



A mixed-methods explanatory sequential community-based study to estimate and understand vaccination coverage of Oral Cholera Vaccine in Bukama Health Zone, DRC

Version 1.1

July 2022

First version	June 2022
Second version	July 2022
Design	Mixed method explanatory sequential study for history of Oral cholera vaccination on Household level in catchment area of Cholera Treatment Units (CTU)
Target population	<u>Quantitative phase:</u> population ≥ 1 year (at time of vaccination) living in the catchment area of the CTU and targeted by the mass vaccination campaign; <u>Qualitative phase:</u> health staff and community leaders
Implementation period	July 2022 – September 2022 (est)
Survey site	<i>Bukama Locality, Haut-Lomami provence, DRC</i>
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List of Abbreviations

CI: Confidence interval
CTC: Cholera Treatment Center
CTU: Cholera Treatment Unit
DRC: Democratic Republic of Congo
DPS: Division Provinciale de la Santé (Local health authorities)
FCDO: Foreign, Commonwealth and Development Office
GDPR: General Data Protection Regulation
GTFCC: Global Task Force for Cholera Control
HA: Health Area (subdivision of Health Zone)
HH: Household
HZ: Health Zone
IDI: In depth interview
MSF: Médecins Sans Frontières
MoH: Ministry of Health
MoU: Memorandum of Understanding
MPH: Master of Public Health
OCV: Oral cholera vaccine
PI: Principal Investigator
PNECHOL: Plan National d'Élimination du Choléra (National Plan for Cholera Elimination)
Reco: relais communautaire, or community health worker
WHO: World Health Organization

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1 Introduction

1.1 Country information

The Democratic Republic of Congo (DRC) is a country in central Africa. It is the second largest country in Africa and the eleventh worldwide. With a population around 92 million, it is the most populous francophone country. DRC obtained independence from Belgium colonization in 30th of June 1960.

The DRC is in the central sub-Saharan Africa, bordered to the northwest by Republic of Congo, to the north by Central African Republic, to the northeast by South Sudan, to the east by Uganda, Burundi, Rwanda and Tanzania, to the south and southwest by Zambia, to the southwest by Angola, and to the west by the south Atlantic Ocean. The country lies between latitude 6° N and 14° S, and longitudes 12° E and 32° East.

Concerning human development, DRC is ranked number 175.¹ According to the WHO, the life expectancy at birth by years is 60.7.² The infant mortality rate is 68.2 per 1000 live births.² The tuberculosis incidence is 321 per 100 000 population, while HIV prevalence adult is 0.8%.²

Figure 1: DRC location and its bordering countries³



¹ UNDP Country Profiles. Accessed May 2022. <https://hdr.undp.org/data-center/specific-country-data#/countries/COD>

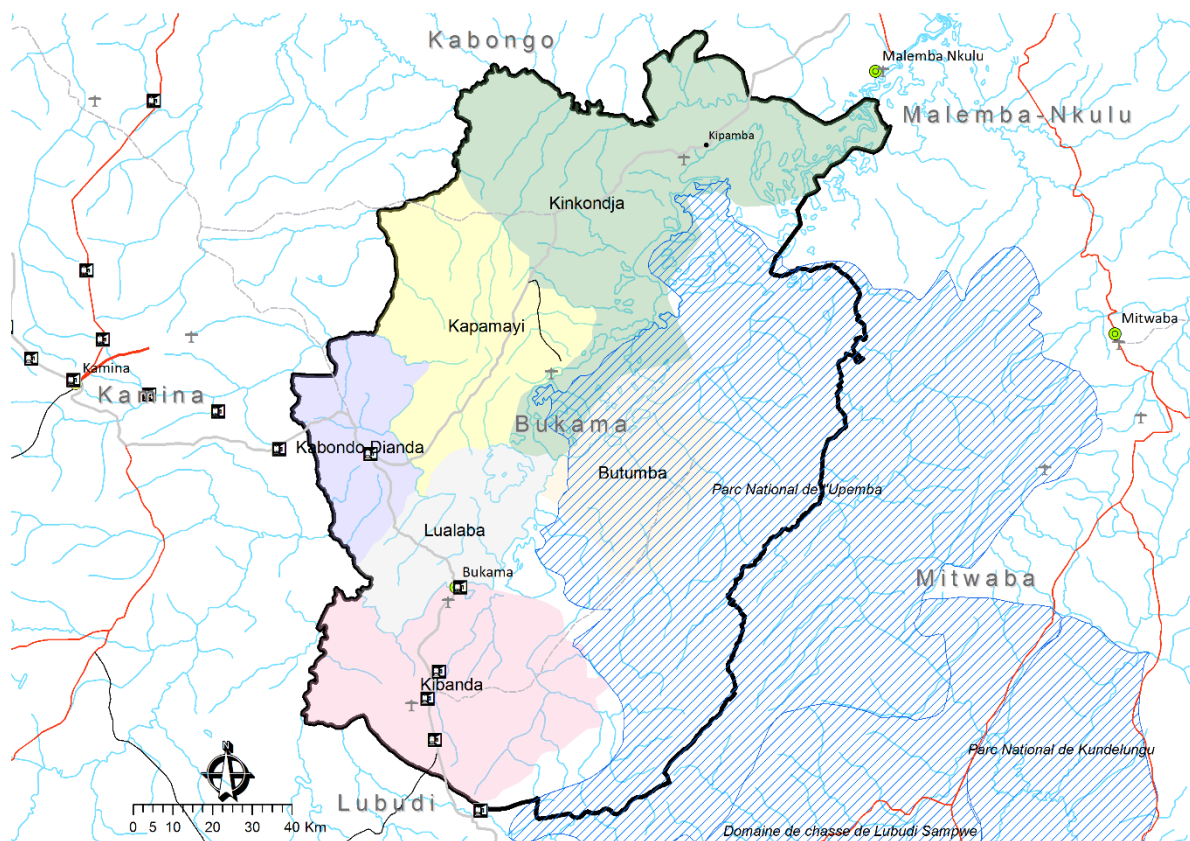
² WHO Global Health Observatory <https://www.who.int/data/gho/data/countries/country-details/GHO/democratic-republic-of-the-congo?countryProfileId=730874c4-6cb8-41f6-adab-5349fdcf5c3d>

³ Nations Online Project. DRC Map. <https://www.google.com/search?q=DRC+map&tbm>

1.2 Bukama:

Bukama is situated in Haut-Lomami province (former Katanga province). It is on the side of Congo River, on the national road number 1. It is considered a large locality with important commercial exchange, though it is less prominent in recent years. The security situation in Bukama is characterized as calm with no armed conflict or population displacement ongoing.

Figure 2: Bukama location and bordering localities⁴



1.3 Cholera in Bukama:

The data of the surveillance for the cholera for the years 2019 and 2020 is shown in the below table:

Table 1: Total number of Cholera cases in the health areas of Bukama Health Zone, DRC, 2019 and 2020⁵

Health area	2019	2020
BYOWA	13	3
GCM	0	0
KABAMOMA	45	0
KABWE	37	1
KATENTAMINE	52	0

⁴ CAID Bukama map. <https://www.google.com/search?q=Bukama+carte&tbm>

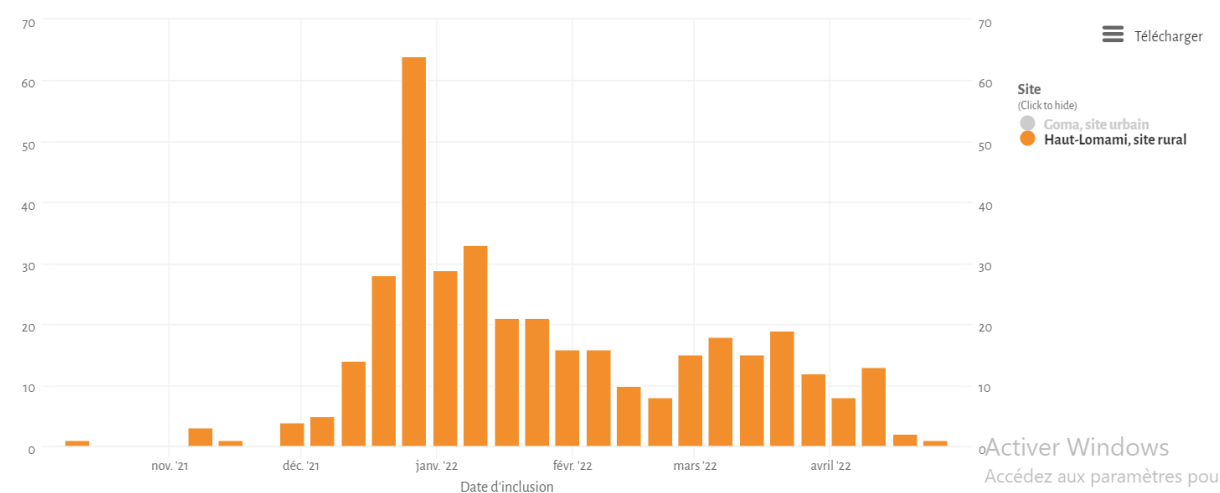
⁵ Data shared by local health authorities, 2021

KATOBWE	25	0
KAZELE	2	3
KIBANDA	89	20
KISANGA WA BYONI	116	14
MAKA	34	0
MAKALA	30	0
MBALA	36	5
MEDICO SOCIAL	75	11
METHODISTE	3	0
MUCHANGA	1	2
MUKULA KULU	0	2
NGOYA LULU	3	0
SHELESHELE	0	0
SNCC	8	0
Health Zone total	569	61

For the period from week 1 to week 33 of 2021, for the whole 19 health areas, the total number of cases is 43 with one death.⁶

From September 2021 through 5 May 2022, 394 suspected cases of cholera have been notified in the zone de santé of Bukama, based on data collected by Epicentre, as illustrated in the graph below:

Figure 3: Cholera cases notified in Bukama Health Zone; Haut Lomami DRC, September 2021 through 5 May 2022.⁵



1.4 Cholera vaccination in Bukama:

Traditional cholera control measures based on improvements of water and sanitation conditions have proven to be effective in areas where large infrastructure investment has been implemented; however, the same measures have proven to be difficult to implement and maintain in the poorest areas of the world. For instance, improving water and sanitation conditions requires important investments and government will over several years or

⁶ Epicentre/MSF internal surveillance data. Accessed May 2022.

decades, which proves difficult in a country with recurrent security and political issues. Moreover, lack of general infrastructures such as easily practicable roads impedes accessibility, adding extra challenge to development of the area. Finally, habits of the local population, combined with general poverty and lack of access to education and appropriate household tools for water sanitation and hand hygiene, need to be addressed for successful implementation of long-term water and sanitation investments^{7,8}. Those issues directly impact complexity of implementing this kind of strategies in areas such as our current study zone, Bukama.

