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| Date | 25/04/2022 | | | |
| **Study details**  Please note that if approved by the OCA Research Committee this concept note will be published on the [*MSF-OCA Research Management and Impact Tool (ReMIT)*](https://remit.msf.org/). Any requests to opt out go to the OCA Research Committee for approval (see **Opting out**). Questions about ReMIT? Email [*remit@oca.msf.org*](mailto:remit@msf.org) | | | | |
| Proposed study title | Vaccination coverage survey after mass vaccination campaign (MVC) against measles in Bongor district, Mayo-Kebbi Est province, Chad, May 2022 | | | |
| Purpose of study | The purpose of the study is to estimate the status of vaccination in the target population in order to forecast future outbreaks in Bongor, and to provide lessons learned for better planning and implementation of prospective vaccination campaigns. | | | |
| Research question | What is the measles vaccination coverage in children aged 6 months to 9 years in Bongor district after the mass vaccination campaign against measles implemented by MSF and MOH ? | | | |
| **Objectives** | * To estimate VAR vaccination coverage in children aged 6 months to 9 years in Bongor district following the mass vaccination campaign against measles implemented by MSF and MOH * To describe the reasons for non-vaccination during the vaccination campaign * To provide recommendations for vaccination strategies and surveillance in this context and similar ones | | | |
| **Background/significance**  *1-2 paragraphs* | Is the study part of an OCA topical research agenda / strategy document?  No  Yes, namely:  Measles is endemo-epidemic in Chad. In 2019, several districts in the country, including Bongor, faced a measles epidemic. A response provided by MSF-H made it possible to treat 790 patients and vaccinate 95,198 children aged 6 months to 9 years with a vaccination coverage of 94.4%.  In 2022, we are facing a new epidemic in the same district. Indeed, according to the definition of the MOH, this district had been on alert since the 7th week - 2022. An investigation conducted by the CERU reported 194 cases and 0 death of measles from the 1st week to the 14th week with an attack rate of 22.7 / 100,000. The most affected age group is that of 6 months to 9 years. Faced with this worrying situation, the following actions have been decided:   * Improve case management by supporting the MOH through capacity building of healthcare staff, distribution of free measles case management kits in health centers * Strengthen the surveillance system in the district through active case finding and community sensitization * Conduct a vaccination campaign targeting children from 6 months to 9 years old (36% of the population) in the district from 29 April to 10 May 2022 * This study will follow the vaccination campaign to determine post-campaign vaccination coverage. | | | |
| ***Study topic***  *Check all that apply* | AMR  Cholera  Ebola  Environmental Health  Emergency  HIV  Leishmaniasis  Malaria  Nutrition  Other disease outbreak  If 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  Sexual violence  Surgery  Tuberculosis  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. | | | |
| Observational study  Randomised trial  Systematic review  Case report  Diagnostic study  If Other, please state: | | Mixed methods study  Qualitative research  Quality improvement study  Prediction model  Other | |
| **Methods - setting** | **Study location/setting:**  Bongor is the main town in the Mayo Kebbi Est region. It is located 245 km southwest of N'djamena and borders Cameroon. It houses the provincial hospital and is made up of 25 health areas : Amdja, Balampouta, Bariam, Biliam Oursi, Bongor Sieke, Bougaire, Bougoudang, Djarwaye, Djoumane, Ere, Fressou, Guizede, Ham, Kim, Kolobo, Koyom, Maguine, Mollom, Nahaina, Tchinvogo, Teleme, Teinaboyna, Urbain 1, Urbain2, Urbain3.  **Conflict:** Study sites are not currently in conflict-affected areas.  **Context (1 paragraph):** Since week 14, 2022, the OCA CERU team has been supporting free measles case management in Bongor district and has planned a VAR vaccination campaign in the district starting April 29, 2022.  This study will assess vaccination coverage at the end of the campaign to ensure that the expected level of coverage has been achieved. | | | |
