|  |  |
| --- | --- |
| Date | Draft 26/03/2024, authors: drc-epidem@oca.msf.org / drc-research@oca.msf.org |
| Proposed study title | Vaccination coverage baseline survey among internally displaced children in Buhima and Mugunga health areas of Goma and Karisimbi health zones, Nord-Kivu Province, Democratic Republic of Congo (DRC) 2024 |
| Purpose of study | To estimate the percentage of zero-dose children in the population of IDP camps and the resident population in adjacent urban areas of Buhima and Mugunga health areas, in order to estimate resource needs for a subsequent vaccination campaign. |
| Research question | What is the proportion of zero-dose children 0 to 11 months and children 12 to 23 month in the population of IDP camps of Buhima and Mugunga health areas vaccination campaign. |
| **Objectives** | Primary objective:* To estimate DTP1 and DTP3 coverage for children aged 0-11mo and 12-23 mo living in the IDP camps of Bulengo and Lushagala, and in the resident population of Goma, Karisimbi and Nyiragongo Zones de Santé.

Secondary objectives:* To estimate camp population sizes living in the IDP camps of Bulengo and Lushagala and their extensions, and in the resident population of Goma, Karisimbi and Nyiragongo Zones de Santé.
* To estimate MCV and BCG coverage for children aged 0-11mo and 12-23 mo for both resident and IDP camps living in the IDP camps of Bulengo and Lushagala and their extensions, and in the resident population of Goma, Karisimbi and Nyiragongo Zones de Santé.
 |
| **Background/significance**  | Since the beginning of 2023, MSF Holland has been delivering primary and secondary healthcare alongside WASH services to the internally displaced persons (IDPs) in Western Goma, who have fled a resurgence of violent conflicts in North Kivu province. To avert disease outbreaks and safeguard the health of an already vulnerable population, MSF Holland is supporting the DRC Ministry of Health and the National Vaccination Programme (Programme Elargi de Vaccination PEV) in conducting a catch-up multi-antigen vaccination campaign in three phases, covering all routine antigens outlined in the national immunization schedule for both the camps and the general urban population of the area.To ascertain the target for the vaccination campaign, the required vaccine doses and all resources for the campaign, a vaccination coverage survey to estimate the percentage of zero-dose and under-immunized children (defined as those who have not received the first dose of diphtheria, tetanus, and pertussis-containing vaccine (DTP1), and those who did not receive the third dose of DTP3 respectively) will be carried out. Simultaneously, the survey will gather shelter and household size data to generate a population estimate for the camps |