While oral cholera vaccine (OCV) has mostly been used in recent years for emergency humanitarian situations and outbreak response, its use for mass campaigns has been monitored in several studies, showing that OCV campaigns are safe, feasible, acceptable, and effective.^{9,10} As a result, and following the strategic recommendations of the GTFCC, WHO now recommends OCV use for mass campaigns in endemic contexts.¹¹

The Expanded Immunization Program of DRC recommends and offers vaccination of pregnant women and children against a variety of health conditions at no cost, but OCV is not included on any of these routine vaccination schedules as of June 2022.¹²

Local health authorities embarked on an OCV campaign targeting 12 of Bukama's 19 health areas. This is the first mass OCV campaign of its kind in Bukama in recent memory. The areas targeted are listed in Table 2. The first round took place in December 2021, and the second took place in late March 2022. The campaign used a door-to-door strategy, involving health center personnel as well as recos for mobilization and vaccine administration. Administrative coverage levels of 97.5% were reported for the first round, and 98.3% for the second round.¹³

Table 2: Health areas targeted for OCV, Bukama Health Zone, 2021 and 2022, by geographical area, with number of villages and 2020 population¹¹

	Health area	Axis	Number of villages	Total population 2020
1	Katentamine	Bukama centre	5	22514
2	Kabamoma	Bukama centre	22	25750
3	Medico sociale	Bukama centre	5	32110
4	Kisanga wa biyoni	Bukama centre	10	25606
5	Makala	Road	12	33814
6	Kibanda	Road	17	25543
7	Kabwe	Road	15	19281

⁷ Davies HG, Bowman C, Luby SP. Cholera - management and prevention. *J Infect.* 2017;74 Suppl 1: S66–S73. doi:10.1016/S0163-4453(17)30194-9

⁸ Montgomery M, Jones MW, Kabole I, Johnston R, Gordon B. No end to cholera without basic water, sanitation and hygiene. *Bull World Health Organ.* 2018;96: 371–371A. doi:10.2471/BLT.18.213678

⁹ Luquero FJ, Grout L, Ciglenecki I, Sakoba K, Traore B, Heile M, et al. Use of *Vibrio cholerae* Vaccine in an Outbreak in Guinea. *New England Journal of Medicine.* 2014;370: 2111–2120. doi:10.1056/NEJMoa1312680

¹⁰ Ferreras E, Chizema-Kawesha E, Blake A, Chewo O, Mwaba J, Zulu G, et al. Single-Dose Cholera Vaccine in Response to an Outbreak in Zambia. *The New England journal of medicine.* 2018;378: 577–579. doi:10.1056/NEJMc1711583

¹¹ Cholera vaccines: WHO position paper – August 2017. *Releve epidemiologique hebdomadaire.* 2017;92: 477–98.

¹² RD Congo Programme Elargie de vaccination. 20 June 2022. <https://www.pevrdcongo.cd/>

¹³ Data shared by local health authorities, April 2022

8	Mbala	River	12	17694
9	Katobwe	River	6	9307
10	Maka	River	10	10069
11	Ngoyalulu	River	15	18155
12	Kazele	River	10	21516
13	Byowa	route	25	18906
	TOTAL		164	280265

Of the 164 villages in the targeted health areas, 109 have an estimated population of at least 500 people and 54 have an estimated population under 500 people.¹¹ The maximum estimated village population in the study zone is 14,892 people and the minimum is 61 people.¹¹

1.5 Ongoing Epicentre Cholera research in Bukama

Epicentre is currently conducting a study in Bukama and Goma, entitled 'Cholera control in endemic regions of Africa: clinical surveillance and cholera shedding study in the context of mass vaccination campaigns, Democratic Republic of the Congo'.¹⁴ This project aims to fill this essential knowledge gap by assessing the impact of OCV mass campaigns. The main objective is "to better characterize cholera transmission in cholera hotspot in DRC and assess the impact of a large vaccination campaign reaching high coverage on sustained control of cholera transmission for at least two years." The evidence generated from this project will be key to develop future strategies regarding cholera vaccine use in endemic settings (e.g. Nigeria, South Sudan and other areas of DRC), including places with higher burden in terms of cholera mortality.

This activity started in Bukama in September 2021 and is expected to continue through mid-2023. This study includes enhanced clinical surveillance of cholera cases in CTCs and CTUs, as well as periodic cholera serosurveys. To interpret and contextualize the results of this clinical surveillance and the serosurveys, a strong understanding of the vaccine coverage, as well as barriers and challenges associated with OCV in these areas, is needed. This understanding of coverage levels will also permit Epicentre/MSF and the MoH to support understanding of the successes and challenges of the past vaccination campaign, as well as targeting and planning of catch-up in areas with low coverage, for the benefit of the population.

2 Rationale

The first phase of this research, a **quantitative** survey, is proposed to establish a community-based estimation of OCV coverage, integrated in existing community structures. The second phase, a **qualitative** investigation, is proposed to better understand the factors related to non-vaccination or refusal of vaccination, specific to this context. This explanatory sequential mixed-methods approach was adopted to allow the team to both 1) understand the vaccination coverage levels and 2) develop strategies to improve coverage in future or catch-up interventions.

¹⁴ <https://clinicaltrials.gov/ct2/show/NCT04853186>

Estimation of vaccination coverage is needed to identify remaining high-risk areas for cholera and to target catch up vaccination activities. It is also needed to better contextualize and interpret data being collected as part of an ongoing Epicentre study 'Cholera control in endemic regions of Africa: clinical surveillance and cholera shedding study in the context of mass vaccination campaigns, Democratic Republic of the Congo' (MSFERB 2104; DRC Comité National d'Ethique de la Santé n288/CNES/BN/PMMF/2020).

For the quantitative phase, this study plans to train and use one teacher from each of the 164 villages in the catchment area as a data collector, allowing data collection in all villages of the catchment area. The methodology is detailed further in later sections of the protocol (Section 4: Study Design). The proposed methodology for the quantitative survey differs from the traditional WHO EPI¹⁵ methodology used for vaccination coverage surveys, but has been adopted in this case because it presents several important advantages pertinent to this context:

- Survey catchment area: The traditional WHO EPI methodology visits only some villages of the catchment area.
 - Typical WHO EPI methodology does not visit every village, so villages with low coverage levels cannot be exhaustively identified using the typical method. In contrast, the methodology proposed here allows for information to be gathered from almost every village (as teachers are present in almost every village), thus allowing for near-exhaustive identification of villages that may have been skipped or missed by the vaccination campaign. This presents an important advantage, especially when the goal of the coverage survey is to target catch-up activities. Local teaching authorities could not provide an exact number of villages that do not have teachers but stated that the number of villages without a teacher is near zero.
- Community engagement: While the traditional WHO EPI methodology relies primarily on outsiders; this methodology allows greater involvement of people based in the communities where we are collecting data.
 - This new approach could create a local network to collect similar information more easily in the future, if needed, for example after additional rounds of vaccination, or vaccination campaigns with different antigens.
 - Some local contacts highlighted that many people can be sceptical or mistrustful of outsiders, and that people living in the catchment area may be more comfortable openly sharing their vaccination status with someone they know (a local teacher) than with an outsider. The risks of using community residents (teachers) as data collectors have been considered and are outlined in the Risks and Mitigation portion of the protocol.
- Neutrality and reliability of data collectors: The traditional WHO EPI methodology relies on bringing outsiders in order to obtain neutral, objective information.
 - Teachers are not employees of the health system and, based on conversations with local stakeholders, can be expected to provide an objective, neutral

¹⁵ WHO Vaccination Coverage Cluster Survey Manual. <https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and-insights/global-monitoring/immunization-coverage/survey-methods#cms>

reflection of realities in the health area, and are not under pressure to present results in a certain light.

- Teachers have a high level of literacy and can be expected to correctly complete simple data collection forms.
- **Logistics:** Areas such as Bukama are difficult to access both externally (at least 2 days by road from nearest large city) and internally (many villages are accessible only by boat or motorcycle and can require over 6 hours to reach from Bukama center). Organizing a traditional WHO EPI methodology survey in such contexts can prove logistically challenging and costly.
 - The methodology proposed here avoids the expense of bringing external data collectors to Bukama, and of transporting the data collectors to randomly selected villages within the zone, because teachers are already present in each village.
 - Teachers travel monthly to Bukama center to receive their payment in person. This methodology capitalizes on existing transit of teachers, training the teachers and distributing data collection forms one month, and recovering the forms and paying the teachers the next month. This avoids excessive transport costs and minimizes extra risks associated with complicated journeys.

Of note, recos were also considered as potential data collectors for this activity, but after in-depth consultation with local partners, recos were excluded as data collectors for this activity, because they were highly involved in the vaccine delivery, and thus were deemed not to have sufficient neutrality to serve as data collectors for this activity.

The second phase of this research, a **qualitative** investigation, is planned to allow a better understanding of the factors (including enablers and barriers) influencing the vaccination status of communities, in order to better organize catch-up and future vaccination activities.

3 Objectives

3.1 Primary objective:

Estimate OCV vaccine coverage in the catchment area of the CTUs, and to understand the factors (including enablers and barriers) affecting coverage levels of persons aged 1 year and above in the 12 health areas of Bukama Health Zone that were targeted for OCV in 2021-2022.

3.2 Secondary objectives:

Primarily through the quantitative phase (coverage survey):

- Estimate the OCV coverage by vaccination round
- Estimate the OCV coverage by age group (1 to 15 years and over 15 years)
- Estimate the OCV coverage with at least one dose
- Estimate the OCV coverage by health area
- Estimate the OCV coverage by village

Primarily through the qualitative phase:

- Understand the factors influencing how and whether vaccination was offered in the village, especially in villages where low coverage was reported.
- Understand the factors influencing whether community members received the vaccination, including organizational factors such as how the vaccine was distributed, as well as personal factors such as vaccine acceptance.

4 Study Design

An explanatory sequential mixed methods approach is planned to estimate OCV vaccine coverage in the catchment area, and to understand the factors (including enablers and barriers) affecting coverage levels.

Quantitative phase (Coverage survey):

Vaccination coverage screening using survey of households by teachers working in villages covering CTU of the catchment area.

Determination of vaccine status will be done by interview of the head of the household by the teacher in the village where he/she is stationed.

Each teacher will be asked to interview a cluster of 32 randomly selected households within the village. In villages with total estimated population of under 500 people, the teacher will be asked to exhaustively interview every household in the village.

Information to collect at household level:

- 1) Total number of household members by age group (1 to 15 years and over 15 years)
- 2) Number of household members vaccinated for first round
- 3) Number of household members vaccinated for second round
- 4) Reason for non-vaccination in the household, if relevant (1) Didn't know about campaign 2) Vaccinators didn't come to house 3) Absent when vaccinators came 3) Not eligible 4) Refused because pregnant 5) Refused because of tradition 6) Refused because of religion 7) Vaccination is dangerous 8) Negative past experience w/ vaccination 9) Not enough vaccine 10) Sick at home 11) Sick in hospital 12) Bad taste 13) Other (explain))

(see data collection tool in Annex 15.1)

In a recent vaccination coverage survey in ex-Katanga region about 6 months after the actual campaign, vaccination cards were recovered in about 10% of children declared vaccinated. In Goma, only a handful of OCV vaccination cards were recovered during a seroprevalence survey (though this happened about 2 years after the campaigns). Based on this experience and as the survey will happen 4 to 7 months after the campaigns, and due to the need to keep the questionnaire as simple as possible, participants will not be asked to show the vaccination card. Only oral report of vaccination history will be requested.

Qualitative phase:

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Community leaders and health workers from villages with high, medium and low vaccination coverage levels will be targeted for inclusion in a qualitative phase through purposive selection, with a planned sample size of 8 to 12 persons, or until thematic saturation is reached. This phase will follow the quantitative phase.

