Addendum to
"Oral cholera vaccines in mass immunization campaigns. Guidance for planning and use" [1]

Specificities of mass immunization campaigns when using Shanchol™ OCV

1. Preamble

The guidance for planning and use of oral cholera vaccines (OCV) in mass immunization campaigns, edited by WHO in 2010, was intended principally for the use of Dukoral® OCV, the only WHO prequalified cholera vaccine at the time.

Most principles and recommendations in this guidance can be applied to Shanchol™ OCV except for those related to the logistics of water, as Shanchol™ OCV does not require any buffer solution. There are some footnotes in the original guidance referring to Shanchol™ OCV specificities. However, additional information is required to inform the implementation of a mass vaccination campaign. The intention of this addendum is to provide additional information, with reference to the titles of chapters, paragraphs and page numbers where each topic is mentioned in the original guidance (presented in square brackets in the relevant section below).

2. Cholera vaccines: general considerations:

The primary immunization schedule with Shanchol™ OCV consists of two doses given at an interval of two weeks.

[2. Cholera vaccines: general considerations (Page 6)]

Characteristics of currently available vaccines

COMMERCIAL NAME	Dukoral® (WC/rBS)	Shanchol™(BivWC)
Protection against	*V. cholerae* O1 for > 50% for 2 years Earliest onset of protection 7 days after 2nd dose	*V. cholerae* O1 and O139 for > 50% for at least 3 years Earliest onset of protection 7-10 days after 2nd dose
Exclusion criteria	Children < 2 years	Children < 1 year
Presentation	Oral suspension (vaccine) and effervescent granules (buffer)	Oral suspension (vaccine)
Shelf-life	3 years	30 months
Storage	Cold chain (+2 – +8 °C)	Cold chain (+2 – +8 °C)
Stability at ambient temperature	1 month at 37 °C	VVM type 14 (14 days at 37°C)
Administration course	2 doses minimum 1 to maximum 6 weeks apart	2 doses at an interval of 2 weeks
Amount of drinking water needed/dose	150 ml for adults and children > 6 years 75 ml for children aged 2–5 years	Administered without any buffer, to be followed by water ingestion
Current price (2013)	~ $ 4.7-9.4 per dose	~ $ 1.85 per dose

[1] http://whqlibdoc.who.int/publications/2010/9789241500432_eng.pdf

WHO prequalified	Yes	Yes

[2.1.3 Characteristics of currently available vaccines Administration course (Page 8)
[2.3.3 Recommendations on the use of OCV in endemic Settings. **Vaccination strategies and sustainability** (Page 13)]

3. Organizing and implementing a mass vaccination campaign

Shancol™OCV is prequalified for 2 doses administered 2 weeks apart. Two weeks are needed between the last day of the 1st round (1st dose) and the 1st day of the 2nd round.
[3. Organizing and implementing a mass vaccination campaign (Page 14)]

- **Planning:**

Target population: Shanchol™ vaccine can be administered to anyone above the age of one year.

If disaggregated figures are not available, a percentage representing the proportion of children < 1 year should be deducted. Usually, 3 %[2] of a population are aged < 1 year.

Example
Target population for a target area of 20 000 inhabitants
The age-range population data are not available; the average figure of 3% of children < 1 year is therefore taken as a basis for calculation. The target population includes all except children < 1 year.
20 000 – (3% x 20 000) = 20 000 – 600 = 19 400 persons

[3.2.1. Planning and supervision. Target population (Page 16)]

- **Human resources:**

Staff for immunization posts

A vaccination team consists of a *minimum* of three people to administer Shanchol™ vaccine.

Person 1: responsible for screening for eligibility and filling out the immunization card
Person 2: vaccinator, responsible for vaccine administration and checking the full ingestion of the vaccine.
Person 3: responsible for filling in tally sheets and stamping (or signing) the immunization card.
A fourth person may be added:
Person 4: communicates health education messages

Although a person responsible for the buffer solution is not needed, an additional person will be necessary to remove the aluminium cap of the vial in vaccination sites expecting high number of vacinees.

[2] 3% for under 1 years % when local population data are not available (EPI module). Alternatively, the percentage of children under 1 year can be estimated by the country birth rate (e.g. http://data.worldbank.org)

[3.2.4. Human resources: Staff for immunization posts (Page 20)]

- **Logistics**

Vaccines

Estimation of vaccine requirements

Taking into account that:

• the target population corresponds to all persons except children < 1 year (3% when local population data are not available)

Example
Vaccine requirements for a population of 20 000 for which age range population data are not available
Number of doses required = target population x 2 doses = 19 400 x 2 = 38 800 doses.

[3.2.5. Logistics .Vaccines (Pag 23)]

Transport and storage of vaccines

A refrigerator with a storage volume of 196 litres is able to hold **10145** doses. Add 15% for additional space in mass vaccination campaign.

More space is needed for transport and storage of OCV vaccines since they are presented in a monodose vial. By comparison, the volume needed to vaccinate 500 people against cholera using Shanchol™ OCV, corresponds to more than **6** times the volume required for measles vaccine[3].

Volume requirement for storage in cold room or refrigerator to vaccinate 20 000 people (40 000 doses), taking into account that vials are of 16.8 ml (for a content of 1.5 ml and 35 vials per package): 672 litres + 15% = 772 litres.

[3.2.5. Logistics Transport and storage of vaccines (Page 24)]

Shanchol™ box size of 35 vials is: 14cm x 10.5cm x 4 cm

Example.

[3] With 15% additional space

International shipment of 200,025 doses of OCV Shanchol™ in Thermocool box shippers with coolants and outer corrugated box.