|  |  |
| --- | --- |
| ***Study topic****Check all that apply* | Is the study part of an approved OCA topical research agenda?  [x]  No [ ]  Yes, namely: If yes, please provide a link to, or submit research agenda with this concept paper |
| [ ]  AMR[ ]  Cholera[ ]  Covid-19[ ]  Ebola[ ]  Environmental Health[ ]  Emergency[ ]  HIV[ ]  Leishmaniasis[ ]  Malaria[ ]  Nutrition[ ]  Other disease outbreakIf Other or Other disease outbreak, please state: | [ ]  Maternal & women's health[ ]  Measles[ ]  Meningitis[ ]  Mental health[ ]  Mortality[ ]  NTDs (excluding leishmaniasis)[ ]  Neonatal & child health[ ]  Non-communicable diseases[ ]  Other | [ ]  Upper/lower respiratory tract disease (excluding Covid-19)[ ]  Sexual violence[ ]  Surgery[ ]  Tuberculosis[x]  Vaccination[ ]  VHF (excluding Ebola)[ ]  Violence[ ]  Water & Sanitation |
| **Methods - design***Check one study design* | Please consult the relevant study reporting guidelines\* listed at the end of this concept note. |
| [x]  Observational study[ ]  Randomised trial[ ]  Systematic review[ ]  Case report[ ]  Diagnostic studyBrief explanation for chosen study design:We are using a standard MSF household sample survey methodology that allows us to compare results with similar surveys carried out in DRC / Nord-Kivu province and elsewhere in recent years. | [ ]  Mixed methods study[ ]  Qualitative research[ ]  Quality improvement study[ ]  Prediction model[ ]  Other |
| **Methods - setting** | **Study location/setting:** Health areas of Mugunga and Buhimba. These health areas are including, apart from the host population, the camps of Bulengo, Lushagala, Lushagala extension, Buhimba, Lwashi, 8eme CPAC, CBCA and Shabindu.. **Context**Fighting between military and rebel groups in Rutshuru and Masisi territories of Nord-Kivu, DRC, has provoked significant population movements into the Goma area, with the creation of large IDP camps on the outskirts of Goma since January 2023. The population of the five main IDP camps in western Goma was estimated at 340,000 in March 2024, with almost a quarter of these IDPs having arrived after Jan 2024. It is thought that in the same period an additional 850,000 IDPs have found refuge with host families or in other accommodation in the resident urban population of Goma. |
| **Methods – participants, procedures, analysis***For retrospective analyses of routine data, if this section is sufficiently complete, this concept note will serve as the study protocol.*  | **Study participants**: The target population includes all children aged 12-23 months in the eligible households of the study population. Households will be selected using simple random sampling from a GIS spatial sampling frame consisting of shelter/houses centroids in the camps and residents areas identified through satellite imagery taken on or after 15 March 2024. The study will take place in April 2024, as part of the preparation phase of a planned multi-antigen vaccination catch-up campaign in the target area.Sampling will use two strata: a) the total population across all five IDP camps, and b) the total population of Goma urban areas in Health Zones of Goma, Karisimbi and Nyiragongo, and specifically their Aires de Santé of Buhimba, Mugunga and Kiziba,Sample size strata IDP- camps 1. Children 0 to 11 months

For the sample size calculation in children 0 to 11 months in the IDP camps, an expected vaccination coverage of 0.6, an alpha error of 0.05 (confidence level of 95%), and a precision of 9% will be used. The total sample size for this strata will be 113.8 childrenBased on a reported average household size of 5 with 4% of population of age 0 to 11 months, we can expect on average a frequency of 0.2 children per household. The expected response rate will be 25%.This will result in 759 households to visit. All the parameters considered are based on the findings of the recent survey (April 2023, in Bulengo and Lushagala) 1. Children 12 to 23 months

Considering the same parameters as aboveand assuming that will expect the same average of children 12 to 23 months per household (0.2), we should be able to find the 113.8 children 12 to 23 months by visiting the same 759 households  Sample size strata 2 – resident population:1. Children 0 to 11 months

For the sample size calculation in cjildren 0 to 11 months in the IDP camps, an expected vaccination coverage of 0.65, an alpha error of 0.05 (confidence level of 95%), and a precision of 10% will be used. The total sample size for this strata will be 87.4 children.Based on a reported average household size of 7 with 3% of population of age 0 to 11 months, we can expect on average a frequency of 0.2 children per household. The expected response rate will be 10%.This will result in 462 households to visit. All the parameters considered are based on the findings of the recent survey (April 2023, in Bulengo and Lushagala) and findings from previous surveys in Eastern DRC.1. Children 12 to 23 months

Considering the same parameters as aboveand assuming that will expect the same average of children 12 to 23 months per household (0.2), we should be able to find the 87.4 children 12 to 23 months by visiting the same 462 households**Data variables:** * Demographic data: age, sex, and resident status of children
* Vaccination status: verbal and card confirmation for the following antigents:
	+ DTP
	+ Measles
	+ BCG
* Reasons for non-vaccination
* Number of members in shelter and household (present, plus permanent residents absent)