Information to collect during interviews:

- Role and background of respondent
- General views of health in the community
- General views and specific experiences around vaccination and cholera vaccination in the community, including challenges and strengths

(Qualitative data collection topic guide in annex 15.2)

A rapid qualitative technique will be used for data analysis, involving the direct analysis from audio recordings. While the traditional coding of verbatim transcripts results in a high level of detail and can facilitate researcher immersion in the qualitative data, some authors have noted that verbatim transcription is also prone to error and that transcription may remove important contextual features that are important to analysis of the qualitative data. The direct coding from linked audio files has been recognized as a tool providing high level of detail and the ability to capture intonations, while reducing coding time.¹⁶ The advantages and disadvantages of rapid qualitative methods have been explored in depth,¹⁷ and several benefits have been identified for its use in outbreaks and resource-limited settings.¹⁸

5 Inclusion and exclusion criteria

Quantitative phase (Coverage survey):

Households will be included in the survey if they satisfy all the following criteria:

- Living in the catchment area (12 health areas of Bukama Health Zone that were targeted for OCV in 2021-2022, as listed in Table 2 above)

and

- Informed verbal consent has been given by the Head of the HH

HH will be excluded from the survey if they satisfy one of the following criteria:

- Refusal of the head of the household or a representative of the HH to participate

Or

- Unable to be contacted

¹⁶ Neal JW, Neal ZP, VanDyke E, Kornbluh M. Expediting the Analysis of Qualitative Data in Evaluation: A Procedure for the Rapid Identification of Themes From Audio Recordings (RITA). *American Journal of Evaluation*. 2015 Mar 24;36(1):118–32

¹⁷ Vindrola-Padros C, Johnson GA. Rapid Techniques in Qualitative Research: A Critical Review of the Literature. *Qual Health Res*. 2020 Aug;30(10):1596-1604. doi: 10.1177/1049732320921835. PMID: 32667277.

¹⁸ Johnson GA, Vindrola-Padros C. Rapid qualitative research methods during complex health emergencies: A systematic review of the literature. *Soc Sci Med*. 2017 Sep;189:63-75. doi: 10.1016/j.socscimed.2017.07.029. Epub 2017 Aug 2. PMID: 28787628.

Qualitative phase:

A person will be included in the study if they meet all the following criteria:

- Live and/or work within the study zone (12 health areas of Bukama Health Zone that were targeted for OCV in 2021-2022, as listed in Table 2 above)
- Chosen through purposive selection
and
- Provided written informed consent

A person will not be included in the study, and will be replaced, if they meet any of the following criteria:

- Refuse to participate in the study
or
- Unable to be found after 2 attempts

6 Definitions

- Household: group of persons eating together, and sleeping under the same roof since at least 2 weeks
- Completely vaccinated person: individual who reports having received two complete doses (one during each round)
- Incompletely vaccinated person: individual who reports having received only one dose either during the first round or during the second round
- Unvaccinated: individual who reports no vaccination

7 Sample size and sampling

7.1 Sample size

Quantitative phase (Coverage survey):

An appropriate sample will be taken to allow for estimation of coverage by village (90 percent confidence interval), health area (90 percent CI), and overall, for the total coverage area (95 percent CI overall and by dose and age group). A design effect of 2 was assumed, to account for the fact that clusters are used, and assuming heterogeneity across clusters.

To estimate the required sample size, calculations were conducted using OpenEpi online tool.¹⁹ Sample sizes were calculated assuming 60% coverage in order to make a conservative estimate of the required sample size. Calculation summaries are included below.

¹⁹ http://www.openepi.com/Menu/OE_Menu.htm

Calculation summaries at the village and health area levels (90 percent confidence interval):

Sample Size for Frequency in a Population	
Population size(for finite population correction factor or fpc)(N):	1000
Hypothesized % frequency of outcome factor in the population (p):	60%+/-1
Confidence limits as % of 100(absolute +/- %)(d):	10%
Design effect (for cluster surveys- $DEFF$):	2
Sample Size(n) for Various Confidence Levels	
ConfidenceLevel(%)	Sample Size
95%	169
80%	76
90%	123
97%	204
99%	275
99.9%	413
99.99%	534
Equation	
Sample size $n = [DEFF * Np(1-p)] / [(d^2 / Z^2_{1-\alpha/2} * (N-1) + p * (1-p))]$	
Results from OpenEpi, Version 3, open source calculator--SSPropor	

Calculation summaries at the overall catchment area (health zone) level (95 percent confidence interval):

Sample Size for Frequency in a Population	
Population size(for finite population correction factor or fpc)(N):	261359
Hypothesized % frequency of outcome factor in the population (p):	60%+/-5
Confidence limits as % of 100(absolute +/- %)(d):	5%
Design effect (for cluster surveys- $DEFF$):	2
Sample Size(n) for Various Confidence Levels	
ConfidenceLevel(%)	Sample Size
95%	737
80%	316
90%	519
97%	903
99%	1271
99.9%	2071
99.99%	2892
Equation	
Sample size $n = [DEFF * Np(1-p)] / [(d^2 / Z^2_{1-\alpha/2} * (N-1) + p * (1-p))]$	
Results from OpenEpi, Version 3, open source calculator--SSPropor	

Based on these calculations, a total of 169 persons should be interviewed per village. This sample size at the village level will also allow the same or better precision to be reached at the health area and catchment area levels.

7.2 Sampling

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With an average household size of 6, data collectors will need to interview 29 households to reach the required sample size per village (169 persons). To account for potential variation in household sizes, and the small portion of the population that is under age 1, a 10 percent margin has been added, and data collectors will be asked to interview 32 households per village.

In villages with fewer than 500 residents (54 out of the 164 villages), data collectors will be asked to conduct exhaustive sampling (visiting every household), in order to minimize the potential biases and challenges associated with systematic sampling, and to simplify the process. Village population counts are based on 2020 data shared by local health authorities.

In villages with 500 or more residents (109 out of the 164 villages) a systematic sampling method will be used. The steps in the systematic sampling methodology are described here:

- 1) Data collector lists 5 key locations (landmarks) within the village on separate slips of paper (i.e. geographic center of village, place of worship, burial grounds, village chief's house, school, health center, market) and folds them up. These locations should represent the geographic diversity of areas of the given village.
- 2) Data collector chooses two of the slips of paper at random.
- 3) The data collector will go to the point named on the first piece of paper and throw a pen into the air. They will proceed in the direction indicated by the tip of the pen and interview every household until the desired 16 households have been visited. If the data collector reaches the edge of the village and has not reached the desired sample size, they will continue snaking back in toward the center of the village and continue this pattern until reaching 16 households.
- 4) The data collector goes to the location named on the second piece of paper and follows the same process described in step 3 above, until 16 additional households have been interviewed, for a total of 32 households.

The data collectors will conduct this process of writing down village landmarks and choosing 2 locations while in the presence of the study team during the training. The study team will note down the starting point locations selected in each village. This is expected to minimize confusion for the data collectors and enhance supervision.

If a household refuses to participate or an adult member of the household cannot be found, the data collector will note this and proceed to the next household, using this methodology.

This methodology is a slightly simplified version of the generally used WHO EPI sampling methodology²⁰ within the village but is expected to be more feasible with surveyors that are not used to cluster data collection, and less time consuming, as it does not require counting houses to the edge of the village. It is still expected to yield reliable results, as different data collectors will start from different points in their respective villages, reducing systematic biases. Intensive training and spot supervision (see Section 12) will ensure that the required methodology is correctly followed.

²⁰ WHO 2018 Cluster Sampling Reference Manual. <https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and-insights/global-monitoring/immunization-coverage/survey-methods#cms>

Qualitative phase:

The selection of participants in the qualitative phase will be informed by the results of the quantitative phase (coverage survey). Specifically, the study team will aim to include respondents from several villages with the lowest reported coverage levels, some with moderate coverage levels, and some with high coverage levels, in order to understand a variety of factors influencing coverage levels. The team will endeavour to also include villages of a variety of population sizes and geographical locations. If results of the quantitative phase do not identify any villages with low coverage, the study team will nonetheless work to include a diversity of villages in the qualitative phase, based on other factors such as urban/rural.

The qualitative data collection is expected to take place in tandem with other planned study activities, such as supportive supervisions, in order to minimize the logistical burden of the data collection, specifically of reaching distant villages. For this reason, the sampling method for the qualitative research will be mainly purposive, but with some degree of convenience sampling. For example, when looking at villages planned for regular study activities, the team will see if any villages with very high or very low vaccination coverage are located nearby and will thus group the qualitative data collection with the planned study activity, and reduce the number of separate trips needed.

Data will be collected through participant-led interviews, guided by a semi-structured topic guide (annex 15.2). The collection of data will continue until thematic saturation is achieved. This can vary but is expected to take about 8-12 individual interviews across the whole study zone. This sample size is intended to be an estimate based on and qualitative research best practices, and is intended to be flexible; it may be adapted slightly in the field based on when thematic saturation is achieved. Participants will be selected purposively in order to cover a range of perspectives, including participants of different sex, age, geography, socio-economic status, etc. Key informants for individual interviews will include health staff and formal and informal community leaders.

Community leaders such as village chiefs and youth leaders, as well as some health staff such as recos, living and/ or working within the study catchment area, will be eligible for inclusion and chosen through purposive selection. When selecting participants, the team will aim to include persons from a variety of backgrounds, including those working in the health sector and those who are not, as well as people of different ages and genders. The team will endeavour to speak with at least 2 people in each village selected (at least 1 non-health leader and 1 health personnel), and to visit at least 4 villages, to improve reliability of results. Ultimately, the number of villages visited will depend on the results of the quantitative survey and the amount of variation observed across villages, as well as when thematic saturation is observed.

8 Data collection

Quantitative phase (coverage survey):

Before starting data collection, the data collectors (teachers) will inform the head of the villages they are going to visit about the survey activities and the purpose behind it.

In the households, the teacher will explain the purpose of the survey to the head of the household or representative in the language he or she is familiar with (Kiluba or French, pending the preference of the participant), and informed verbal consent process will be obtained to conduct the interview. The head of household is defined as an adult living in the household who self-identifies as able to answer questions relating to the health of household members. All refusals will be recorded, and those forms retained to document participation rate. All data will be collected on a paper questionnaire.

The data collected will be:

- Aire de santé (health area)
- Village name
- Number of residents in household, by age group (1 to 15 years and over 15 years)
- Number of household members vaccinated (verbal) by dose (1 and 2)
- Reasons for non-vaccination in household, if relevant

Qualitative phase:

Data will be collected through participant-led interviews guided by a semi-structured topic guide. Formal and informal community leaders, as well as health system workers such as recos, will be purposively selected and interviewed individually, to gain their views, and so that they may feel comfortable speaking freely without fear of contradicting or undermining another key figure in the community.

The collection of data will continue until thematic saturation²¹ is achieved. This can vary but is expected to take about 8-12 individual interviews.

Participants will be explained the purpose of the study written informed consent will be sought prior to beginning any interview or discussion. Interviews will be audio-recorded, with participant permission. If the participant refuses to have the interview audio recorded but still wishes to participate, they can still participate, and the interviewer team will note their responses with paper and pen. The data collection will be led by the PI with the help of a local translator to undertake IDIs. We will identify a translator with experience in healthcare activities or community mobilization (e.g. nurse, health promoter not involved in the project at the time of data collection), ideally with previous experience in qualitative research.

The translator will be trained to gain understanding of: 1) research topic, 2) process of qualitative data collection, 3) interviewer skills, 4) reflexivity (i.e. the PI and the translator will also reflect together on how translator's background and own active construction of meaning will affect the translation).²² The translator will jointly plan and conduct the interview sessions with the PI, revising afterwards a sample of audio-recordings to ensure consistency between the answers and their translation. During data analysis, the translator may also be involved to

²¹ Saunders B, Sim J, Kingstone T, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant*. 2018;52(4):1893-1907. doi:10.1007/s11135-017-0574-8

²² Temple B, Young A. Qualitative research and translation dilemmas. *Qualitative research*. 2004, 4(2):161-178

double check possible meanings and interpretations of the data.²³ To ensure that the translator is translating questions and responses appropriately, a research project staff member who speaks the local language will observe a subset of 1 to 2 early interviews, to assure the translation is accurate.

