

Generic protocol for vaccine coverage
post implementation of a mass
vaccination campaign with oral cholera
vaccine

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1. Background

Cholera is an infection of the intestines caused by the bacterium *vibrio cholerae*. The infection is usually transmitted by consumption of contaminated food or water. It can lead to severe watery diarrhea, dehydration and in some cases, death. The World Health Organization currently prequalifies two safe and effective oral vaccines. Vaccination campaigns can take place to prevent or quickly stop large outbreaks. Additional background on cholera and vaccines can be found in the World Health Organization website.

Vaccination coverage estimates help determine population vulnerability and improve future planning of health activities. Administrative estimates, computed by dividing the number of vaccinations provided by the number of people eligible for that vaccination are often inaccurate, especially if good records are not kept during vaccination, or if population estimates are wrong. Surveys rely on house to house interviews after the vaccination campaign and are less affected by errors in population estimates compared to administrative coverage estimates. In the case of mass oral cholera vaccine campaigns, we are also interested to know what proportion of this target population received a single dose or the complete two doses.

2. Survey Objectives

Evaluate the vaccination coverage from a mass vaccination campaign using oral cholera vaccine.

3. Methods

When implementing a VC survey it is prudent to be familiar with the requirements of the local government and ensure that the protocol complies with the ethics board requirements. Vaccine coverage surveys are normally deemed non-research and do not require additional review.

3.1 Sampling

This survey will utilize a two-phase cluster design. In the first phase, a fixed number of population groupings or “clusters”, such as neighborhoods, villages or health zones are selected. In the second phase, a fixed number of households within each cluster is selected, and information gathered on one or several eligible individuals residing there. If separate estimates are needed for different areas, such as urban and rural areas, or for specific age groups, additional information and interviewees will be needed (see Appendix 1).¹

¹ Technical support should be sought to develop the sampling strategy and determine the total number of people needed in the survey, but Appendix 1 and the following sections provide an overview.

3.2 Sample size

For this cluster survey, we will assume 50% vaccination coverage (to be safe, as this leads to the highest number of survey participants). We will assume a design effect (DE) of 2 to account for differences within and between clusters and a confidence of 95% (equivalent to a 5% probability being wrong). These values should be confirmed with a statistician on a context specific basis, however.

As can be seen in table 1, for precision of +/-7%, our target sample size is 196 people. This base figure must be doubled for a DE=2, thus we need at least 392 individuals in the survey.² If stratified estimates are needed, such as age group specific estimates, 392 of individuals in each age group would be required.

Table 1 shows the base sample size needed for this survey varying by vaccination coverage estimates and desired precision levels. Appendix 1 contains additional material on sample size estimation.

Table 1. Sample size calculation able for vaccination coverage survey
Base number of interviewees needed for a given vaccination coverage and desired precision

| | | Precision (+/-error) | | | | |
|----------------------|-----|----------------------|------|-----|-----|-----|
| | | 1% | 3% | 5% | 7% | 9% |
| vaccination coverage | 10% | 3446 | 384 | 139 | 71 | 43 |
| | 20% | 6109 | 683 | 246 | 126 | 70 |
| | 30% | 8003 | 896 | 323 | 165 | 100 |
| | 40% | 9136 | 1024 | 369 | 189 | 114 |
| | 50% | 9513 | 1066 | 384 | 196 | 119 |
| | 60% | 9136 | 1024 | 369 | 189 | 114 |
| | 70% | 8003 | 896 | 323 | 165 | 100 |
| | 80% | 6109 | 683 | 246 | 126 | 70 |
| | 90% | 3446 | 384 | 139 | 71 | 43 |

This number should be multiplied by the design effect and the number of strata to obtain the final sample size

The sample size estimates included in this table assume 95% confidence and design effect (DE)=1
Source: <http://www.openepi.com/v37/SampleSize/SSPropor.htm>

3.3 Cluster Selection

For the computed sample size, about 30 clusters should be selected (minimum 25) proportionate to population size. Additional guidance is provided in Appendix 1.

3.4 Household Selection

Within each cluster the number of households to be interviewed is computed by dividing the sample size by the number of clusters we intend to visit. Here, 392 people / 30 clusters = 13.06, or rounding up, 14 households in each of the 30 clusters.

² Targeted population are: 12 months and older for Shanchol vaccine; 24 months and older for Dukoral vaccine. Pregnant women should be excluded from vaccination, survey and sample size calculation.

Once the clusters are selected, choosing each home to be interviewed can be done in several ways. If a list of households exists, for instance with the village chief, these can be chosen at random. Otherwise two steps are needed: 1) selecting the first

home, and 2) selecting subsequent homes to be interviewed.

If the cluster is not too big, once the borders and geographic center is located (with the help of local residents), a direction can be chosen at random by spinning a pen on the ground; all houses on one side in the selected direction are then counted, from the center to the edge of the cluster. Then a random number should be selected between 1 and the last home numbered in that direction. See Appendix 2 for a random number table and instructions for its use. This will be the first home to be interviewed. If spinning the pen results in a direction that does not include any homes, it can be spun again, but it should not be done because it points to an inconvenient location.

If the cluster is too large to be walked within a reasonable time from center to edge, it can be divided in two or four sections (for instance North, South, East, West) and one of these chosen at random. The procedure is then the same as described above, except the center and border are for that section only.

To select subsequent homes to be interviewed, interviewers can simply go to the next nearest home to the last one interviewed until the required number of homes is reached. If the interviewer is unsure, he or she can explore or ask. If two are at the same distance the next home can be the one closest on the right.