Total No. of Shippers	**127 Shippers**
Total No. of Vials Per Shipper	**1575**
Shipper Dimension	**58 X 47.5 X 39 Cms**
Total Weight	**2,730 Kgs +/- 5%**
Total Volume	**13.716 Cub. Meters**
No. of Gel Packs / Shipper	**09 Packs**
Gel Pack Size	**21.6 cm X 14.6 cm**
Electronic Device & Type	**Vax Alert & WHOType 1**
Delivery Preparation Lead Time	**04 Days**
List of Documents Accompany with Cargo	**Invoice, Packing List, CDL, Certificate of Analysis, Certificate of Origin, Summary Lot Protocols, Vaccine Arrival Report**

Source : Shantha Biotech[Replace example Logistics. 3.2.5. Transport and storage of vaccines. page 24.]

Steps from central to peripheral level: cold-chain requirements

Vaccines temperature monitors are not required in the vaccine boxes during transport from central to peripheral level because each vial has a vaccine vial monitor (VVM).

[3.2.5. Steps from central to peripheral level: cold-chain requirements (Page 25)]

Materials other than vaccines:

Measuring cups and scissors are not necessary when using Shanchol™ OCV but water containers and cups would be required to provide water after vaccine administration.

Pliers or a butter knife are necessary to open the metallic cap of the Shanchol™ OCV vials.

[3.2.5 Logistics. Transport and storage of materials other than vaccines. (Page 30)]
[3.3.2. Immunization session. The following materials are required, per team, at each vaccination post. (Page 38)]

- ## Immunization session

Organization of vaccination posts

There is no need to have a responsible person for buffer solution preparation and pouring the correct amount of buffer solution into the cup.

- A vaccination team will consists of a *minimum* of three people for Shanchol™ OCV

[3.3.2. Immunization session. Organization of vaccination posts. Model for 1st dose session/study (Figure Page 37)]
[3.3.2. Staff: Immunization team.(Page 39)]
[3.3.2. Preparation and administration of the vaccine. (Page 40)]
[3.3.2 Model for 1st dose session/study (Figure Page 44)]

[3.5. Mass vaccination campaign linked to research studies. (Page 43)]
Annexes 3.Staff required and relevant job description. Preparation of buffer solution: (Page 57)
Annex 6: Team composition in different settings Team member (Page 72) and TOTAL PERSONS IN ONE TEAM (Page 73)

Activities at the vaccination post

Since fasting 1 hour before and after ingestion of vaccine is not required with Shanchol™ OCV it should not be part of the screening process of the target population before receiving the vaccine. In addition fasting requirement will not be included in the staff training or in the health education messages at the vaccination post training.

[Planning of activities. 3.3.1. Training (Page 33)]
[3.3.2. Activities at the vaccination post. Health education messages (Page 39)]
[3.3.2. Activities at the vaccination post. Screening (Page 39)]
Annexes 3 Staff required and relevant job description. Screening and issuing vaccination cards. (Page 57)

Screening

The population must be screened to control their eligibility to receive the vaccine
For Shanchol™ OCV the eligibility criteria are:

- To be over > 1 year old,
- Currently the vaccine is not recommended for use in pregnancy due to limited data available and lack of specific studies. However, it is a killed vaccine, given orally and acts locally in the intestine. In theory vaccination should not pose any risk to the fetus. Administration may be considered after a benefit-risk evaluation.
- Fasting 1 hour before vaccine intake is not required.

[3.3.2. Activities at the vaccination post. Screening. (Page 39)]

Preparation and administration of the vaccine

Vaccine preparation: Remove the aluminium cap of the vial with pliers or a butter knife.
Vaccine ingestion: The vaccine is presented as a suspension. After a vigorous shaking of the vial, squirt all 1.5 ml suspension into the mouth of the recipient.
[3.3.2 Preparation and administration of the vaccine. (Page 40)]
[3.5 Mass vaccination campaign linked to research studies. Staff. (Page 43)]

4. Annexes

Vaccinator terms of reference

- Remove the aluminium cap of the vial with pliers or a butter knife
- Shake the vial vigorously and squirt all 1.5 ml suspension into the mouth of the recipient
- Check ingestion, particularly for young children, and report it on the vaccination card.
- Offer water to all vacinees
- Dispose of the vaccine vials, vials caps, water cups and other disposals into the appropriate waste bins.

[Annex 3. Staff required and relevant job descriptions. Vaccinator terms of reference. (Page 57)]

5. Annex: Tally sheets and summary tables

Age groups: 1-4 years, 5-15, > 15 years old
[Annex 5: FORM 1 (Page 66)]
Age groups: 1-4 years, ≥5 years old
[Annex 5: FORM 2 (Page 67), FORM 3 (Page 68)]

6. Other general recommendations:

- OCV is freeze sensitive. One of the most common errors is to put frozen ice packs in cold boxes for transport. Ice packs should be somewhat/half melted in order to not freeze OCV during transport.

[3.4. Common errors that may diminish campaign Effectiveness. (Page 41)

- Marking fingernails is no longer recommended as the mark for the first dose will disappear before the 2nd round session. Marking will be useful if goods are distributed to the vaccinees as part of a WASH intervention (e.g. soap, chlorine). Issuing vaccination cards is preferred and they will be requested in vaccination campaign evaluations.

[3.2.5. Logistics. Registration material. (Page 28)]

- The additional storage percentage of 35% in the “Oral Cholera Vaccine guidance” is commonly used for routine vaccination.
  A 15% is now recommended for mass vaccination campaigns. This percentage is applied in the addendum for storage needs calculations.

[3.2.5. Logistics Transport and storage of vaccines (Page 24)]