Field notes will be taken during IDIs and contextual observation within visited villages, according to recommendations by Phillippi and Lauderdale.²⁴ The content of field notes will help to the interpret and put into context underlying meanings of verbalized perspectives.

Following the steps for data management by Halcomb and Davidson,²⁵ the PI will take notes during IDIs, to capture researchers' impressions on the non-verbal communication and interaction that are not recorded on verbatim sections of the participants' response. As soon as possible after the IDIs, the PI will review the fieldnotes and expand on the initial impressions with more thoughtful comments and perceptions (i.e. reflective journaling). All these notes will be later revised and complemented by listening again the audiotape. The field notes will be discussed daily with the team in the field involved in the study to gather their views on emerging themes and adjust data collection process if needed.

A preliminary version of the qualitative data collection tool is included with this protocol (see Annex), but will be modified and added to, based on the results of the first (quantitative) phase of the study. This methodology is part of the explanatory sequential mixed-methods approach.

9 Data entry and analysis

Quantitative phase (coverage survey):

Data will be entered into a REDCap database by a data entry clerk using a laptop computer. Data will be entered once all data has been collected, approximately one month after the start of the data collection process. Data cleaning will be done to check for inconsistencies in data entry and responses. Data analysis will be conducted using STATA 17 (StataCorp, College Station, TX, USA) or R software.

No names or name-related data will be collected during the study, reducing the risk that participants will be identifiable after the study has been completed.

The main outcome of the analysis will be the overall vaccination coverage in the catchment area. Secondary outcomes will be the percentage of people in the target age group vaccinated by each vaccination campaign, vaccination coverage by village, vaccination coverage by aire de santé (health area), vaccination coverage by age group, and reasons for non-vaccination.

²³ Caretta MA. Situated knowledge in cross-cultural, cross-language research: a collaborative reflexive analysis of researcher, assistant and participant subjectivities. *Qualitative Research* 2015, 15(4) 489–505. DOI: 10.1177/1468794114543404

²⁴ Phillippi J, Lauderdale J. A Guide to Field Notes for Qualitative Research: Context and Conversation. *Qualitative Health Research*. 2018 Feb 1;28(3):381–8.

²⁵ Halcomb EJ, Davidson PM. Is verbatim transcription of interview data always necessary? *Applied Nursing Research*. 2006;19(1):38–42.

Vaccine coverage will be calculated according to age group, and at village, aire de santé and global level using the following :

$$VC = \frac{\text{Total number of vaccinated individuals}}{\text{Total number of individuals}} * 100$$

All indicators will be calculated as proportions with 95% confidence intervals (95%CI). Estimates of actual design (cluster) effect will also be calculated for each variable and those with effects greater than 1 will be reported. Where appropriate, differences in proportions will be measured using Pearson χ^2 test and p-value (p) will be presented.

Qualitative phase:

Data will be collected through in-depth interviews, guided by a semi-structured topic guide. The collection of data will continue until thematic saturation is achieved (anticipated after 8-12 key informant interviews). Interviews are anticipated to last 30 to 60 minutes each.

Data will be translated from the local language (primarily KiLuba) into French (the main language spoken by the research team) by a research assistant(s) (local researcher or recent university graduates where possible, or someone with a health promotion/ outreach background) hired specifically for this task, during the interview.

We will perform thematic data analysis directly from audio recordings, a rapid qualitative technique employed by Greenwood et al.²⁶ Once familiarized with audio files and field notes as described above, the PI and another researcher will independently code a subset of interviews and decide on a coding scheme, and the PI will code all audio files using a secured and password protected system such as Microsoft OneNote. Then codes will be collated under potential themes and, using thematic maps, the PI with a subset of the other field research investigators will then review if the themes are coherent in relation to the codes and representative of the entire dataset. Finally, themes will be named, appropriately described, and supported and illustrated by verbatim extracts from the dataset, relating the analysis in answer to the research questions.²⁷

The research team includes members with expertise in operational research and qualitative methods, who will ensure that the work undertaken will follow appropriate methodological and ethical guidelines. A continuous exercise of reflexivity will be done by the PI and the researchers closely involved in data collection and analysis, gaining consciousness about how socio-cultural, gender and professional background, experience, and beliefs, as well as the emotional responses from the interaction with participants can influence the research process and the interpretation of results.²⁸

The use of multiple informant sources (health workers, informal and formal community leaders) and different methods for data collection (IDIs, field notes) will help to triangulate the findings and offer different perspectives approaching the same subject.²⁹

²⁶ Greenwood M, Kendrick T, Davies H, Gill FJ. Hearing voices: Comparing two methods for analysis of focus group data. *Applied Nursing Research*. 2017 Jun 1;35:90–3.

²⁷ Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*. 2006;3(2):77–101.

²⁸ Dodgson JE. Reflexivity in Qualitative Research. *Journal of Human Lactation*. 2019 May 1;35(2):220–2.

²⁹ Tessier S. From Field Notes, to Transcripts, to Tape Recordings: Evolution or Combination? *International Journal of Qualitative Methods*. September 2012:446-460. doi:10.1177/160940691201100410

To ensure reliability, the PI will share the field notes and listen a subset of audio-recordings with other study members in the field during the data collection period.

The study will include all participants' perspectives and opinions, not just the dominant but also those that may be deviating. The PI will verify and ensure that any discrepancies in the data are noted and discussed until consensus is reached.

Merging of results from quantitative and qualitative phases:

The results of the quantitative phase of the study will inform the revision of the topic guide and the purposive selection of participants for the qualitative phase of the study. The qualitative data will serve to better understand or explain key points from the quantitative phase, specifically to better understand why some villages have higher coverage levels than others.

An interim report with findings from the quantitative phase (coverage survey) may be released. The results of the quantitative and qualitative phases will be used together in concert to form the final report of findings and provide recommendations. Specifically, the results of the quantitative phase will give information on variations in coverage across villages, and the qualitative information is expected to complement this data with information on why such variations may have been observed, and how future activities can best be operationalized to address any gaps identified.

10 Ethical principles and Authorization

10.1 Community involvement

Local staff and partners, especially health authorities and teachers, will play a key role in helping to carry out the study. Local stakeholders, including recos, health authorities, and teaching authorities were consulted as part of the study design process, and through their input, the design using teachers as data collectors for the quantitative phase was decided upon. Community engagement shows respect to the community and should improve survey content relevance and enhance security for both survey staff and participants. Authorities and communities (such as village heads, religious leaders, opinion makers) in the survey area will be informed about the purpose of the survey.

The team will endeavor to engage local researchers, such as recent university graduates, in the qualitative data collection, if possible (see section 9). If appropriate, advice from academics in Lubumbashi originating from the study area will be sought and they will be involved in the study process.

Epicentre commits to sharing of survey results with the communities who participated in the survey. The local community will be involved and informed through Epicentre team and the data collectors hired by Epicentre. The Epicentre team in place in Bukama will decide about the best venues to display the results, but this may include posters in the supported UTCs/CTCs, schools, and/or transmission of findings through local recos, teachers, or other local partners.

10.2 Ethical approvals

The protocol will be submitted for approval by MSF ERB and the local MOH Ethical Committee in Lubumbashi.

An agreement (MoU) will be signed with the Ministry of Health regarding this study. An informational letter will be shared to BCZS (Bureau Central de la Zone de Santé) to inform them of the study, including the study objectives and methods that will be used.

The PNECHOL will be constantly associated with the study, as well as the Ministry of Health local representatives.

The survey will be conducted in accordance with the Council for International Organisations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects and International Ethical Guidelines for Epidemiological Studies³⁰ and with national guidelines for research ethics evaluation for studies involving human subjects in DRC.³¹

The MSF medical responsible in the field (UrgEpi medical responsible based in Lubumbashi, in combination with Epicentre nurse supervisor based in Bukama) will advise the study team on the emergency and non-emergency referral practices when finding sick people in the study village.

The Principal Investigator is overall responsible for ethical compliance of the study. Participant privacy will be respected during the interviewing process. Staff will be trained in how to assess for appropriate conditions to help maintain confidentiality during the interview process, including choosing the optimal location when a setting makes privacy difficult (e.g., single room dwelling).

10.3 Informed consent process

Privacy and confidentiality in the data collected from the participants will be ensured both during and after the conduct of the screening. All participants included in the study will have the study activity explained to them in a language with which they are familiar (Kiluba or French, based on the preference of the participant). It will be explained to all participants that they are free to refuse to participate in the study or to withdraw at any time, and to decline to answer any questions without any negative consequences on their current or future care for them or their family. No incentives or compensation will be provided to any respondents. Everyone approached for the study is completely free to participate or not.

³⁰ Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for health-related research involving humans - CIOMS Geneva 2016. <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (accessed November 24, 2020)

³¹ Ministry of Health. LIGNES DIRECTRICES POUR L'EVALUATION ETHIQUE DE LA RECHERCHE IMPLIQUANT DES SUJETS HUMAINS EN R.D. CONGO.

The consent form and information letters will be translated into local KiLuba language, the primary local language for this population, and then back translated into French to ensure the accuracy of the translation. Before the start of the study, and participants will be able to choose in what language they prefer procedures to be explained.

Due to the COVID-19 pandemic, the informed consent process will follow prevention measures recommended to reduce contact with participants/objects, such as physical distancing, a clean pen for each participant and staff, hand hygiene and surgical masks to minimize the risk of infection between the study team and participants.

The informed consent forms will be kept in a locked cabinet and separately from other study documents. The information sheets and the consent forms are provided in appendices 15.3 and 15.4.

Quantitative phase (coverage survey):

Considering that asking for vaccination history is not an invasive process, and that we expect high numbers of illiterate persons and expect difficulties to identify literate witnesses outside of the study team, we will only seek an oral consent from participants for this activity. Verbal consent will be sought from every household at the time of visit by the data collector, with the designated head of household answering the questions for all relevant members of the household. He/she may choose to delegate answering the questions to another member of the household, or to individuals regarding their own vaccination status if relevant.

The data collection activities, as well as study procedures, risks and benefits, will be explained to heads of household by the data collector (appendix 15.3), before the household's inclusion in the research study. Participants will be read all information about the study in the appropriate local KiLuba language, will be given the opportunity to accept or decline participation for their household and to ask any questions they may have related to study. They will also be informed that their participation is free and voluntary, that they are free to decline to participate or to withdraw at any time without any negative consequences on their current or future care. The study team will testify that the head of household effectively gave their verbal consent (see appendix 15.3) and a copy of the information sheet and the consent form will be left to the participant. The informed consent process will be held in a calm and private place to ensure privacy and confidentiality.

Due to the possible difficulties to identify the exact status of minor running households, combined with previous experience of surveys in the same region showing that the case where emancipated minor is the only one able to represent the household appeared very rarely, households run by minors (emancipated minors) will not be included in the activity.

Qualitative phase:

Participants will be offered written informed consent in their local language prior to participating. The data collection activities, as well as study procedures, risks and benefits, will be explained to the participant by the data collector (appendix 15.4), before the person's inclusion in the research study. Participants will be read all information about the study in French or KiLuba language (based on their preference) and will be given the opportunity to

accept or decline participation. They will also be informed that their participation is free and voluntary, that they are free to decline to participate or to withdraw at any time. The study team will testify that the head of household effectively gave their written consent (see appendix) and a copy of the information sheet, and the consent form will be left with the participant. The informed consent process will be held in a calm and private place to ensure privacy and confidentiality.