| **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 and be shared on the MSF Field Research site. This enables compliance with journal requirements for observational studies. For opt-out requests see* ***Opting out*** | **Study participants**:  **Sample size:**  The sample size was calculated using ENA SMART software (SMART, 2019) based on the following inputs:   * Average household size of 6 * 36% of children aged 6 months to 9 years * Estimated coverage of 80% * Confidence intervals of 95% * Precision of 5% * Design effect of 3 * Non-response rate of 10%   This returns a sample size of 803 children in 459 households (46 clusters of 10 households). To prevent cases where a cluster might not exist or is not identifiable, we choose to have 5 clusters in reserve.  **Sampling**  The vaccination coverage survey will use two-stage cluster sampling methodology. The target population for this mass vaccination campaign is approximately 86,530 children aged 6 months – 9 years. Vaccination cards will be given out to children during the campaign.   * **1st stage**: Clusters will be selected based on probability proportional to population size (PPS), using population data from the MOH. This choice will be made using the ENA SMART 2019 software. * **2nd stage:** Spatial Sampling or systematic sampling will be used to select 10 households in each of 46 clusters.   If multiple households live in the same compound, a household will be randomly selected by numbering them and generating a random number on the tablet. All eligible children in each selected household will be included in the study.  The household head (≥18 years) will be asked about the age and vaccination status of all children in the household aged 6 months to 9 years.  If a selected household will not be available after two visit attempts (morning and afternoon), or is not willing to respond, that household will not be replaced.  **Anticipated dates for data collection** are May 12 – 17, 2022.  The household head will be asked to provide consent for the survey questionnaire, which will collect information on:   * Total number of persons from 6 months to 9 years of age living in the household, age & sex * Measles vaccination status for all persons from 6 months to 9 years of age in the household (using vaccination card history, or oral history when vaccination cards are not available). * Reasons for non-vaccination   **Data variables (quant):** Main outcomes are measles vaccination status by oral history or card. If the child is not vaccinated reasons for non-vaccination will be asked. Variables collected for each child 6 months to 9 years in the household: age, sex, vaccination status and reasons for non-vaccination of applicable**.**  **Data sources and collection:** Data collectors will use KoboCollect software on smart phones during face-to-face interviews with household heads. Paper questionnaires will be available as backups. To ensure data quality, intense training and close supervision of data collectors will be assured. For data security and integrity, smart phones and paper questionnaires will be kept in a locked box in the field and later in MSF offices (locked), databases will be password protected, and only study research team will have access.  **Data analysis:** Data cleaning will be done to check for inconsistencies in data entry and responses. Data analysis will be conducted using R. All indicators (e.g. sex and age of the survey population) will be calculated as proportions with 95% confidence intervals. Where appropriate, differences in proportions will be measured using Pearson χ2 test and p-values (p) will be presented. | | | |
| **Resources/costs:** | * 12 data collectors (6 teams of 2 data collectors) * Each team completes 1-2 clusters (10-20 households) per day, depending on travel time. * 6 days for the data collection * 2 days training + 1 pilot day + 6 days survey = 9 days * 8 cars: 6 cars for 6 teams of data collectors + 2 cars for supervisors * 8 smartphones (1 smartphone / team + 2 in reserve) * Training materials (office space, projector, flipboard, small notebooks) * Recording materials (pens, paper questionnaires, clipboards, backpacks) * Food & drink for training days * Security materials (visibility, radios) | | | |
| **Planned dates**  *List proposed* ***start/end date******[mm/yyyy]*** *of each stage and any time restrictions* | **Start date:** April 25th, 2022  **Protocol development:** 5 working days, April 25th – 29th, 2022  **Ethics review:** Not needed  **Study preparation:**   * **09 working days** Avril 26th - May 06th, 2022: questionnaire programming, logistical planning (cars/security), photocopies, recruitment of interviewers * **3 working days**, May 09th - 11st May, 2022: training of surveyors and pilot survey day   **Data collection: 6 days,** May 12nd – 17th, 2022  **Data analysis: 5 working days, May** 18th - 24th, 2022  **Write up (report): 5 working days,** May 25th – 31st 2022 | | | |
| **Ethics - exemption from review by the MSF ERB (Ethics Review Board)** | 1. Is your study a retrospective review of routinely collected data and thus a candidate for exemption from MSF ERB review?   No  Yes  *Complete the OCA Ethics Review Exemption Template (see Annex) and submit with this Concept paper.* | | | |
| 1. Will your study use an [MSF Intersectional Standardised Survey Protocol](http://fieldresearch.msf.org/msf/handle/10144/618942)?   No, continue with question 4  Yes, continue with question 3   1. If you used an MSF Intersectional Standardized Survey Protocol, does it meet the [MSF ERB Exemption criteria for surveys](http://fieldresearch.msf.org/msf/handle/10144/618799)?   No  Yes | | | |