Interviewers should adhere to a single definition of *household*. A common definition is: *a group of people who have lived together for at least 2 weeks, who eat together and sleep under one roof, and follow the direction of one head of household*.

In the case of compounds where several households exist, for instance a group of brothers who live in one enclosed area but have separate homes or huts, one should be selected at random, but a note should be made about how many head of households were in that compound.

Once the specified number of households has been reached (i.e. 14), interviews in that cluster can stop. If a particular age strata has been specified, however, interviewees should continue until that number from each age group has been interviewed (i.e. 14 of each age group).

3.5 Selection of participants within the household

In some studies all eligible household members are interviewed. In others only one, or one from each age group, is selected at random for interview. The latter approach (1 random individual) requires additional adjustments in the analysis, thus the number of eligible individuals per household should be recorded for each interviewed household.

3.6 Special Circumstances

Alternative approaches can be used, but these are recommended for this survey:

- Only private homes should be selected. Public institutions such as schools or abandoned or empty structures should not be selected.
- If the family is not there at the time of the interview, but is currently living there, the interviewer should make a note of it and attempt an interview later that day.

- For apartment buildings, it is best to select one home at random but make note of how many apartments were present in the building.
- If all homes in the cluster are interviewed and still more are required to complete the required homes for that cluster, the team can move on to the next nearest home in the closest town/village. The team leader should be consulted if possible, otherwise informed at the end of the day.
- Some areas will need to be excluded from the survey due to inaccessibility or safety concerns. Exclusions should be handled at the time of cluster selection. If an area becomes inaccessible after this, the team leader, not the interviewers, should select a replacement. Areas should not be excluded because they are harder to reach.
- If in doubt about anything, interviewers should call a supervisor
- Data collection forms should be adapted to context-specific, likely, complications. For instance, if compounds or polygamous marriages are common.

3.7 The Interview

Interviewers should be trained to approach residents with respect, and ask questions in a neutral and non-judgmental manner. After the interviewer has introduced him or herself and the family member has consented to participate, the interview should be carried out at a steady pace, not so fast that answers become unreliable, but not so slow that it becomes inefficient and too time consuming for interviewees.

For children, interviewers should attempt to interview the children's mother, as they will usually provide more accurate answers about the child's vaccination status than others. It is preferable to conduct the interviews in the presence of the children, as they sometimes can fill in information or may have been vaccinated without the parents' awareness. Vaccination cards and registry logbooks provide the best evidence that the vaccination took place, but sometimes they are lost, incomplete or not filled. In these cases verbal information is recorded.

Both interviewers in a team should work together, rather than split up. Two will be better able to catch an error in recording or if an unclear answer is given. Minimally, team mates should review each other's work for properly filled out forms. The point of having two interviewers per team is not so that they conduct interviews separately; it is for accuracy and security. In situations of mixed gender teams, when only a female team member is allowed to enter the house, the male team member can review the paperwork for completeness and legibility, and also select the next household and start the informed consent process.

3.7.1 The Informed Consent Process

In the informed consent process, the interviewer introduces him or herself, explains what information they are collecting and why they are collecting it. It describes potential risks and benefits to participants and clarifies that people are free to participate or not without any risk of harm or discrimination. It also provides the opportunity for participants to ask questions so they can make an informed decision on whether they wish to participate. Interviewers should be trained to encourage participation, but not pressure people to

participate. Acceptance by the community leader and local health worker can be very helpful to encourage participation.

The information letter should be read or summarized by the interviewer or read by the participant if he or she is able. If the person agrees to participate they should sign the form, unless the team leader has specified that verbal consent has been approved for that particular context. An example of information letter and a consent form are provided in Appendix 3. If the interviewee is not able to write, a witness should be there during the process and can sign in the respective place, so long as the participant verbally agrees and provides their thumbprint. In most coverage surveys written is not required (oral consent is sufficient). Once the form is signed, data collection can begin.

3.7.2 Filling the Vaccination Coverage Questionnaire

Please see Data collection form for the cholera vaccination coverage survey found in Appendix 4

- The interviewer fills in the date and survey team responsible,
- Next, all information for one individual (that is, one row) should be completed before starting on the next individual on the next row. This information should be collected for all household members who were eligible for vaccination (people at last 1 or 2 years of age (depending on the vaccine type) who were not pregnant at the time of the vaccination campaign).
- A serial number was assigned to each vaccinated person during the campaign and appears in the vaccination card and again in the Registry Logbook (this may not be the case for all campaigns). This serial number should be written, for the first household member who was eligible for vaccination should be written in the first line of the first column. If the information is missing then the interviewer should write down all information that could help identify the interviewee, such as age or birthday, household, parents' information, etc.
- The age, or birthdate, from the vaccination card or registry logbook should be entered next, to the right of the corresponding serial number. If it is not recorded or unknown, it can be estimated. A calendar of major local events can help the interviewer pinpoint the age roughly.
- Next the information from the vaccination card is filled. For first dose, "C" is circled if the "C" appears in the vaccination card for first dose, "I" is filled if the card states an incomplete first dose was given, or "N" is filled if the card states that the first dose was not given. If the card is missing cross the section out with an X. The same is repeated for the second dose.
- Next, the person (or parent in case of a child) is asked whether a complete first and second dose was received (for that child), and the form filled accordingly as "C" for complete, "I" for incomplete, or "N" for not received. If the information contradicts that of the card, the interviewer can inquire but should still record what the person states, and make a note that this discrepancy was noted.
- Next, the same information is collected and filled from the registry logbook for first and second dose in the same manner as described above for card.