Minors will not be included in the qualitative phase, as the number of minors who are community leaders or health staff is expected to be very low, and the desired information is expected to be able to be collected adequately from adults.

10.3 Confidentiality

The data collected from the participants will be treated with privacy and confidentiality both during and after the study. During the interviews, privacy will be respected, and the staff will be trained and how respect privacy and confidentiality including choosing the optimal location while carrying the interview.

Quantitative phase (coverage survey): The data collectors (teachers) will receive a specific training module on confidentiality during their training. They will also sign a confidentiality agreement (Annex 15.5).

Qualitative phase:

To ensure that participants can speak freely, confidentiality of responses will be emphasized, and data collectors will be trained to find a private place to conduct the interview, where the respondent can speak without fear of being overheard by their supervisor (especially in the case of a health worker) or by other community members or leaders.

10.4 Data storage and protection

All study forms, including consent forms, will be sent at the end of the study to the MSF office in DRC and stored by MSF for 5 years securely in a dedicated locked cabinet, which will be opened only in case of a participant's requests to access, modify, or withdraw their data. After the research team has left the site, the data will be kept under the responsibility of the MSF Head of Mission, who will remain in contact with the study team.

All data and databases will be password-protected, GDPR-compliant and stored on a secured server ("the study server") at Epicentre in France for 5 years and then permanently deleted. Access to the study database on the study server will be limited to the study co-investigators and the organisations authorized by law.

Quantitative phase (coverage survey):

Data capture

Names of participants will not be collected, and data collectors will be counselled to select a semi-private location to conduct the interview, and to store the forms in a secure location, under lock and key if possible (though lock and key may not always be available in certain field locations). Once the paper forms are brought to the Epicentre office in Bukama, they will be stored in a locked cabinet at the Bukama project office. The central study database (RED Cap)

will also be protected with an MSF password. This password will be accessible only to the essential staff, as designated by the PI. Data in the central study database will be reviewed weekly by the study supervisors to check for issues.

Data preservation

Data in the central study database (RedCAP) will be downloaded in Excel format and saved weekly by the PI to the dedicated study server to prevent against accidental data loss. Once all data has been collected and entered, the final database will be downloaded and saved in Excel format to the study server, and the RedCAP portal for the study will be closed and inactivated. The final study database will be password protected and saved in headquarters Epicentre in Paris for 5 years following the study.

Qualitative phase:

Data capture

Names of participants will not be collected, and data collectors will be trained to select a semi-private location to conduct the interviews.

Data preservation

All paper notes will be stored in a locked cabinet at the Bukama project office, until transported to the MSF office at the end of the study. All relevant digital files, including audio recordings, field notes, and, once available, codes, will be uploaded to a password protected study server. Only relevant study staff (those actively involved in data interpretation and analysis, as designated by the PI) will have access to the folder. After 5 years the study database will be destroyed.

10.5 Risks and Mitigation Plans

Benefits to the participants

There are no direct benefits for the participants, but benefits are anticipated indirectly at the community level. A better understanding of the vaccination coverage levels and facilitators and barriers to vaccination in the area will allow better tailored programming and more efficient use of resources, including possible targeting of catch-up campaigns and better implementation of future campaigns. The information will also contribute to a better understanding of cholera cases and transmission, and of the impact of cholera vaccination campaigns. This information will thus indirectly help us to protect the participants and their community better from cholera in the future.

Operational benefits to public health

This methodology will allow estimation of vaccination coverage at the village level, in all villages of the catchment area, allowing for specific targeting of catch-up activities to any and all villages that may be found to have low coverage. Accurate data on vaccination status are of tremendous importance for advocacy on local, national, and international levels. This activity is conducted in partnership with local health authorities, with a goal of targeting catch-up activities, if needed. The qualitative data should also allow for catch-up activities or future campaigns to be organized in a way that is well suited to community needs. The results will also support interpretation of data collected as part of an ongoing study on OCV effectiveness, currently underway by Epicentre.

Risks No physical harm is expected from the information collection for this study, as the study is non-invasive and only involves interviews, no sample collections. Nevertheless, asking the interviewees about personal information may feel intrusive and in village contexts there may be limited privacy. Using local staff and careful training on interview techniques can mitigate this. Possible risks and accompanying mitigation measures are detailed below:

Risk	Mitigation
Confidentiality of participant responses.	<p>Participant names will not be collected, and interviewers will be trained to conduct the interviews in an appropriate chosen location, as much as possible, to ensure privacy. Study staff will be trained to keep everything secure and confidential, and study documents will be kept in a locked cabinet only accessible by the study team.</p> <p>Given that the quantitative data collectors (teachers) live in the same community where they are collecting data, the importance of confidentiality will be underlined in a special module of the training, to reduce risk of confidentiality breaches.</p> <p>Additionally, the appropriate legal and confidentiality agreements with data collectors will be settled.</p>
Risk of participant discomfort if a respondent is a student in the data collector (teacher)'s class. (quantitative portion/ coverage survey only)	<p>Heads of households will be the primary respondents in this survey, responding on behalf of their household members. It is not anticipated that any people who are still students in school would be responding to the data collector. Individuals, such as children, who are not the head of household, will not be responding to the data collector.</p> <p>To further minimize this risk, only aggregate data will be collected.</p>
Risk of impact on trust, if teachers overstep their regular activities	<p>Community leaders will be informed and transparently explained the survey, the reason why the teachers will be involved and possible impacts. The community leaders will be free to refuse that the survey happen in their village if there is any doubt on the way to proceed.</p>

	<p>Moreover, it will be made clear with data collectors that they will be allowed to stop data collection would they notice any negative impact on their relationship to the community. They will then be asked to contact the supervisor and corrective measures can be proposed; if no solution is found, data collection in the village will be stopped. After completion of the survey, they will also be interviewed on their perception of this work to identify any issue of this kind and gain experience.</p>
<p>Risk of participant stigmatisation, especially if any participant is a student in the teacher's class (quantitative portion/coverage survey only)</p>	<p>Training of data collectors will include a module reinforcing the importance of confidentiality, and to avoid making any moral judgment based on the status of any person as vaccinated or non-vaccinated.</p> <p>To further minimize this risk, only aggregate data will be collected.</p> <p>In case the community authorities or the head of household do not feel comfortable with the study, the household will not be included. The head of household will also be free to withdraw his/her consent at any time over the course of the study.</p>
<p>Bias of results due to the teacher's respected position in the village (quantitative portion/coverage survey only)</p>	<p>During the informed consent process (i.e Annex 15.3), teachers will emphasize the neutrality of their position as data collector and the importance of sharing accurate information.</p> <p>In order to minimize the risk of people feeling pushed to provide a certain answer, training will insist on the way for data collectors to present themselves as a neutral person, that they were not involved in the campaign, have no personal interest to any kind of answer and that the answer will not impact on the teacher-family relationship. The training will also insist that head of households are free to not answer questions if they are not comfortable.</p> <p>Teachers were selected for this activity after intensive consultation with a variety of</p>

	<p>community stakeholders and leaders, because they are considered as someone neutral and independent within the village, who can be trusted to collect and relay neutral and accurate information.</p> <p>Additionally, teachers were viewed as preferable to outsiders, as community members may feel more at ease sharing freely with someone they know and trust rather than with an outsider.</p>
COVID-19 transmission and other health risks	<p>COVID-19 transmission is currently low in the study area. Nonetheless, study staff will be briefed on proper technique to minimize COVID spread, such as maintaining at least 1 meter distance from respondents, and conducting interviews outdoors or in well-ventilated spaces as much as possible and compatible with confidentiality requirements. Masks will be provided to data collectors.</p> <p>If the COVID-19 situation changes substantially, other protective measures may be considered and implemented.</p> <p>If any participant suffering from any medical symptoms is found during the data collection, a nurse from the nearest health post will be informed, even if it is a person who declined to participate.</p>
Risk of humanitarian misconception, or people feeling obliged to participate due to the connection with MSF	<p>It will be made very clear in the informed consent documents that participation is totally voluntary and has no effect on access to care. This will also be explained to community leaders prior to commencing the survey activity in a community.</p>

Data collectors protection and support

This study design relies on school teachers who are not usually involved in this kind of data collection. The survey will be explained to all teachers, and they will be free to decide whether they want to participate or not. Only those who are voluntary to participate will be selected to become data collectors. The data collectors will be given enough time (a few weeks) to be able to run the activity at their own pace and without any disturbance to their regular teaching activity. The data collection could for instance happen on school recess day or vacation, or be split in different time slots. All questions they may have will be answered either during the training, or afterwards by calling supervisor or receiving supervisor visit (see section 12.2).

They will all receive incentive calculated in accordance with the workload attributed and position level, based on MSF administrative salary grids.

11 Collaboration

This survey will be carried out in collaboration between Epicentre, MSF and MOH-DRC, with the support of local teaching authorities (Prefectures of Teachers for Haut Lomami, and Sub-Prefectures of Teachers for Bukama and Luena).

Epicentre is the study sponsor and is responsible for the funding, which has been secured in partnership from the funder Wellcome Trust. MSF is involved in the study as an operational support. Epicentre oversees the field part of the screening, the analysis and report writing. Permission for publication must be obtained from Epicentre and the MoH. Study results will belong to Epicentre and the MoH-DRC.

12 Implementation of the survey in the field

12.1 Selection and tasks of the data collectors

Quantitative phase (coverage survey):

One teacher per village will be identified with the help of the local teaching authorities. The task of the teachers will be to collect the necessary data for the survey.

General selection criteria for all interviewers:

- Teacher currently actively working in an aire de santé (health area) covered by the survey, and living and/ or working in the village where they will collect the data
- Able to read and write in French, and
- Fluent in the local language (KiLuba), and
- Available for the time of the survey (training days, interview days, and data return day), and
- Have no known conflict of interest (specifically, the teacher should NOT also be employed by the local health authorities, such as in the role of Reco, as is sometimes the case)

If multiple teachers who meet the selection criteria are available within the same village, the local teaching authorities will help to select which teacher to include for the activity, as is often the case when collaborating with local authorities. In cases where multiple teachers in one village are eligible and the local authorities do not wish to recommend just one, then one will be selected at random by Epicentre, from a list of eligible persons furnished by local authorities.

Qualitative phase:

A research assistant/translator will be identified for the purpose of the activity. The team will seek to identify someone with the following profile, potentially among local university students or recent graduates, or among the regular pool of already recruited persons identified for such activities.

Selection criteria for the research assistant/translator:

- Able to read and write in French, and
- Fluent in the local language (KiLuba), and
- Available for the time of the survey (training days, interview days, and review of audio recordings), and
- Have no known conflict of interest (specifically, should NOT also currently be employed by the local health authorities)
- Experience with qualitative research / interviews / focus group discussions would be a plus
- Health promotion or anthropology profile would be a plus

12.2 Supervision

The principal investigator is the overall responsible for the final version of the protocol, the quality of the research, the data analysis and report writing.

The principal investigator will ensure that the following tasks are performed:

- Preparation of all necessary document for the survey
- Secure the necessary local approvals (including that of the local ethics committee)
- Preparation of the field component of the survey (training of the study teams, logistics, materials) together with the MSF team in the field
- Follow-up of the field component of the screening
- Data quality checking and analysis
- Report writing
- Ensures ethical compliance during implementation of the study through supervision and training.

Quantitative phase (coverage survey):

In-person supervision for this activity will be complicated, because of the large geographical size of the survey zone, and logistic difficulties of travel within the zone. To account for this challenge, data collectors will be trained intensively and provided with a memory-aid guide before leaving the training. Also, the data collection tool will be as simple as possible, to decrease the need for supervision.