| 1. Do you believe that your study is exempt from ERB review for another reason?   No  Yes, because:  *Complete the OCA Ethics Review Exemption Template (see Annex) and submit with this concept paper.* | | | |
| **Ethics -- non-exempt studies**  *Do not complete this section if you have applied for exemption from MSF ERB review.* | **Benefits:** Measuring vaccination coverage will inform MSF whether the campaign achieved herd immunity or whether additional vaccination activities are needed.  Better understanding of reasons why children are not vaccinated can help inform and improve subsequent vaccination campaigns.  **Risks:** There is no risk to the survey participants as no identifying data are collected and the GPS coordinates are not retained with the survey data. However, there is some intrusion on the privacy of the household, which some households may find uncomfortable. Our interviewers will be trained to ensure privacy and help people feel comfortable.  **Consent**: After a brief description of the study objectives to the head of household, data collectors will ask if the head of household consents to take part in the survey. Consent will therefore be verbal.  **Confidentiality:** Privacy and confidentiality of the data collected from the participants will be ensured both during and after the conduct of the survey. Participant names will not be recorded on questionnaires, and individual person records will be linked only to a household number throughout the data entry and analysis process. Any data that could be combined with other data sources to make individual records potentially identifiable will not be distributed outside the survey location or appear in any report or publication.  **National/local review:**   1. Has a protocol been submitted to or approved by National/ Local Ethics Review Committee(s)?   No/Not yet  Yes   1. If not yet submitted, please indicate when and to which committee the protocol will be submitted: Protocol will be shared with national and district (Health Delegate) authorities. 2. If not planned to be submitted to local committees, please note why not | | | |
| **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/:w:/s/Researchsystem/EfCcV3m67ulEpRJ61fpeg3sBJaVnhdvghe8S-TZ4xxPaCA?e=Rc4J3j) | **Name**: Judicaël ADADJA Epidemiologist  **Email address**: [chad-epi-flying@oca.msf.org](mailto:chad-epi-flying@oca.msf.org) | | | |
| **Study Coordinator (SC)**  *Overall responsible for study, must be MSF HQ staff, usually topic specialist or epi advisor. Responsible for: updating ReMIT, translating findings into impact, appropriately disseminating materials (see later section). TOR is* [*here.*](https://msfintl.sharepoint.com/:w:/s/Researchsystem/EfCcV3m67ulEpRJ61fpeg3sBJaVnhdvghe8S-TZ4xxPaCA?e=Rc4J3j) | **Name**: Gregoire Falq  **Email address:** [Gregoire.Falq@london.msf.org](mailto:Gregoire.Falq@london.msf.org)  Is the topic specialist / topic holder informed/involved? Yes | | | |
| **MSF research team** | **Epidemiologist:** Judicaël ADADJA  **Email address**: [chad-epi-flying@oca.msf.org](mailto:chad-epi-flying@oca.msf.org)  Responsibilities: Concept paper, Research protocol conception and submission to MSF-OCA Research Director for approval. Selection and training of data collectors and data encoders. Supervision of data collection in the field. Data analysis, interpretation, and survey report writing.  **CERU MTL Chad:** Maria Francescas ZAMARO  **Email address**: [chad-eru-mtl@oca.msf.org](mailto:chad-eru-mtl@oca.msf.org)  Responsibilities: Support of teams during intervention for successful implementation of VCS.  **CERU data manager Chad:** Allafi Bow Gamaou  **Email address**: [chad-eru-data@oca.msf.org](mailto:chad-eru-data@oca.msf.org)  **Responsibilities**: Training of data collectors and data encoders. Supervision of data collection in the field.  **Medical Coordinator Chad:** Deo Gratia Kabila  **Email address:** [chad-medco@oca.msf.org](mailto:chad-medco@oca.msf.org)  **Responsibilities**: Overall Support teams during intervention for successful implementation of VCS. Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results.  **Deputy medical coordinator Chad:** Ibrahim Barrie  **Email address** : [Chad-medco-dep@oca.msf.org](mailto:Chad-medco-dep@oca.msf.org)  **Responsibilities**: Overall Support teams during intervention for successful implementation of VCS. Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results.  **Epi Advisor:** Gregoire Falq  **Email address:** [Gregoire.Falq@london.msf.org](mailto:Gregoire.Falq@london.msf.org)  **Responsibilities**: Remote support to Epi for survey implementation and report writing.  **Vaccine Advisor: Kartini Gadroen**  **Email address**: kartini.gadroen@amsterdam.msf.org  Responsibilities: Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results.  **Health Advisor: Prince ALFANI**  **Email address**: prince.alfani@berlin.msf.org  **Responsibilities**: Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results. | | | |