**Data sources and collection**: We will use mobile electronic data collection systems (smartphones and KoboCollect forms) to collect household and individual information. All information will be collected in an anonymous way (i.e. no personal identifiers such as name or address will be collected). Data will be stored in secure encrypted servers, and only research team members will have access.**Data analysis:** Data management, data cleaning and analysis will be done using Microsoft Excel and R 4.3.0 (The R Foundation for Statistical Computing) with RStudio.The analysis will be weighted to calculate averages, percentages, and their respective 95% confidence intervals, taking into account the sampling design and the population estimations for each strata of interest. |
| **Resources/costs:**  | Cost of:* Investigator and co-investigators
* Survey development, including setup of electronic data collection
* Team of household interviewers and their supervisors
* Training resources for interviewers
* Team mobility and communication
* Data analysis and report writing

The total cost is estimated at 7,500 USD. |
| **Planned dates***List proposed* ***start/end date******[mm/yyyy]*** *of each stage and any time restrictions* | **Concept Paper (submission to Research Committee):** April 2024**Protocol development:** submission to MSF Research Committee April 2024**Ethics review:** Concept noteto be submitted to the Goma Ethics Board (ULPGL) after RC approval**Study preparation:** April 2024**Data collection:** April 2024**Data analysis and preliminary results:** end of April 2024**Write up (report):** May 2024**Write up (other study outputs):** -June and July 2024 (if needed) |
| **Ethics**  | **Benefits:** Findings from the study will help identify gaps in vaccination coverage, in particular in the context of internally displaced populations. The results will help MSF, the Zonal Health Offices (BCZ) for Goma and Karisimbi, and the provincial PEV to establish detailed planning for the upcoming multi-antigen vaccination campaign May – June 2024. **Risks:** a)In the camp environment, principles of informed consent and confidentiality may be difficult to fully apply, given language barriers, chaotic camp structures, and a general environment of fear and mistrust. To mitigate these risks our interviewers will be trained on confidentiality techniques and how to properly explain study objectives to interviewees and community in general. Health promotion teams will also help with messaging about the study. b) Due to expected population movements into and out of camps before and during the survey, the sample base may be uncertain. We have accounted for non-respondent households in our sample survey.**Involvement of / collaboration with relevant local stakeholders:** Throughout study preparation and study implementation we will work closely with the provincial PEV, the BCZ of the respective health zones, camp management and representatives of the camp population to reach a common understanding of study objectives and procedures, ensure safety and minimize risks for study participants, and to ensure that study findings and conclusions are shared effectively.**Obtaining informed Consent**: We will explain to each head of the selected households the survey objectives, benefits, and procedures involved. Including the fact that they are free to refuse participation or to withdraw at any moment of the interview. The head of the household will be asked to provide informed verbal consent to participate in the study.**Confidentiality and privacy:** All information will be collected in an anonymous way (i.e. no personal identifiers such as name or address will be collected). Data will be stored in secure encrypted servers and only research team members will have access.**How will the study demonstrate respect for study participants:** Interviewer teams will be trained on confidentiality, research ethics and the specific risks for, and vulnerabilities of study participants, and will receive guidelines for personal study team interactions, with a focus on empathy, respect, and non-judgement. The study protocol will provide a detailed plan for study communication, including follow-up and sharing of results with participants and partners.**In-country permissions and regulatory review:** 1. Has a protocol been submitted to or approved by National/ Local Ethics Review Committee(s)?

[x]  No/Not yet [ ]  Yes1. If not yet submitted, please indicate when and to which committee the protocol will be submitted:

Protocol to be submitted to the Goma Ethics Review Board hosted by the Université Libre des Pays des Grands Lacs (ULPGL), Goma, once approved by OCA Research Committee. 1. If not planned to be submitted to local committees please note why not, and which alternative permissions have been obtained:

**Do you believe your study meets MSF ERB criteria for exemption from full review?:**1. No.
2. Yes, because it is a retrospective review of routinely collected data. If so, it must meet all [5 criteria to qualify for exemption](https://fieldresearch.msf.org/handle/10144/618714)
3. Yes, because it is a survey that follows the MSF Intersectional Standardized Survey Protocol. If so, it must meet the [exemption criteria](https://scienceportal.msf.org/assets/6996)
4. Yes, for any other reason (please explain here)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| **Roles and responsibilities**If responsibilities are split differently between the roles outlined below or held by other members of the research team, please describe clearly in the sections below. ReMIT responsibility must be held by an MSF staff member. |
| **Primary Investigator (PI)***Responsible for carrying out the study with support and consultation from research team. Will usually lead on all journal correspondence. TOR is* [*here*](https://msfintl.sharepoint.com/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%E2%80%8B%E2%80%8B/Research%20System%20Processes/Research%20Team%20ToR.pdf) | Mitima Jean-Marie Limenyandedrc-epidem@oca.msf.org |
| **Study Coordinator (SC)***Overall responsible for study, must be MSF HQ staff, usually topic specialist or epi advisor. Responsible for: ensuring HA and PI have fulfilled their roles; ensuring everyone named in this CP is clear about their involvement; updating ReMIT, translating findings into impact, appropriately disseminating materials (see later section). TOR is* [*here.*](https://msfintl.sharepoint.com/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%E2%80%8B%E2%80%8B/Research%20System%20Processes/Research%20Team%20ToR.pdf) | Isidro Carrion-Martin <isidro.carrion-martin@london.msf.org> (Study Coordinator)Is the topic specialist / topic holder informed/involved? YesKartini Gadroen Kartini-Gadroen@amsterdam.msf.org (MSF Vaccine Adviser) |
| **MSF research team** | Wolfgang Webber, drc-research@oca.msf.org (OCA DRC Research Coordinator)Kartini Gadroen Kartini-Gadroen@amsterdam.msf.org, MSF Vaccine AdvisorLindsay Bryson Lindsay.Bryson@stockholm.msf.org, Health Adivsor Nadia Lwimbo Kummer, drc-medco@oca.msf.org, Medical Coordinator, MSF OCA DRC North Kivu |
| **Field involvement** | Are national/other field staff informed/included as co-investigators?[ ]  No [x]  YesWill protocol development include field team input?[ ]  No [x]  Yes If no to either of above, please provide explanation:Please describe any planned capacity building activities for national staff:It will be the first time for Jean Marie, to be principal investigator in a survey like this, he will be supported and coached by other senior members of research team. Data collectors will be trained on vaccine coverage surveys. |
| **Health Advisor (HA)***Responsible for facilitating study operationally, ensuring desk/field have agreed to study and feeding back to PI/SC.* | Name of relevant HA(s): Lindsay BrysonIs/are the HA(s) supporting the study on behalf of the countries they manage? [ ]  No [x]  Yes |
| **External partners/MoH** *Name, position, role of external collaborators.* | **International: --****Local**: Division Provincial de la Santé Nord-Kivi DRC / Programme élargi de vaccinationBureau Central de la Zone de Santé (BCZ) Karisimbi and Goma**Community**: Camp management authorities, representatives of the camp population / Block leadersAre resource agreements in place, e.g. Open Access publication costs?[x]  No [ ]  Yes, namely: |
| **Competing interests**  | The research team declares: no competing interests. |
| **Data management and sharing***Contact details of those responsible for ensuring data are managed and shared in accordance with MSF’s Health Data Protection Policy and GDPR* | Isidro Carrion-Martin <isidro.carrion-martin@london.msf.org>Data management plan: Data will be collected on smartphones using KoboCollect. Smartphone are password protected. Data will be uploaded to kobo.msf.org and stored there for the duration of survey analysis. Data will be extracted from the KoBo database in Excel format and transferred to secure MSF SharePoint servers for analysis. All data will be securely deleted once the final survey report has been published. All data is password protected, and data access is limited to members of the survey team.Will data be shared with an external partner such as an academic institution?[x]  No [ ]  Yes, namely:*Complete the* [*OCA Data Sharing Agreement*](https://msfintl.sharepoint.com/%3Aw%3A/s/Researchsystem/EUzjH4uorYtApQ2oduCHxO0BQXa7WT97eyajiqacMxr-1w?e=tnvzUh) *and submit for Medical Director signature.* |
| **Opting out** *All concept papers and/or (ERB approved) protocols are made available on ReMIT and the MSF Field Research website*. Questions about ReMIT? Email  *oca.research@london.msf.org* | This concept paper and/or accompanying protocol cannot be made available on:[ ]  ReMIT; because: [ ]  MSF Field research website; because:  |
| **Implementation/ impact and dissemination**Responsibility of the Study Coordinator (unless otherwise noted in roles/responsibilities section) |
| **Implementation/impact** | Findings from the study will help MSF, the Zonal Health Offices (BCZ) for Goma and Karisimbi, and the provincial PEV to establish detailed planning for the upcoming multi-antigen vaccination campaign May – June 2024. Furthermore, the indicators on zero dose children may be very useful to better plan similar vaccination campaigns in other IDP areas in eastern DRC (considering the lack of reliable indicators). Finally, this indicator could be very powerful to assess the performance of multiantigen campaigns in these camps or in other areas of eastern DRC (i.e. having an idea of what the baseline is allows for comparison of post vaccination coverage estimates). This is crucial in a moment in which multi antgens campaigns are a high strategic ambition of MSF OCA |
| **Dissemination** *Note on journal publication - MSF has an Open Access (OA) journal publication policy. Fee reduction must be requested* ***at article submission.*** *See* [*guidance*](https://msfintl.sharepoint.com/%3Ab%3A/r/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%E2%80%8B%E2%80%8B/Publication%20and%20Dissemination/Publication%20and%20data%20advice.pdf?csf=1&web=1&e=lCVTiD) *on publication.* | **Dissemination of findings:** MSF: reports and presentations: distribution and presentation to project teams, mission coordinators, and headquarter advisersCommunity: Reports and leaflets/posters to camp management, representatives of camp populationIn country partners (including MoH): reports to DPS, BCZInternational dissemination (including WHO and other agencies, scientific publication):**Budget: Has budget been allocated for dissemination, including potential scientific editing costs?****Yes****Agreements**Authorship: Jean Marie, MoH colleagues, Wolfgang, Nadia, Lindsay, Kartini, IsidroHas the dissemination plan got the support of the Health Advisor (HA)? [ ]  No [x]  Yes*Research outputs must be sent in parallel, before wider distribution, to the OCA Research Committee for quality review and to the HA, who will have 1 week to raise any context concerns with the Committee. Context concerns arising since Concept paper approval or quality of output likely the main reasons to postpone outputs.* |

