5: Dose 1 & 2 Summary

How many?

1 sheet per peripheral base

What for?

Summarize information already collected and written on:

- 1st dose daily summary sheet
- 2nd dose daily summary sheet
- Vaccination round summary (1st dose)
- Vaccination round summary (2nd dose)

- Record vaccine used and wasted during the 2 rounds (detailed per peripheral post, for round 1, round 2 and total)
- Record percentage of vaccine wastage during the 2 rounds (detailed per peripheral post, for round 1, round 2 and total)
- Record the number of people vaccinated during the 2 rounds (detailed per peripheral post, for round 1, round 2 and total)
- Record the percentage of coverage during the 2 rounds (detailed per peripheral post, for round 1, round 2)
- Record vaccine coverage after 2nd dose

Who fills it in?

The peripheral coordinator

When?

1 x at the end of the vaccination campaign

To be sent where?

Send a copy to the regional coordinator at the end of the campaign

Why?

Information for the regional coordinator

3. REGIONAL LEVEL

Form 3: Vaccination round summary

How many?

2 sheets per regional base (1 per dose)

What for?

Summarize information coming from *Vaccination round summary* sheets given by each peripheral coordinator

- Record vaccine used and wasted during the round (detailed per peripheral base)
- Record the number of people vaccinated (age range; sex) during the round (detailed per peripheral base)
- Record the number of people who refused the vaccine (refused; very sick)

Who fills it in?

The regional coordinator

When?

1 x per dose session, after recovering *Vaccination round summary* sheets from each peripheral coordinator

To be sent where?

Send a copy to the central coordinator at the end of each dose session

Why?

So that the central coordinator may complete ONE *Vaccination round summary* sheet at his/her level.

Form 4a: 1st Dose daily summary (to be used for round 1)

Form 4b: 2nd Dose daily summary (to be used for round 2)

How many?	1 sheet of each, per regional base
What for?	Summarize information coming from <i>Daily summary</i> sheets given by each peripheral coordinator • Record vaccine used and wasted during the round (detailed per peripheral base and per day) • Record the percentage of vaccine wastage during the round (detailed per peripheral base and per day) • Record the number of people vaccinated during the round (detailed per peripheral base and per day) • Record the coverage of the round (detailed per peripheral base and per day) • Record the number of people who refused the vaccine (refused; very sick)
Who fills it in?	The regional coordinator
When?	Each day when recovering data from peripheral coordinators or 1 x per dose session after recovering all <i>Daily summary</i> sheets from all peripheral coordinators
To be sent where?	Send a copy to the central coordinator at the end of each dose session
Why?	So that the central coordinator may complete: • ONE Form 4a, at his/her level, at the end of round 1 • ONE Form 4b, at his/her level, at the end of round 2

Form 5: Dose 1 & 2 Summary

How many?	1 sheet per regional base
What for?	Summarize information already collected and written on: — 1st dose daily summary sheet — 2nd dose daily summary sheet — Vaccination round summary (1st dose) — Vaccination round summary (2nd dose) • Record vaccine used and wasted during the 2 rounds (detailed per peripheral post, for round 1, round 2 and total)

- Record percentage of vaccine wastage during the 2 rounds (detailed per peripheral post, for round 1, round 2 and total)
- Record the number of people vaccinated during the 2 rounds (detailed per peripheral post, for round 1, round 2 and total)
- Record the percentage of coverage during the 2 rounds (detailed per peripheral post, for round 1, round 2)
- Record vaccine coverage after the 2nd dose

Who fills it in?

The regional coordinator

When?

1 x at the end of vaccination campaign

To be sent where?

Send a copy to the central coordinator at the end of the campaign

Why?

So that the central coordinator has the information

4. CENTRAL LEVEL

As for the regional level, but at central level.

Five key summary sheets are needed for overall analysis of the vaccination campaign:

Form 3: Vaccination round summary (round 1)