- After these three sections have been filled, the interviewer begins to fill out information on the next eligible household member and their corresponding serial number.
- Some additional questions related to vaccine accessibility, acceptability, and potentially wat/san access could be included in the questionnaire if a separate survey is not possible

4. Communication of the results

The survey leader should ensure that both the health authorities and the communities involved in the survey receive, through appropriate channels, the main outcomes from the survey. A workshop with the health authorities and partners should be organized to share the results at local level. Further, it is advisable to organize a meeting with the local community leaders, so they may receive an information leaflet with the main outcomes of the survey. They can in turn distribute the information in their respective communities.

5. Timeline

- Planning and implementing this survey should be achievable within 10-20 days, as long as the necessary clearance is obtained beforehand.
- 2-3 days should be budgeted for coordination meetings with local authorities, staff recruitment, and logistical preparation (temporary base, cars,). Support from an experienced person in logistics is advisable.
- 3-4 days should be budgeted for training and pilot testing
- 4-6 days should be budgeted for data collection
- 2-4 days should be budgeted for debriefings, and finalizing accounting and data entry
- Additional time might be needed for travel to and from headquarters, as well as briefing and debriefing at capital or regional level.

6. Survey coordination

The survey should be done in coordination with health and local authorities. Appendix 5 provides recommendations for survey coordination.

Appendices

Appendix 1 – A guide to sampling and sample size

Sampling

It is rarely possible to interview everyone targeted in a mass vaccination campaign. This would only happen if the vaccinated population is small and lives close to each other, such as a small refugee camp, school or small community. In most cases, however, a coverage survey gathers information from a sample of people believed to represent well the population that was targeted in the vaccination campaign. The key is for the sample to be selected at random so that everyone in the target population has the same chance of being selected. The most appropriate sampling technique depends on the information available. For instance, if good satellite images or a complete list of residents exists, houses or people can be chosen at random from these. This is called simple random sampling. If residences are neatly organized into rows, we can systematically interview people in for instance every 5th household; this is called systematic sampling.

Most of the time less information is available, so we select a fixed number of households to interview from several population groupings. These groupings, or *clusters*, can be neighborhoods, blocks, settlements, villages, health zones, etc. Cluster sampling requires less background information on the population but also requires more people to be interviewed. A *two-stage cluster survey design* means that the clusters are selected first, and in a second stage, households and individuals are selected from within those clusters.

Some practical exercises for selecting clusters proportionate to population size follow below the section on sample size determination.

Sample Size

The number of people needed for the survey, or sample size, depends on how sure we wish to be about our estimate (confidence), the precision (+/- error) we are after, the proportion of people actually vaccinated, the number of strata (separate estimates) we are aiming for, and in the case of cluster surveys, the difference between vaccination coverage inside the clusters compared to between them (Design Effect, DE).

As shown in Table 1 in the main protocol, the higher the desired precision, and the closer the vaccination coverage is to 50%, the more people we will need overall or per stratum. Similarly, the more certain we wish to be about our estimate (confidence), the higher the required sample size will be. An accepted standard is 95% confidence, which allows for 5% chance that the true value is beyond the stated precision.

Cluster selection example

Example for 1) Two stage cluster sampling (stratified by 3 age groups), and 2) spin the pen (EPI) method for household selection within clusters

Objective: to measure vaccination coverage after a cholera mass vaccination. Sample size requirements have been determined to be 392 people from each of three age groups: 1-4 (for Shanchol) / 2-4 (for Dukoral), 5-14, 15+ years of age. Based on the age distribution of this population we can assume we will find on average at least one of each age group in most households.

The goal is 30 clusters with 14 households interviewed in each cluster (30x14=420 people of each age group)

obtain a list of all villages with their approximate population in the area to investigate

If population figures are not available, ask locals to assign a relative size to each village. One village can be used, village A, to assign the size to the other villages in relation to A (half as big, twice, three times bigger, etc).

- List the villages in any order along with their estimated population
- Create a running cumulative population (RCP) next to each village population
- The first village has 155 people, so the CP=155
- The second village has 1200 people, so the RCP = 155 + 1200 = 1355
- The next has 360, so RCP = 1355+360= 1715
- And so on...
- Select 30 clusters proportionate to population size, from the list of villages:
- Calculate total cumulative population (TCP)
- TCP = the sum of the all the village populations = 33360
- Calculate the sampling interval (i)=TCP / total desired clusters =
- $TCP = 33\,360 / 30 = 1112$
- Select the 1st cluster with a random selection of a number between 1 and i (r)
- Use the random number table for a number between 1 and 1112
- Let's say this random number (r) is 756
- The first cluster is in village 2, since 756 is more than the CPP at the first village (155), but less than the CPP at the second village (1355).
- Determine the successive clusters by adding the sampling interval $r+i$, $r+2i$, $r+3i$until the last cluster $r+30i$.
- The second cluster will be in village 4 since $r+i = 756 + 1112 = 1868$ and this falls between the CPP of village 3 and 4.
- The third cluster is $r+2i$ ($756 + (2 \times 1112)$) =2980 which is greater than the CP of village 4 but less than the CP of village 5.
- And so on until 30 clusters are reached