Several modes of communication, including back-ups, will be shared with the data collectors, to account for potential difficulties of communication within the study zone. A toll-free phone hotline, staffed daily by an Epicentre Nurse Supervisor, will be made available in case of any questions or uncertainty. In the event of difficulties in establishing the toll-free hotline, a strategy of distributing phone credit cards will be adopted instead. We anticipate there will be very few data collectors (teachers) who do not have at least one cell phone within their family; those without phones will be counselled to borrow a phone from a trusted contact or a fellow teacher in a nearby village should they need to contact the supervisory team. Teachers will also be made aware that the nursing teams in all local UTCs are in contact with Epicentre, and that if all other measures fail, the staff in the nearest UTC could assist them with contacting an Epicentre supervisor. An Epicentre Nurse Supervisor will also visit each targeted health area at least once during the approximately month-long data collection period, to provide spot-check supervision.

In addition to these training and remote supervision measures, some in-person spot supervision will be conducted, to ensure that data collectors are following the requested procedures, and to a high quality. Throughout the course of the data collection period (approximately one month), a supervisor (member of the research team) will visit villages in the catchment area and meet with the data collector and conduct a spot supervision by reviewing the completion of tools such as the consent forms and data collection form, and by speaking with local community leaders or community members to understand how the activity is progressing. This spot supervision will not be possible in every village due to logistical challenges. Data collectors will be informed of the possibility of spot supervision, with the aim that the possibility of supervision increases the quality of work of all. Spot supervision will occur in at least one village per each of the 12 health areas, over the course of the 1-month data collection period.

Qualitative phase:

The PI will lead all interviews in collaboration with the research assistant (translator). A piloting phase will be employed to make sure the research assistant is properly translating and transcribing. During this piloting phase of approximately 1 day (at least 2 interview sessions), local staff who are fluent in the local language (Kiluba), such as nurse supervisors, will assist during and after each interview, to make sure the research assistant is translating appropriately and completely. If the research assistant proves to be very strong, they may conduct some small subset of interviews independently of the PI. The PI will decide if this is possible.

12.3 Suggested support of MSF in the field

- Light administrative support for survey preparation at the field level such as presentation of the survey protocol to the relevant national or MoH ethics committee or institutional review board, payment of survey data collectors (teachers).
- Human resources and administrative support, such as support with study team contracts and payment of data collectors, and organization and supervision of payment of data collectors upon completion of the activity. Final salary costs will be supported by the Wellcome Trust grant.

12.4 Training of data collectors

A small training meeting will be held with associated staff such as logisticians, community liaisons, drivers and data clerks to explain the overall study and their roles and expectations.

Quantitative phase (coverage survey) (teachers):

1.5 day of training will be given to all teachers to familiarize them with the background of the survey, the questions to be asked, and the information to be given to the survey participants or their parents/guardians/caretakers. The training will be given in French by an Epicentre or MSF staff member (anticipated to be a nurse supervisor or epidemiologist). It consists of an intensive review of the questions to be asked and the information to be given to the screening participants or their parents/guardians/caretakers and should include role-plays. As the interviews will be held in the local language, the training facilitator will ensure that all interviewers are using the same and correct wording for providing information to the

households and for the interviews. The person delivering the training will receive support from the PI in planning the training and developing training materials. To allow for close training, the training will be delivered in 2 sessions, with approximately 60 participants per session. The lead trainer will be assisted by an Epicentre nurse supervisor during the training.

In addition to covering the survey questions and how to complete the survey form, the training will cover basic information about cholera, signs and symptoms of dehydration, and when and how to refer a person exhibiting danger signs.

Teachers will also receive memory-aid support tools with clear and concise instructions on how to conduct the activity, which they can carry home with them to their respective villages to conduct the survey.

Teachers in the Bukama sub-division convene in person on a regular basis (approximately monthly) for several days at a time, to receive their payment from the authorities. The training of teachers will be organized during this already scheduled teacher meeting, to capitalize on the gathering, with the permission of relevant authorities (the local sous-préfète of teachers).

One potential challenge is the lack of cell phone network in much of the study zone. Cell phone numbers of the teachers will be collected by the study team, where possible, to facilitate follow-up if needed. Cell phone numbers of teachers will be stored in a secure location and only contacted via the professional phones of Epicentre staff. Cell phone numbers of data collectors will be deleted from phones after use. The teachers will also receive a hotline number (numéro vert) to call for free in case of any questions or concerns.

Qualitative phase:

The PI is experienced in qualitative methods and will be the primary person to conduct the qualitative interviews, but will provide an in-depth training to the research assistant in order to assure high quality work. The training will be delivered by the PI at a site to be confirmed in Bukama. The training will also include a summary of the results of the first phase of the study (quantitative phase/coverage survey), followed by an introduction to qualitative research, an in-depth walk-through of all study tools, as well as numerous role plays.

This training will end with a pilot in a nearby village(s). The pilot will allow for evaluation of the topic guide, familiarizing the research assistant (translator) with the topic guide, and to allow adaptation of the guide for the field if necessary. The principal investigator will explain the purpose of the pilot to participants. During the pilot, a total of 1-2 community members/leaders will be interviewed. The results of the pilot will not be included in the final results and will be destroyed.

12.5 Timeframe in the field

Quantitative phase (coverage survey):

The following number of days are needed for the field part of the survey:

- 1-2 days for final preparation of the survey in the field, to plan the survey days, to plan movements (if needed), to check materials for the survey, to organise photocopies of

questions and further required information sheet, to define working conditions of the selected teachers, such as working hours and payment

- 1.5 day training
- 1 teacher can finish his/her catchment area in 2-3 days (16-24 working hours)
- As the teachers only convene in Bukama approximately once per month, results are expected to take one month to be received, even though the actual data collection should take substantially less than one month. Data collectors will be able to collect data at their own pace during the one-month data collection period, such as during non-working hours and on weekends.

In the exceptional case that certain teachers cannot reach Bukama to deliver their results, alternative arrangements will be considered, such as meeting an Epicentre supervisor within the health area where the teacher is stationed.

Qualitative phase:

- Each interview is expected to last about one hour. With time for introductions and consent, 90 minutes to 2 hours could be allocated per interview.
- Approximately 6-10 interviews total are expected to take place, with one to three interviews per village.
- The qualitative interviews will be conducted as an add-on to ongoing project activities, such as other previously planned supervisions or data collections. As such, the qualitative interviews are expected to take place little by little over a period of approximately one month, to allow for the data collectors to move to the targeted villages along with regularly scheduled movements, and to minimize the need for extra movements.

12.6 Estimated Timeline (may be modified pending ethical approval timing)

	May 2022	June 2022	July 2022	August 2022	September 2022	October 2022	November 2022
Protocol development	X	X					
Ethical review		X	X				
Training and start of quantitative data collection			X				
End of quantitative data collection (turn in forms)			X	X			
Quantitative analysis and preliminary report				X			
Quantitative portion: Results sharing				X			

Revision of qualitative interview guide and purposive selection				X	X		
Training of qualitative data collectors				X	X		
Qualitative data collection					X		
Qualitative transcription, translation, and analysis					X	X	
Final report writing and sharing						X	X

Quantitative phase (coverage survey):

The teachers gather in Bukama town approximately every month around the 20th of the month to receive their payment. Data collectors (teachers) will be trained when they come for their pay once the ethical approval has been received. Data collection will occur at the teacher's own pace outside of working hours over several days during the period of approximately four weeks following the training, and collection of the forms when the teachers return to Bukama for their regular meeting and payment.

Teachers are expected to conduct this activity outside of their regular working hours (such as on the weekend), as to not disrupt their regular work activities. Teachers will also be counselled to conduct the data collection during hours that are appropriate to local community rhythms, to minimize disturbance.

Qualitative phase:

Data collection for the qualitative phase will begin once the data collection for the quantitative phase has been completed, thus allowing purposive selection of villages with low, medium and high coverage levels. Qualitative data collection may be conducted in concert with ongoing study activities (such as supervision or other Epicentre data collections), in order to reduce the number of movements and associated costs and logistical burden.

12.7 Safety considerations

The study team will always follow Epicentre/MSF safety and security protocols. The Epicentre team continually engages with local governmental and communal leaders, and this will continue prior to and throughout data collection, in order to improve acceptance and security of the study team. The study area of Bukama and the surrounding province of Haut Lomami is relatively calm, except for potential for flare-ups in violence, which have not occurred recently.

12.8 End of data collection

Data collection for the quantitative phase is anticipated to end approximately one month after it starts, at the monthly meeting of teachers in Bukama. Data collectors will be able to collect data at their own pace during the one-month data collection period, such as during non-working hours and on weekends. For the qualitative phase, data collection is expected to occur intermittently over a period of several weeks, based on the rhythm of other project/study activities.

Data collection may be stopped early if security concerns make the data collection unsafe, but this is not anticipated, as for quantitative phase the data collectors are all residents of the areas where they collect data, and for both phases, Epicentre/MSF is well known throughout the catchment area. If data collection must be halted early, this decision will be made by the PI in consultation with the team present in Bukama. Depending how much data has been collected at the time of an early study stop, the PI will decide whether the data collected so far can be analysed in a meaningful way, and if so, the data will be analysed, and results shared.

13 Logistics

13.1 Supplies needed

Quantitative phase (coverage survey):

See Table 3 below for a list of required supplies.

Table 3 Supplies needed for the field part of the quantitative phase (vaccination coverage survey), (per 1 teacher)

Item	No. needed per teacher
Consent form and information page	100
Questionnaire	1
Eraser	1
Pencil sharpener	1
Plastic folder	1

Qualitative phase:

See table 4 below for a list of required supplies.

Table 4 Supplies needed for the field part of the qualitative phase (total)

Item	No. needed total
Consent form and information page	15
Interview guide hard copy	15
Pencil	2
Eraser	2

Pencil sharpener	2
Plastic folder	2
Audio recorder (such as professional smartphone)	2

13.2 Transport

Quantitative phase (coverage survey):

The teacher is from the local community, so cars, motorcycles, or other modes of transport are not needed. The teachers come regularly for required in-person meetings in Bukama via their own means or public transport.

For supervision of data collectors, supervision is expected to take place in concert with existing project activities, meaning that no to minimal additional logistical or budgetary support is required for this transport.

Qualitative phase

Qualitative data collection expected to take place in concert with existing project activities, meaning that no to minimal additional logistical or budgetary support is required for this transport.

13.3 Estimated Budget

Item	Cost, per unit (USD)	Units needed	Total cost, USD	Total cost, FC
Incentive for teachers, per day (164 teachers*4 days)	8	656	5248	10647232
Printing	700	1	700	1 423 800,00
Refreshments during training	400	1	400	813 600,00
Papeterie	500	--	500	1 017 000,00
Communication (toll-free hotline)	150	1	150	305 100,00
Data entry clerk (monthly) – 2 clerks for 2 weeks each	600	1	600	1 220 400,00
Transport supplement for supervision and qualitative data collection	500	1	500	1 017 000,00

Qualitative research assistant /translator (monthly, for 4 weeks)	600	1	600	1 220 400,00
TOTAL			8698	17664532

Teachers will receive incentive pay but are not expected to receive additional per diems, as they are in their home villages where they stay regularly.