|  |
| --- |
| **\*Study Reporting Guidelines**To assist authors in writing up their studies to meet scientific journal criteria |
| Observational studies – [STROBE](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0040296) ([& extensions](http://www.equator-network.org/?post_type=eq_guidelines&eq_guidelines_study_design=0&eq_guidelines_clinical_specialty=0&eq_guidelines_report_section=0&s=+STROBE+extension&btn_submit=Search+Reporting+Guidelines))Randomised trials – [CONSORT](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000251) ([& extensions](http://www.equator-network.org/reporting-guidelines/consort/))Systematic reviews – [PRISMA](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000097) ([& extensions](http://www.equator-network.org/reporting-guidelines/prisma/))Case reports – [CARE](http://jmedicalcasereports.biomedcentral.com/articles/10.1186/1752-1947-7-223) | Qualitative research – [SRQR](http://journals.lww.com/academicmedicine/Fulltext/2014/09000/Standards_for_Reporting_Qualitative_Research___A.21.aspx) ([& extensions](http://intqhc.oxfordjournals.org/content/19/6/349.long))Diagnostic studies – [STARD](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4623764/) Quality improvement studies – [SQUIRE](http://qualitysafety.bmj.com/content/17/Suppl_1/i3.long) Prediction model studies - [BMJ](http://www.bmj.com/content/350/bmj.g7594.long) |