Example: Identify the clusters (villages) to investigate

Cumulative population TCP = 33360, Sampling interval (i) = 33360/30 = 1112

Random number (r) = 756, random number chosen between 1 and 1112

| Villages | Village's population | Running Cumulative Population (RCP) | Corresponding population figure | Number of clusters in each village |
|----------|----------------------|-------------------------------------|---------------------------------|------------------------------------|
| 1 | 155 | 155 | | |
| 2 | 1200 | 1355 | 756 | Cluster N°1 |
| 3 | 360 | 1715 | | |
| 4 | 230 | 1945 | 1868 | Cluster N° 2 |
| 5 | 2800 | 4745 | 2980, 4092 | Clusters 3 & 4 |
| 6 | 555 | 5300 | 5204 | Cluster N°5 |
| 7 | 423 | 5723 | | |
| 8 | 578 | 6301 | | |
| 9 | 3450 | 9751 | 6316, 7428, 8540, 9652 | Clusters 6 à 9 |
| 10 | 344 | 10095 | | |
| 11 | 622 | 10717 | 10764 | Clusters N°10 |
| 12 | 2567 | 13284 | 11876, 12988 | Clusters 11 & 12 |
| 13 | 666 | 13950 | | |
| 14 | 870 | 14820 | 14100 | Cluster N°13 |
| 15 | 450 | 15270 | 15212 | Cluster N°14 |
| 16 | 470 | 15740 | | |
| 17 | 689 | 16429 | 16324 | Cluster N°15 |
| 18 | 345 | 16774 | | |
| 19 | 780 | 17554 | 17436 | Cluster N°16 |
| 20 | 999 | 18553 | 18548 | Cluster N°17 |
| 21 | 783 | 19336 | | |
| 22 | 569 | 19905 | 19660 | Cluster N°18 |
| 23 | 370 | 20275 | | |
| 24 | 821 | 21096 | 20772 | Cluster N°19 |
| 25 | 1450 | 22546 | 21884 | Cluster N°20 |
| 26 | 1388 | 23934 | 22996 | Cluster N°21 |
| 27 | 233 | 24167 | 24108 | Cluster N°22 |
| 28 | 458 | 24625 | | |
| 29 | 1297 | 25922 | 25220 | Cluster N°23 |
| 30 | 3020 | 28942 | 26332, 27444, 28556 | Clusters N°24 à 26 |
| 31 | 579 | 29521 | | |
| 32 | 645 | 30166 | 29668 | Cluster N°27 |
| 33 | 255 | 30421 | | |
| 34 | 366 | 30787 | 30780 | Cluster N°28 |
| 35 | 476 | 31263 | | |
| 36 | 866 | 32129 | 31892 | Cluster N°29 |
| 37 | 789 | 32918 | | |
| 38 | 442 | TCP = 33360 | 33004 | Cluster N°30 |

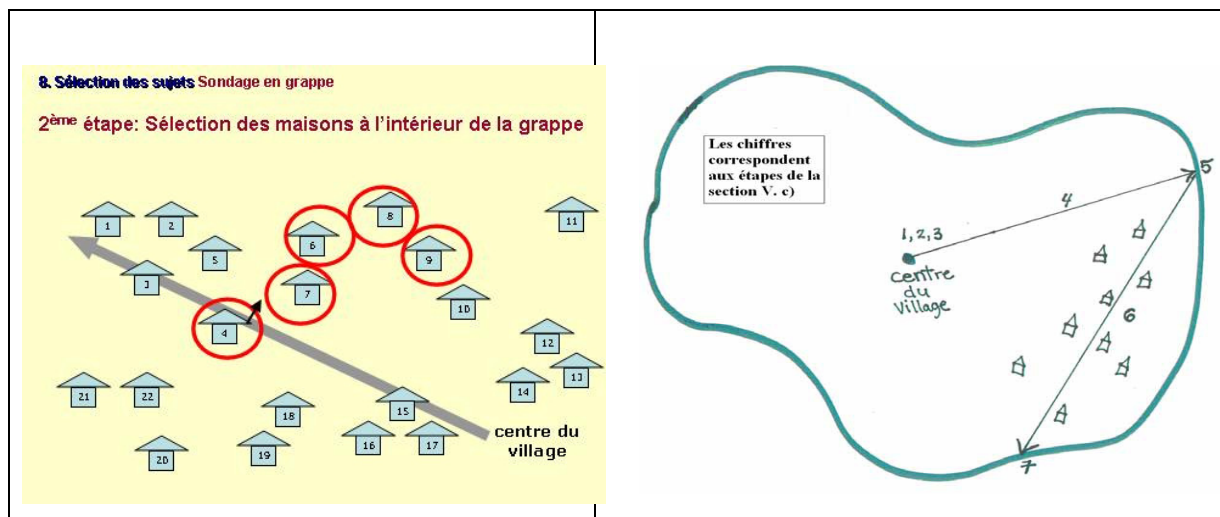
Stage 2: Selection of houses within the clusters

Determine the first house to investigate in each cluster in the following way (Figure 3):

- Walk around the section/village to demarcate it and identify its geographical centre (local people can help in this process);
- Go to the centre of the section/village;

- Choose a direction at random, for instance by spinning a pen on the ground, and mark the direction it indicates when it stops;
- Follow the direction indicated by the pen, from the centre to the border of the section/village, and count the number of houses encountered.
- To determine the first house, randomly select a number (r) from amongst the total number of houses counted.
- The next house is selected by proximity from the first house identified, for instance the closest house to the 1st one is selected.
- If houses have multiple households, select one in each house by randomization
- Assess all non-pregnant people at least 1 years of age in each household.

Figure 3: EPI method to select the first house



*Source : example and figures based on material from MSF Rapid Assessment Manual, 2011

Appendix 2 – Random Number Table

This table allows the interviewer to select a house or individual at random. For instance, if one needs to choose between a number between 1 and 5, a spot in the paper is selected with a pen and eyes closed. If the pen lands on a number within that range (1-5) then that number is selected; otherwise the pen is moved right to next number in the same line until a number in the desired range is found. For two digit numbers, for instance for a number between 1-50, the same process is repeated but we move right in blocks of two until a two adjacent numbers are found within the range 01-50. If the end of the page is reached, we continue with the left-most number on the following line down.