14 Expected results

The results of this work are expected to be useful for decision making on several levels, both operationally and for the broader scientific community:

- The results of this study, specifically the coverage data, can immediately inform local health authority, Epicentre, and MSF-OCP public health decisions. Information on reasons for refusal, as well as the results from the qualitative portion, can help to inform future campaigns and vaccination activities, especially the accompanying health promotion messages. The results of the qualitative portion are also expected to be useful in informing the organization of catch-up campaigns and other vaccination activities in the area.
- The results of this study are also expected to inform the interpretation of results of an ongoing study, 'Cholera control in endemic regions of Africa: clinical surveillance and cholera shedding study in the context of mass vaccination campaigns, Democratic Republic of the Congo' currently underway in this zone, led by Epicentre.
- Finally, as this study presents a novel approach that is designed to be more logistically feasible in rural settings, the successes and challenges of this new approach may be shared, so that it might be adapted or adopted by others/

14.1 Report and Dissemination Strategy

The principal investigator will prepare a survey report after calculating the OCV coverage from the aggregated data provided by the teachers.

Local level: An interim report of findings with essential estimates of vaccination coverage levels will be shared with local health authorities including the Médecin Chef de Zone and the Vaccination Officer of Bukama for their review, as well as representatives of the Provincial Ministry of Health (DPS). A final report integrating findings from both the quantitative and qualitative phases will be shared and may be in the form of a concise written document and/or a PowerPoint presentation, depending on the preference of local authorities. Results will also be shared with the supervisor (infirmier superviseur) of each CTC/UTC supported by Epicentre in the health zone. A meeting or workshop for dissemination of the results may be organized in Bukama.

Community and participants: The Epicentre team in place in Bukama will decide the best venues to display the results, but this may include posters in the supported UTCs/CTCs, schools, and/or transmission of findings through local RECOS, teachers, or other local partners. Feedback on results will be shared to the teachers who served as data collectors.

National level: Results will be shared with the PNECHOL in the form of a concise written report and/or a PowerPoint presentation.

International level: Results may be shared at a scientific conference or through a publication in a scientific journal. Depending on the results and experience implementing the study, the study team may endeavour to share not only the specific results of this research, but also share the novel methodology employed. Publications will be jointly led by Epicentre and the Ministry of Health and authorship of any scientific publication will follow ICJME guidelines.

14.2 Limitations

Participant refusal to participate is a potential limitation, especially if there are high levels of refusal, or systematically higher refusal in certain areas. Refusals will be documented at the household level (quantitative phase) and individual level (qualitative phase) and respected.

Another limitation is the potential for biased responses from persons who were involved, directly or not, in the actual organisation of the campaign. This has been mitigated by selecting teachers, who are not part of the health system, as they are considered neutral and capable of presenting unbiased results, as well as through spot supervision of the data collectors. Nevertheless, relationships, influence dynamics as well as precise view on campaign organisation at village level are not fully known. Care will be taken to inform relevant authorities.

Another limitation could be that participants in the qualitative phase, especially recos, may be hesitant to answer questions openly due to the potential perception that the activity is a supervision or performance evaluation. This will be mitigated by providing a specific informed

consent process wherein it will be explained that answers will be kept confidential, and that this activity is not in any way a performance evaluation.

Despite every effort to optimize the validity of the results, the study organizers recognize that this novel approach may have some limitations or impacts on data quality that could be difficult to predict. To contextualize and informally validate the results of this novel methodology, Epicentre is already planning to integrate a question on OCV vaccination status in a future cluster-based serosurvey in the area; this will allow for triangulation and validation of the results of this novel community-based vaccination coverage survey approach.

15. APPENDICES

15.1 Data collection tool (households)



Possible reasons for non-vaccination :

1) Didn't know about campaign 2) Vaccinators didn't come to house 3) Absent when vaccinators came 3) Not eligible
 4) Refused because pregnant 5) Refused because of tradition 6) Refused because of religion 7) Vaccination is dangerous
 8) Negative past experience w/ vaccination 9) Not enough vaccine 10) Sick at home 11) Sick in hospital 12) Bad taste 13)
 Other (explain)

Zone de santé : Bukama

Aire de santé : _____

Village name : _____ Data collector name: _____

Date of data collection: _____

Household number	Consent to participate ?	Number of residents	Number of household members vaccinated OCV, dose 1	Number of household members vaccinated OCV, dose 2	Reason(s) for non-vaccination, if relevant (give code numbers)
1	<input type="checkbox"/> Yes <input type="checkbox"/> No (end)	Age 1 - 15 :			
		Over age 15:			
2	<input type="checkbox"/> Yes <input type="checkbox"/> No (end)	Age 1 - 15 :			
		Over age 15:			
3	<input type="checkbox"/> Yes <input type="checkbox"/> No (end)	Age 1 - 15 :			
		Over age 15:			
4	<input type="checkbox"/> Yes <input type="checkbox"/> No (end)	Age 1 - 15 :			
		Over age 15:			
5	<input type="checkbox"/> Yes <input type="checkbox"/> No (end)	Age 1 - 15 :			
		Over age 15:			
6	<input type="checkbox"/> Yes <input type="checkbox"/> No (end)	Age 1 - 15 :			
		Over age 15:			
7	<input type="checkbox"/> Yes <input type="checkbox"/> No (end)	Age 1 - 15 :			
		Over age 15:			

If a person's vaccination status is unknown, consider them as not vaccinated.

(Document will continue until up to 100 households per site)

15.2 Interview guide, qualitative phase (subject to revisions, pending completion of the quantitative phase)

A mixed-methods explanatory sequential community-based study to estimate and understand vaccination coverage of Oral Cholera Vaccine in Bukama Health Zone, DRC, Version 1.0, June 2022

Zone de santé : Bukama

Aire de santé : _____ Data collector name : _____

Village name : _____ Date of interview : _____

Written informed consent: ☐ Yes (continue) ☐ No (end)

Note : This guide is adaptable and flexible. You are not obligated to explore all of the subjects in this guide. The questions and prompts are there to provoke and stimulate discussion. You can skip certain topics and spend more time on others.

1. Introduction

During the in-depth interview, it is important to be a good listener, empathetic, and non-judgmental. As a reminder, the participant's well-being is most important. Initial questions should help to put the participant at ease and establish a rapport of trust. When introducing the content of the interview, it is important to remind the participant that his or her answers will be kept confidential in the reports, and that he or she is free to refuse to answer the questions and to withdraw from the study without any negative consequences.

Before you begin the interview, make sure the person you are about to interview is comfortable and at ease, that the location is private, and then remind them of the objectives of the interview. Prior to starting the interview, ensure that you have fully explained the purpose of the study and seek written informed consent (Appendix 15.4). Tell the participant that there is no 'right' or 'wrong' answer, and we just want to learn about their personal opinions and experiences.

- Find a comfortable and quiet place where the respondent(s) feel comfortable and free to express themselves).
- Introduce yourself (name, role, etc)

Thank you for agreeing to speak with us today. My name is And

- Ask the participant to introduce themselves. Do not record their name.

I will now start the audio recording.

<p>Could you please explain your role within the community ?</p> <p>-age</p> <p>-mother or father ?</p> <p>-how many children ?</p> <p>-occupation ?</p> <p>-in this role for how long ?</p>	
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2. Health in general (Just use a few of these questions, to put the participant at ease, and have them start thinking about health)

<p>In your opinion, what are the elements of a healthy life ?</p> <p><i>-good health</i></p> <p><i>-worries/ health problems</i></p> <p><i>-physical health</i></p> <p><i>-mental/ psychological health</i></p>	
<p>What are some of the most important health issues in this community?</p>	
<p>Actions you take to keep good health or to improve your health</p>	

3. *Vaccination (you can spend more time on this section, especially to get the participant to talk about their experience with the most recent OCV campaign)*

<p>What do you know about vaccination ?</p> <p><i>-What is vaccination?</i></p> <p><i>-How does vaccination work?</i></p> <p><i>-Who should be vaccinated?</i></p> <p><i>Who should not be vaccinated?</i></p> <p><i>-What diseases can be prevented with vaccination?</i></p> <p><i>-Benefits of vaccination</i></p> <p><i>-Risks of vaccination</i></p> <p><i>-Tell me about a personal experience with vaccination, for your or a family member</i></p>	
<p>What do you know about vaccination against cholera?</p> <p><i>-What is cholera vaccination?</i></p> <p><i>-How does cholera vaccination work?</i></p> <p><i>-Who should be vaccinated with the cholera vaccine?</i></p> <p><i>Who should not be vaccinated?</i></p> <p><i>-Benefits of cholera vaccination</i></p>	

<p><i>-Risks of cholera vaccination</i></p> <p><i>-Personal view as positive or negative</i></p> <p><i>-Would recommend family take it? Or not? Why?</i></p>	
<p>What is your personal experience with oral cholera vaccination in this community (December 2021 and March 2022)?</p> <p><i>-When, where, organized by who?</i></p> <p><i>-Door to door, or at the health center?-Community reaction</i></p> <p><i>-Challenges</i></p> <p><i>-Strengths</i></p>	
<p>In your opinion, in order to function well, how should an oral cholera vaccine campaign be organized in this community?</p> <p><i>-Tell an example of/talk about a time when a health intervention or vaccination campaign in this community that was well organized and accepted</i></p> <p><i>-Tell an example of a health intervention or vaccination campaign in this community that faced many challenges or was not successful</i></p>	
<p>Is there anything else you would like to share with us ?</p>	

End of guide

Do you have any questions for us ?

[After answering the questions]

I will now stop the audio recording. We thank you very sincerely for your collaboration and contribution.

15.3 Informed Consent sheet and verbal form, quantitative phase, head of household



Information sheet and verbal consent form for head of household (survey)

Project Title: Vaccination coverage study in the Bukama Health Zone, DRC, June 2022

Organizations involved in the study: Epicentre, Médecins sans Frontières (MSF) (14-34 avenue Jean Jaurès, 75019 Paris, France) and the Ministry of Health of DRC (Government Building - Boulevard du 30 juin, Kinshasa, DRC)

(This informed consent document has two parts:

The information sheet – which gives you information about the study and all the aspects associated
Certificate of verbal consent – where the study team will indicate that you agree to participate in the study. There will be two copies of this consent form and one will be given to you to keep.)

Introduction and goals of the study:

Thank you for taking the time to listen to our information about this study, my name is.....

As you might already know Epicentre/Médecins sans Frontières (MSF) jointly with and the Ministry of Health are supporting health care projects and research in this area.

Today we are carrying out a survey to estimate the numbers of individuals that have been vaccinated against cholera. With this survey, Epicentre/MSF hopes to improve their work as a medical organisation in the use of vaccination to protect the community against outbreaks of cholera. Secondly, MSF/Epicentre's intention is to use the results of the survey to raise awareness of the vaccination situation in your community, to support the MoH to improve future health activities. The name of your village may be used in or reports, but details of individual households will not be disclosed. The data that we collect could be shared with health authorities.

Why was my household chosen for this survey?

Your household was chosen randomly among households of the village, because you are living in the area previously selected for oral cholera vaccination (December 2021 and March/April 2022) to participate in the study. As you match these criteria, we would like to propose to you to participate.

What does it mean for me and my family to participate?

If you agree to participate to the survey, we will ask you questions such as the vaccination history of the members of your household and yourself. We will also ask general questions regarding how many persons are living in your household. This interview will be conducted by trained staff. The interview should not last more than 10 minutes.

Do I have to take part in the survey?

Your participation in this survey is voluntary and you are free to participate or not, even if the head of the neighbourhood/village has agreed. If you do not wish to participate, your access to care will remain unchanged and it will not affect the usual medical care you or your family will receive in the health centres, now or in the future. If you choose to participate, you may decline to answer any question without any consequences and you may also decide to stop your participation at any time during the study without giving reason. In this case, we will stop the procedures with you, and we will ask you if you accept that we keep the data collected so far or not.