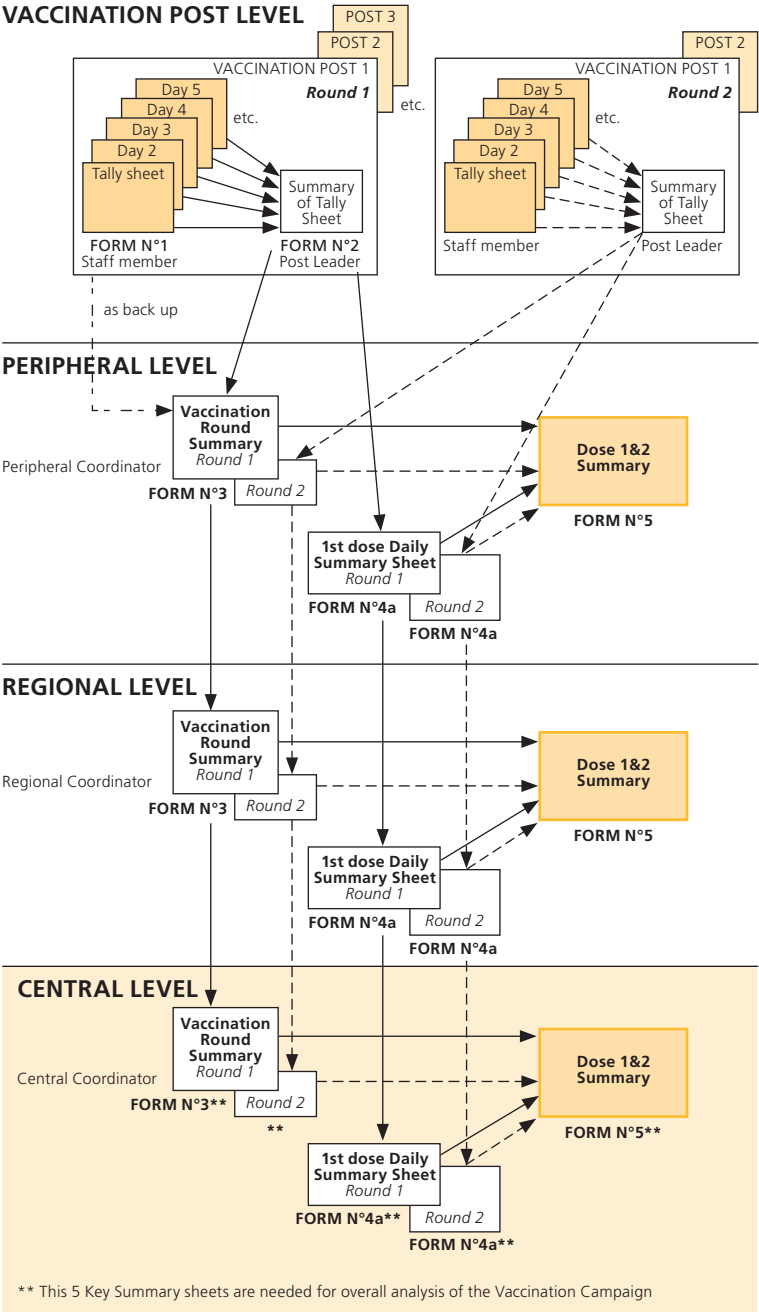
Form 3: Vaccination round summary (round 2)

Form 4a: 1st dose daily summary

Form 4b: 2nd dose daily summary

Form 5: Dose 1 & 2 summary

VACCINATION POST LEVEL



References

1. Cholera vaccines: WHO position paper. *Weekly Epidemiological Record*, 2010, 85(13):117–128.
2. *Oral cholera vaccine use in complex emergencies: what next?* Report of WHO meeting, 14–16 December 2005, Cairo. WHO/CDS/NTD/IDM/2006.2 http://www.who.int/cholera/publications/cholera_vaccines_emergencies_2005.pdf).
3. Watson JT, Gayer M, Connolly MA. Epidemics after natural disasters. *Emerging Infectious Diseases*, 2007, 13(1) (www.cdc.gov/ncidod/EID/13/1/1.htm).
4. Florent N et al. Negligible risk for epidemics after geophysical disasters. *Emerging Infectious Diseases*, 2006; 12(4):543–548.
5. *First steps for managing an outbreak of acute diarrhoea*. Geneva, WHO, 2003 (WHO/CDS/CSR/NCS/2003.7 Rev.1; http://www.who.int/cholera/publications/first_steps/en/index.html); *Acute diarrhoeal diseases in complex emergencies: critical steps*. Geneva, WHO, 2004 (WHO/CDS/CPE/ZFK/2004.6; http://www.who.int/cholera/publications/critical_steps/en/index.html); *Cholera outbreak: assessing the outbreak response and improving preparedness*. Geneva, WHO, 2004 (WHO/CDS/CPE/ZFK/2004.4; http://www.who.int/cholera/publications/cholera_outbreak/en/index.html).
6. Jertborn M, Svennerholm AM, Holmgren J. Evaluation of different immunization schedules for oral cholera B-subunit whole-cell vaccine in Swedish volunteers. *Vaccine*, 1993, 11:1007–1012.
7. Chaignat CL et al. Cholera in disasters: do vaccines prompt new hopes? *Vaccines*, 2008, 7(4): 431–435.
8. Meeting of the Strategic Advisory Group of Experts on Immunization, October 2009: conclusions and recommendations. *Weekly Epidemiological Record*, 2009, 84(50): 526–528.
9. Ali M et al. Herd immunity conferred by killed oral cholera vaccines in Bangladesh: a re-analysis. *Lancet*, 2005, 366:44–49.

For further information, please contact the
Global Task Force on Cholera Control
cholera@who.int or visit our web site at
www.who.int/cholera



World Health
Organization

ISBN 978 92 4 150043 2



9 789241 500432