TABLE B Random digits

| Line | | | | | | | | |
|------|-------|-------|-------|-------|-------|-------|-------|-------|
| 101 | 19223 | 95034 | 05756 | 28713 | 96409 | 12531 | 42544 | 82853 |
| 102 | 73676 | 47150 | 99400 | 01927 | 27754 | 42648 | 82425 | 36290 |
| 103 | 45467 | 71709 | 77558 | 00095 | 32863 | 29485 | 82226 | 90056 |
| 104 | 52711 | 38889 | 93074 | 60227 | 40011 | 85848 | 48767 | 52573 |
| 105 | 95592 | 94007 | 69971 | 91481 | 60779 | 53791 | 17297 | 59335 |
| 106 | 68417 | 35013 | 15529 | 72765 | 85089 | 57067 | 50211 | 47487 |
| 107 | 82739 | 57890 | 20807 | 47511 | 81676 | 55300 | 94383 | 14893 |
| 108 | 60940 | 72024 | 17868 | 24943 | 61790 | 90656 | 87964 | 18883 |
| 109 | 36009 | 19365 | 15412 | 39638 | 85453 | 46816 | 83485 | 41979 |
| 110 | 38448 | 48789 | 18338 | 24697 | 39364 | 42006 | 76688 | 08708 |
| 111 | 81486 | 69487 | 60513 | 09297 | 00412 | 71238 | 27649 | 39950 |
| 112 | 59636 | 88804 | 04634 | 71197 | 19352 | 73089 | 84898 | 45785 |
| 113 | 62568 | 70206 | 40325 | 03699 | 71080 | 22553 | 11486 | 11776 |
| 114 | 45149 | 32992 | 75730 | 66280 | 03819 | 56202 | 02938 | 70915 |
| 115 | 61041 | 77684 | 94322 | 24709 | 73698 | 14526 | 31893 | 32592 |
| 116 | 14459 | 26056 | 31424 | 80371 | 65103 | 62253 | 50490 | 61181 |
| 117 | 38167 | 98532 | 62183 | 70632 | 23417 | 26185 | 41448 | 75532 |
| 118 | 73190 | 32533 | 04470 | 29669 | 84407 | 90785 | 65956 | 86382 |
| 119 | 95857 | 07118 | 87664 | 92099 | 58806 | 66979 | 98624 | 84826 |
| 120 | 35476 | 55972 | 39421 | 65850 | 04266 | 35435 | 43742 | 11937 |
| 121 | 71487 | 09984 | 29077 | 14863 | 61683 | 47052 | 62224 | 51025 |
| 122 | 13873 | 81598 | 95052 | 90908 | 73592 | 75186 | 87136 | 95761 |
| 123 | 54580 | 81507 | 27102 | 56027 | 55892 | 33063 | 41842 | 81868 |
| 124 | 71035 | 09001 | 43367 | 49497 | 72719 | 96758 | 27611 | 91596 |
| 125 | 96746 | 12149 | 37823 | 71868 | 18442 | 35119 | 62103 | 39244 |
| 126 | 96927 | 19931 | 36809 | 74192 | 77567 | 88741 | 48409 | 41903 |
| 127 | 43909 | 99477 | 25330 | 64359 | 40085 | 16925 | 85117 | 36071 |
| 128 | 15689 | 14227 | 06565 | 14374 | 13352 | 49367 | 81982 | 87209 |
| 129 | 36759 | 58984 | 68288 | 22913 | 18638 | 54303 | 00795 | 08727 |
| 130 | 69051 | 64817 | 87174 | 09517 | 84534 | 06489 | 87201 | 97245 |
| 131 | 05007 | 16632 | 81194 | 14873 | 04197 | 85576 | 45195 | 96565 |
| 132 | 68732 | 55259 | 84292 | 08796 | 43165 | 93739 | 31685 | 97150 |
| 133 | 45740 | 41807 | 65561 | 33302 | 07051 | 93623 | 18132 | 09547 |
| 134 | 27816 | 78416 | 18329 | 21337 | 35213 | 37741 | 04312 | 68508 |
| 135 | 66925 | 55658 | 39100 | 78458 | 11206 | 19876 | 87151 | 31260 |
| 136 | 08421 | 44753 | 77377 | 28744 | 75592 | 08563 | 79140 | 92454 |
| 137 | 53645 | 66812 | 61421 | 47836 | 12609 | 15373 | 98481 | 14592 |
| 138 | 66831 | 68908 | 40772 | 21558 | 47781 | 33586 | 79177 | 06928 |
| 139 | 55588 | 99404 | 70708 | 41098 | 43563 | 56934 | 48394 | 51719 |
| 140 | 12975 | 13258 | 13048 | 45144 | 72321 | 81940 | 00360 | 02428 |
| 141 | 96767 | 35964 | 23822 | 96012 | 94591 | 65194 | 50842 | 53372 |
| 142 | 72829 | 50232 | 97892 | 63408 | 77919 | 44575 | 24870 | 04178 |
| 143 | 88565 | 42628 | 17797 | 49376 | 61762 | 16953 | 88604 | 12724 |
| 144 | 62964 | 88145 | 83083 | 69453 | 46109 | 59505 | 69680 | 00900 |
| 145 | 19687 | 12633 | 57857 | 95806 | 09931 | 02150 | 43163 | 58636 |
| 146 | 37609 | 59057 | 66967 | 83401 | 60705 | 02384 | 90597 | 93600 |
| 147 | 54973 | 86278 | 88737 | 74351 | 47500 | 84552 | 19909 | 67181 |
| 148 | 00694 | 05977 | 19664 | 65441 | 20903 | 62371 | 22725 | 53340 |
| 149 | 71546 | 05233 | 53946 | 68743 | 72460 | 27601 | 45403 | 88692 |
| 150 | 07511 | 88915 | 41267 | 16853 | 84569 | 79367 | 32337 | 03316 |

Appendix 3 – Letter of Information and Informed Consent

Information letter:

I am working in collaboration with Ministry of Health of *Country name*. We are trying to study cholera, which is very common in this country.