There will be no compensation for your participation in this survey. We will not distribute anything.

What are the possible benefits?

There is no direct benefit for you but the information that we collect in this study will contribute to a better understanding of cholera cases and transmission, and of the impact of cholera vaccination campaigns. This information will thus help us to protect you and your community better from cholera in the future.

What are the possible risks?

We do not expect any physical risk for you or your family members to participate in this survey. However, asking you personal questions about your health or giving out personal information may be upsetting for you. You can refuse to answer any questions without any consequences. You are also free to stop the interview at any time without any further impact.

There is also a risk related to the loss of confidentiality. The interviewers will be trained to ensure that your privacy is respected and to ensure the confidentiality of the discussion. To decrease this risk, they will be meticulously trained in interview techniques and will keep study related documents secured in a locked cabinet accessible by the study team only. The data we collected will not contain the names of the participants.

How will our personal information be protected?

The information you provide will remain confidential. We will not record your name or the names of the members of your household. Only the names of the participating neighbourhoods/villages will be recorded. A survey number will be assigned to each household, without identifying the participants and we will not record the location of your house. Only the study team can access to the data we collected. The data will be collected on paper and then entered in a computer. The paper study documents will be kept in a safe locked cabinet either in Bukama, Kinshasa, or in Europe (at MSF's headquarters) and will be only accessible by the study team. The electronic data will be stored on a secured encrypted server at Epicentre in France. All data and study documents will be archived for 5 years and then destroyed.

Will the results of the survey be shared?

Once the study is completed, the information collected will be analysed and the health local authorities that participated in the survey will receive a summary of the results.

The final report will be shared with all partners (Ministry of Health, MSF-OCP, Epicentre and Wellcome Trust). We will also work with the local authorities and head of villages to share the results of the study with the community.

The results of the survey may also be used in international publications.

Who has reviewed the study?

The Ethical Review Board of the Ministry of Health of DRC *insert the name of the local ethics committee and its address* on [xx/xx/2022] and the Ethics Review Board of MSF on the [xx/xx/2022] have reviewed and approved the study.

Who can I contact if I have a complaint or question?

Complaints or questions should be addressed to either:

- Name Surname, local study coordinator, MSF OCP or Epicentre, DRC at provide an active local phone number xxxxxxx@paris.msf.org (contact local)
- Name Surname, epidemiologist, Epicentre at xxxxxxx@epicentre.msf.org (principal investigator)

Do you have any questions about the survey? Do not hesitate to ask us about our work, we will be happy to answer.

[After answering the questions]

We thank you very sincerely for your collaboration and contribution.

In case you have any questions after the interview has been completed, you are free to contact the survey supervisor at the contact above.

Please go through the information sheet before seeking consent

The information sheet was fully explained to the head of household and his/her questions have been answered to his/her satisfaction. He/she gave voluntary consent to answer the questions in the questionnaire for the household.

The participant is free to withdraw from the study at any time.

Does the head of Household agree for their household to participate in this study?

☐ YES ☐ NO

Village name: _____

Household number: _____

I have explained the purpose of this research to the participant. To the best my knowledge, he/she understands the purpose, procedures, risks and benefits of this research.

Date: ____ / ____ / 2022 (day/month/year)

Name of the person taking the consent: _____

Signature of the person taking the consent: _____

[Only if the participant provides informed verbal consent may the household be included.]

[The interviewer can only proceed with data collection if the head of household gives informed verbal consent].

Do not forget to leave a copy of the information sheet with the participant

15.4: Informed consent information page, qualitative phase



Information Form for Participants (qualitative phase)

Please read the information page before asking for consent and the signature

Vaccination coverage study in the Bukama Health Zone, DRC.

Organizations involved in the study: Epicentre, Médecins sans Frontières (MSF) (14-34 avenue Jean Jaurès, 75019 Paris, France) and the Ministry of Health of DRC (Government Building - Boulevard du 30 juin, Kinshasa, DRC)

Thank you for taking the time to speak with us. This informed consent document has two parts:

The information sheet – which gives you information about the study and all the aspects associated

Certificate of written consent – where the study team will indicate that you agree to participate in the study. There will be two copies of this consent form and one will be given to you to keep.

Introduction and goals of the study:

My name is _____. As you might already know Epicentre/Médecins sans Frontières (MSF) jointly with and the Ministry of Health are supporting health care projects and research studies in this area.

Today we are carrying out a study to better understand the community perceptions of cholera vaccination in this area, experience with cholera vaccination, and the challenges and strengths relating to vaccination in this area. We wish to speak with people who are involved in the health of communities, including health agents, recos, and community leaders, to better understand their opinions on the functioning of cholera vaccination campaigns in this area.

With this survey, Epicentre/MSF hopes to improve their work as a medical organisation in the use of vaccination to protect the community against outbreaks of cholera. Secondly, MSF/Epicentre's intention is to use the results of the survey to raise awareness of the vaccination situation in your community, to support the MoH to improve future health activities. The name of your village may be used in or reports, but details of individual participants will not be disclosed. The data that we collect could be shared with health authorities.

Why was I for this survey?

You were chosen because you live or work within the health areas of the study zone, and you are a formal or informal community leader or health worker. The questions will relate mainly to your personal perceptions and experiences with the community health system and with cholera vaccination.

What does it mean for me to participate?

If you agree to participate, we will ask you to participate in an individual interview. An individual interview is expected to take 30 to 60 minutes, and you will be asked to share your thoughts with a study team member. This interview will be conducted by trained staff.

Confidentiality and use of study data:

The study team will make every effort to protect your confidentiality: we will not share your individual thoughts or responses with anyone outside this team. All data collected will be shared only within the study team and will be secured in the offices of MSF in Goma, Kinshasa, or Paris for a period of 5 years before being destroyed.

So that we can better capture and review the responses of participants, the discussion will be audio-recorded. The audio recordings will not be shared outside the Epicentre/MSF study team. The information you share may be included in the study results, but will not be attributed to you directly, and your name will not be shared. The general overall results of the study will be shared with the health authorities, but individual responses will not be shared. Anything you say will not be tied to your name but may be included more generally in the study results alongside the responses of other participants. If you do not agree to have your responses audio recorded, you can still participate, and we will instead take notes of your responses using pen and paper.

The names of anyone participating in this study will not be collected and all responses will remain anonymous. The individual responses will not be shared outside of the Epicentre/MSF study team. Your name will not be written down or shared with anyone. If you are a health worker, we will not inform your supervisor whether you chose to participate or not. This activity is not a supervision or evaluation of your work in any way. Your responses will not be tied to your name.

Do I have to participate?

Your participation in this study is voluntary and you are free to participate or not, even if other people in your village have agreed. If you do not wish to participate, your access to care will remain unchanged and it will not affect the usual medical care you or your family will receive in the health centres, now or in the future. If you choose to participate, you may decline to answer any question without any consequences and you may also decide to stop your participation at any time during the study without giving reason. Your participation will not affect your employment status, and your participation or refusal to participate will not be shared with your employer. In this case, we will stop the procedures with you, and we will ask you if you accept that we keep the data collected so far or not.

There will be no compensation for your participation in this survey. We will not distribute anything.

What are the possible benefits?

There is no direct benefit for you but the information that we collect in this study will contribute to a better understanding of cholera cases and transmission, and of the impact of cholera vaccination campaigns. This information will thus help us to protect you and your community better from cholera in the future.

What are the possible risks?

We do not expect any physical risk for you to participate in this survey. However, asking personal questions or giving out personal information may be upsetting for you. You can refuse to answer any questions without any consequences. You are also free to stop the interview at any time without any further impact.

There is also a risk related to the loss of confidentiality. The interviewers will be trained to ensure that your privacy is respected and to ensure the confidentiality of the discussion. To decrease this risk, they will be carefully trained in interview techniques and will keep study related documents secured in a locked cabinet accessible by the study team only. The data we collected will not contain the names of the participants.

How will our personal information be protected?

The information you provide will remain confidential. We will not record your name. Only the names of the participating neighbourhoods/villages will be recorded. Only the study team can access to the data we collected. Any audio recordings will be transferred to a computer, and any notes written on paper will then entered in a computer. The paper study documents will be kept in a safe locked cabinet either in Bukama, Kinshasa, or in Europe (at MSF's headquarters) and will be only accessible by the study team. The electronic data will be stored on a secured encrypted server at Epicentre in France. All data and study documents will be archived for 5 years and then destroyed.

Will the results of the survey be shared?

Once the study is completed, the information collected will be analysed and the health local authorities that participated in the survey will receive a summary of the results.

The final report will be shared with all partners (Ministry of Health, MSF-OCP, Epicentre and Wellcome Trust). We will also work with the local authorities and head of villages to share the results of the study with the community.

The results of the survey may also be used in international publications, but will never include individual names.

Who has reviewed the study?

The Ethical Review Board of the Ministry of Health of DRC *insert the name of the local ethics committee and its address* on [xx/xx/2022] and the Ethics Review Board of MSF on the [xx/xx/2022] have reviewed and approved the study.

Who can I contact if I have a complaint or question?

Complaints or questions should be addressed to either:

- Name Surname, local study coordinator, MSF OCP or Epicentre, DRC at provide an active local phone number xxxxxxxx@paris.msf.org (contact local)
- Name Surname, epidemiologist, Epicentre at xxxxxxx@epicentre.msf.org (principal investigator)

Do you have any questions about the survey? Do not hesitate to ask us about our work, we will be happy to answer.

[After answering the questions]

We thank you very sincerely for your collaboration and contribution.

In case you have any questions after the interview has been completed, you are free to contact the survey supervisor at the contact above.

Vaccination coverage study in the Bukama Health Zone, DRC.

Please go through the information sheet before seeking consent

The information sheet was fully explained to the participant and his/her questions have been answered to his/her satisfaction. He/she gives voluntary consent to answer the questions in the questionnaire for the household.

The participant is free to withdraw from the study at any time.

I give my informed consent to participate in this study ☐ YES ☐ NO

I agree to have my responses audio recorded ☐ YES ☐ NO

Date : ____/____/2022

Name of participant: _____ Signature or fingerprint:

If the participant is illiterate,

I certify that the information in the information sheet and consent form was accurately explained to the participant. I confirm that the participant has had the opportunity to ask questions, and that he/she freely gave informed consent.

Name of the witness _____

able to read and write

(this person should be chosen by the participant and must not have any connection with the research team)

Date _____

(dd/mm/yy)

Signature of the witness _____

I explained the purpose of the study to the participant and answered all his/her questions. To the best of my knowledge, he/she understands the purpose, procedures, risks and benefits of this study and voluntarily accepts to participate in the study.

Name of person
taking the consent _____

Date _____
(dd/mm/yy)

Signature of the person taking the consent _____

A copy of this information sheet and informed consent form was provided to the participant.

A mixed-methods explanatory sequential community-based study to estimate and understand vaccination coverage of Oral Cholera Vaccine in Bukama Health Zone, DRC, Version 1.0, June 2022

15.5 : Sample data collector confidentiality agreement



Data collector confidentiality agreement *(exact wording may be modified as needed pending precise administrative details of the agreement under which the data collectors are engaged)*

Vaccination coverage study in the Bukama Health Zone, DRC

The data collector undertakes to respect professional confidentiality for the duration of the contract and after the expiry thereof, and to treat with appropriate discretion any information that he/she may be party to, as a direct result of his/her role or through his/her presence in the organisation.

Name : _____

Signed: _____

Date: _____