Cholera is responsible for many cases of severe diarrhoea in children and adults in *Country name*. Cholera can be prevented by drinking safe water and practicing good hygiene. All information related to safe water and practicing good hygiene is available in health post and Public Health structures.

Like some other diseases, it is possible to prevent cholera by using an effective vaccine. A vaccine for cholera that is given by mouth is now available in other countries. This vaccine has been shown to protect against cholera. Rarely, some mild gastrointestinal symptoms (diarrhoea, abdominal pain, nausea) have been associated with use of vaccine.

We request for your permission to enrol you (or your child/ward) in this study. You were selected since you (or your child/ward) are a resident of *City name* and you (or your child/ward) were part of the target population for the vaccination against cholera.

If you agree to participate, you will be requested to answer a few questions about you (or your child/ward), including where you live, some characteristics of your household, and whether you (or your child/ward) child received the cholera vaccine given in *date1* and *date2*. The answers to these questions will help us assess the percentage of people vaccinated. The results of this study will improve our knowledge about this vaccine, help increase the use of the vaccine in *Country name* and other countries, and thus benefit society.

The expected duration of the study is about fifteen minutes. By participating in this survey you will not experience any physical discomfort.

There will be no financial expense for participating in this survey and no payment will be given to you (or your child/ward). All information that you provide will be kept confidential. We will store all records in a safe place under lock and key and use the information only for the purpose of this project.

You (or your child/ward) do not have to take part in this research if you do not wish to do so, and refusing to participate will not affect your (or your child/ward's) medical care in any way. You (or your child/ward) will still have all the benefits that you (or your child/ward) would otherwise have.

If you have any questions you may ask them now or later. If you wish to ask questions later, you may contact *person1*, telephone X1.

This proposal has been reviewed and approved by the Ethical Board of *Country name*, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact *person2*, telephone X2.

Informed consent

CONTACT:

I declare that the information letter concerning the survey on “Using the oral killed cholera vaccine in an epidemic situation in **City, Country**” has been read to me. I have clearly understood the objectives of the survey, its advantages and inconveniences. I have obtained clear responses to all my questions. I also have understood that I can withdraw from the study at any moment without any prejudice or blame being attributed to me (or to my child).

I agree to participate in the study under the conditions presented in the information note.

Name of the participant:

First name _____

Last name _____

Status (circle): Participant Legal representative of the participant

Signature or Thumbprint* of participant or legal representative:

Place _____

Date _____

*If the participant/parent or legal representative is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent (information note) is read and explained to the participants, and after they have orally consented to their participation in the survey, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or legal representative, and that informed consent was freely given by the participant or legal representative.

Name of person witnessing consent:

First name _____

Last name _____

Signature _____

Appendix 4 –Example of data collection forms for Cholera Vaccination Coverage

EXAMPLE 1

Date : / /
Survey team responsible :

| | | Vaccination card | | Interview | | Registry Logbook | |
|----------------------------|-------------------|--|-------------|------------|-------------|------------------|-------------|
| Serial Number ¹ | Birth date or Age | First dose | Second dose | First dose | Second dose | First dose | Second dose |
| | | Circle the right answer C = Complete vaccination* I = Incomplete vaccination** N = vaccine not administered | | | | | |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |
| | | C I N | C I N | C I N | C I N | C I N | C I N |

(1) in case of absence of serial number, please state all information that could help to localize interviewee

* individuals who drank and swallowed 2 complete doses (full amounts) of the cholera vaccine with the recommended timeframe

** individuals who did not ingest the full amount of any one of the administered doses (including those who spit out or vomited after dosing).

EXAMPLE 2

Etude de la couverture vaccinale de la campagne de vaccination contre le choléra

| | | | | |
|----------|------------------------------|----|--|-------------------------|
| A | DONNEES ENQUETEURS | | | |
| A1 | DATE DE L'ENQUETE : __/__/__ | A2 | NUMERO DE L'ENQUETEUR : _____ | |
| A3 | SOUS-PREFECTURE : | A4 | VILLAGE : _____ | A5 N° DE GRAPPE : _____ |
| A6 | N° DE LA MAISON : ____ | A7 | NOMBRE DE PERSONNE RESIDANT DANS LA MAISON : [] | |

B. VACCINATION CONTRE LE CHOLERA

La semaine passée, une campagne de vaccination contre le choléra a été organisée par le Ministère de la Santé. Elle concernait toutes les personnes à partir de 1 an. Il fallait se rendre dans un site de vaccination où on remplissait une carte de vaccination avant de recevoir un médicament dans la bouche.

Une campagne similaire avait été organisée à la fin du mois de mai.

C.1. Des personnes résidant dans cette maison sont-elles allées se faire vacciner contre le choléra ? Non ₀ [] Oui ₁ [] Ne sait pas ₉ []

Si des personnes sont allées se faire vacciner, demander d'aller chercher les cartes de vaccination.

Si la personne ne sait pas répondre à cette question, demandez si un autre adulte de la maison est présent et peut répondre à cette question.

Si aucun autre adulte présent ne sait répondre à cette question, demandez si vous pouvez repasser plus tard.

C.2. Pour les enfants âgés de 1 à 4 ans (prenez les informations en discutant avec les parents des enfants puis vérifiez sur la carte si possible).

| Id | Age | Sexe | Vacciné contre le choléra ? | Nombre de doses reçues | 1 ^{er} tour (du xx/xx/xxxx au xx/xx/xxxx) | | | | 2ème tour (du xx/xx/xxxx au xx/xx/xxxx) | | |
|----|-----|------|-----------------------------|------------------------|---|---------------------|-----------------|-------------------------|--|---------------------|----------------------------|
| | | | | | dose reçue ? | Vérifié sur carte ? | Habitait à XX ? | Raisons non vaccination | dose reçue ? | Vérifié sur carte ? | Raisons de non vaccination |

| | (en années) | Homme=0 Femme=1 | Non = 0 Oui = 1 NSP = 9 | 0 = 0 1 = 1 2 = 2 >2 = 3 NSP = 9 | Non=0 Oui=1 NSP=9 | Non=0 Oui=1 | Non=0 Oui=1 NSP=9 | Voir codes (NA si vacciné) | Non=0 Oui=1 NSP=9 | Non=0 Oui=1 | Voir codes (NA si vacciné) |
|-----|----------------|--------------------|-------------------------------|--|-------------------------|----------------|-------------------------|----------------------------------|-------------------------|----------------|----------------------------------|
| 2.1 | | | | | | | | | | | |
| 2.2 | | | | | | | | | | | |
| 2.3 | | | | | | | | | | | |
| 2.4 | | | | | | | | | | | |
| 2.5 | | | | | | | | | | | |
| 2.6 | | | | | | | | | | | |
| 2.7 | | | | | | | | | | | |
| 2.8 | | | | | | | | | | | |

C.3. Pour les enfants âgés de 5 à 14 ans (*prenez les informations en discutant avec les parents des enfants, puis vérifiez sur la carte si possible*).

| Id | Age | Sexe | Vacciné contre le choléra ? | Nombre de doses reçues | 1 ^{er} tour (du xx/xx/xxxx au xx/xx/xxxx) | | | | 2 ^{ème} tour (du xx/xx/xxxx au xx/xx/xxxx) | | |
|-----|----------------|--------------------|---|--|--|------------------------|-------------------------|----------------------------------|---|------------------------|----------------------------------|
| | | | | | dose reçue ? | Vérifié sur carte ? | Habitait à XX ? | Raisons non vaccination | dose reçue ? | Vérifié sur carte ? | Raisons de non vaccination |
| | (en années) | Homme=0 Femme=1 | Non = 0 Oui = 1 NSP = 9 | 0 = 0 1 = 1 2 = 2 >2 = 3 NSP = 9 | Non=0 Oui=1 NSP=9 | Non=0 Oui=1 | Non=0 Oui=1 NSP=9 | Voir codes (NA si vacciné) | Non=0 Oui=1 NSP=9 | Non=0 Oui=1 | Voir codes (NA si vacciné) |
| 3.1 | | | | | | | | | | | |
| 3.2 | | | | | | | | | | | |
| 3.3 | | | | | | | | | | | |

| | | | | | | | | | | |
|-----|--|--|--|--|--|--|--|--|--|--|
| 3.4 | | | | | | | | | | |
| 3.5 | | | | | | | | | | |
| 3.6 | | | | | | | | | | |
| 3.7 | | | | | | | | | | |
| 3.8 | | | | | | | | | | |

C.4. Pour les adultes (15 ans et plus) (prenez les informations en discutant avec les personnes concernées ou le responsable du ménage s'ils sont absents puis vérifiez sur la carte si possible).

| Id | Age | Sexe | Vacciné contre le choléra ? | Nombre de doses reçues | 1 ^{er} tour (du xx/xx/xxxx au xx/xx/xxxx) | | | | 2 ^{ème} tour (du xx/xx/xxxx au xx/xx/xxxx) | | |
|------|-------------|--------------------|-------------------------------|--|--|---------------------|------------------------------|----------------------------|---|---------------------|----------------------------|
| | | | | | dose reçue ? | Vérifié sur carte ? | Habitait à Kabak / Kakossa ? | Raisons non vaccination | dose reçue ? | Vérifié sur carte ? | Raisons de non vaccination |
| | (en années) | Homme=0 Femme=1 | Non = 0 Oui = 1 NSP = 9 | 0 = 0 1 = 1 2 = 2 >2 = 3 NSP = 9 | Non=0 Oui=1 NSP=9 | Non=0 Oui=1 | Non=0 Oui=1 NSP=9 | Voir codes (NA si vacciné) | Non=0 Oui=1 NSP=9 | Non=0 Oui=1 | Voir codes (NA si vacciné) |
| 4.1 | | | | | | | | | | | |
| 4.2 | | | | | | | | | | | |
| 4.3 | | | | | | | | | | | |
| 4.4 | | | | | | | | | | | |
| 4.5 | | | | | | | | | | | |
| 4.6 | | | | | | | | | | | |
| 4.7 | | | | | | | | | | | |
| 4.8 | | | | | | | | | | | |
| 4.9 | | | | | | | | | | | |
| 4.10 | | | | | | | | | | | |
| 4.11 | | | | | | | | | | | |

| | | | | | | | | | | |
|------|--|--|--|--|--|--|--|--|--|--|
| 4.12 | | | | | | | | | | |
| 4.13 | | | | | | | | | | |

Appendix 5 – Recommendations for survey coordination

Coordination with authorities

The survey should be done in coordination with health and local authorities. Written permission to conduct the survey from health authorities will be needed from central level (the Ministry of Health in the capital), and State or District level. Additionally meeting with local leaders to explain and plan/ organize the survey is advisable. This process also serves as a way to become aware of potential security risks for the interview team.

On each day of the survey, the interview team would be well advised to meet with the head of the cluster, such as village chief, before starting their work. Coordinating with the corresponding health area workers and with people involved in micro-planning for OCV is also a good idea. They often have maps, population figures and are well known in the community.

Debriefing with the health authorities after the survey is finished and passing on a copy of the report is always appreciated. Acknowledging their support in a report is also good idea.

Social Mobilization

It is important to let the community know when and why a survey team is coming. This helps ensure a high turnout for the survey. For this involving a local community health worker or focal person is advisable. In turn, this person may request a town crier to make a public service announcement. Providing the focal person a stipend for 2 days work is common, the first for informing the community about the survey and its timing, and a second for accompanying the team on the day of the survey. A small fee for the public service announcement may also be involved. Communities can be difficult to find, especially if roads are not marked. Those in charge of health for that community can be very helpful in this regard.

Assembling and training interview team

Health authorities often have a group of people they rely on for surveys and other community health work. These teams are often experienced and can be a good choice for interviewer. Other networks can be relied upon for assembling a team of interviewers and supervisors, such as NGOs and rural health workers. Advertising in local papers will undoubtedly expand the number of candidates, but the turnout can be quite large and time consuming to sort through. Once a few candidates are identified, word will spread quickly through these networks. While this method can be exploited, it can also lead to an interview team of friends and not necessarily a good reflection of the diversity of a population. For instance, interviewers may be similar in age, gender, religious or clan affiliation, which can be construed by others as a hiring bias and favoritism.

A formal interview process is highly advisable, including a written test to demonstrate reading comprehension, level of organization, and ability to follow written and verbal instructions. Good interviewer qualities include good social skills, politeness, communicate respectfully, and also being non-threatening while at the same time commanding respect. Health workers often make good interviewers, although a health background is not needed

for the position. Interviewers should be organized and attentive to detail; references should be checked.

In some contexts men may not be allowed to enter the home if the head of household is not present. In that case all female or mixed gender teams may be preferable.

Team Size

Enough people should be short listed and trained, in order to be able to select those who do well during the training and to be able to retain at least two people as backups. During the training it may also become apparent which candidates can become supervisors. Depending on the budget, teams of two people with one being senior to the other, and a supervisor for each two to three teams is advisable.

The total number of interviewers needed will depend on the amount of time and availability of logistics. In general, each team should be able to cover one cluster of 15-20 households per day. If distances between clusters are short, two clusters per team can be calculated. Unless several supervisors are available, 10 teams is a good upper limit. If we calculate 4 households per team per hour, a cluster should be completed by a team in 4 hours. Distances to and from the starting point, time to brief and organize, meet with the head of the village, and select the starting point should be taken into account, and could add up to several hours combined. In this scenario, 8 teams interviewing 14 households in one cluster per day, would take 4 days to complete 30 clusters.

Team training

A team should undergo at least 2 days of training and a field test day. In the two days of training, the team leader should cover administrative matters, then go over relevant parts of this protocol and spend a few hours on each form they need to fill. It is advisable to spend a block of time on a form, practice it through role playing, and then take a break before moving on to another form. Good ventilation, frequent breaks and a variety of activities is a good way to keep trainees motivated and aware. Long power-point presentations are usually not very effective.

On the last day of training, a field test can be carried out, where teams go into a community not participating in the survey (which can be near the training site for ease) and all learned techniques are put to the test. Interviewers should be able to find the cluster boundaries, center, select the first house using the random number table, carry out the consent process, enter data and identify the next house to be interviewed. Supervisors should accompany teams one at a time to check for good technique.

Data entry personnel should also be considered. It is best to enter data on a daily basis during data collection as it allows the supervisor to spot mistakes early on and clarify common problems. If two or more computers are available, two or more data people should be hired. Several techniques exist, but one reading and the other entering the data leads to less mistakes. Alternatively, two identical sets of entries by two different people ("double data entry") is the ideal way to enter data, which is then compared with a computer program to identify discrepancies.

Logistical considerations

Logistical needs will depend on the context.

Transportation: Teams will likely need a vehicle to get to and from the starting point and the cluster. If clusters are near each other, one team per two cars may be enough. It is a good idea for a vehicle and driver to remain near the teams for added security.

Communication: radios or mobile phones can be very useful for the team to ask questions to the supervisors, ask for additional support, or assist them in case of a medical or security problem. In most cases, interviewers will have their own phones and prepaid call-minutes is sufficient to ensure good communication.

Printing: Access to a photocopier or print shop is essential, unless all material will be printed beforehand. A laptop, extra battery and small printer is quite useful.

Funds: for purchases and payments.

Recommended list of materials which should be carried by the interviewer daily:

- pens (or pencils and sharpeners)
- a small notebook to write notes
- a clipboard to use with interview
- a copy of the instruction manual
- extra copies of the questionnaires
- a random number table
- an events calendar with important local dates to help determine people's ages in case they do not know/remember
- plasticized card with important phone numbers
- a copy of any letter of authorization to conduct the survey
- Identification
- Chalk, which can be used to mark houses when selecting first house by spin the pen method
- A small backpack or other article to carry this material
- Additional material: water, food and an umbrella should be considered in some contexts.