| **Field involvement** | Are national/other field staff informed/included as co-investigators?  No  Yes  Will protocol development include field team input?  No  Yes  Please describe any planned capacity building activities for national staff:  Training for data collectors and data encoders | | | |
| **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): **Prince ALFANI**  Is/are the HA(s) supporting the study on behalf of the countries they manage?  No  Yes | | | |
| **External partners/MoH**  *Name, position, role of external collaborators.* | **International:** None  **Local:** Chad MoH via Bongor District  **Community**: None  Have **resource agreements**, e.g. Open Access publication costs been reached?  No  Yes, namely: | | | |
| **Competing interests** | Members of the research team declare 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* | **Name:** Judicaël ADADJA  **Email**: [chad-epi-flying@oca.msf.org](mailto:chad-epi-flying@oca.msf.org)  **Data management plan**: Data will be entered into smart phones using KoBo questionnaires. CSV files will be password protected and exported for analysis into R software. After the survey is completed, the questionnaires (paper versions) and the electronic database will be stored at the MSF Headquarters or country management level for 5 years after the survey.  Will data be shared with an external partner such as an academic institution?  No  Yes, namely:  *Complete the OCA Data Sharing Agreement 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*. | 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** | Finding from this survey will help MSF Chad mission and well as other MSF projects in similar settings to better plan and implement vaccination campaigns. In addition, these survey results could be used for advocacy in favour of vaccination campaigns. | | | |
| **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/:w:/s/Researchsystem/ERuSJx0O_ZRIkVG8m7lI0gwB_YKjA5jlLrG7mAeN2iiDrQ?e=YbL9X6) *on publication – authorship, how to apply for fee reduction, funding, conflict of interest, and response to journal data deposition requests.*  *Internal reports remain on Sharepoint, not ReMIT.* | **Dissemination of findings:** *Dissemination survey finding will be mainly through the survey report.*  MSF – project, mission, headquarters: Survey report  Participants: Not applicable  Community: Not applicable  In country partners (including MoH):  International dissemination (including WHO and other agencies, scientific publication):  **Agreements**  Authorship: *list possible authors (at least 1st and last):*  Has the dissemination plan the support of the Health Advisor (HA)?  No  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.* | | | |
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| **\*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) |

Annex 1. OCA Ethics Review Exemption Template

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| **Research exemption proposal**  Template to be filled out and submitted to OCA Research Committee along with a concept paper when requesting exemption from ERB review. See[MSF ERB guidance on exemption criteria](http://fieldresearch.msf.org/msf/handle/10144/618714). Please use the[MSF Research Ethics Framework – Guidance document](http://fieldresearch.msf.org/msf/handle/10144/305288)to answer the questions below. |
| ***Title (same as for Concept paper):*** *Vaccination coverage survey after mass vaccination campaign (MVC) against measles in Bongor district, Mayo-Kebbi Est province, Chad, May 2022* |
| ***Name of Primary Investigator (PI):*** Judicaël ADADJA (Epidemiologist) |
| ***Has a protocol been submitted to or approved by National/ Local Ethics Review Committee(s)?***  No  Yes  ***If not yet submitted, please indicate when and to which committee the protocol will be submitted:***  Protocol will not be submitted to any ethical review board.  ***If not planned to be submitted to local committees, please note why:***  The authorization for the intervention in Bongor district provided by MoH to MSF-OCA includes mention of a measles vaccination coverage survey to be carried out by MSF-OCA after the mass vaccination campaign. |
| **1. Exemption Criteria** |
| * 1. Is the study based on routinely-collected clinical data from pre-existing, established programmes?   No  Yes |
| * 1. Is the study descriptive/evaluative or a targeted evaluation?   No  Yes |
| * 1. Explain here how confidentiality is respected – how you will ensure that no individual patient identifiers are revealed or used?   Privacy and confidentiality in the data collected from the participants will be ensured both during and after the survey. Participant names will not be recorded, and individual records will be linked only to a household number throughout the data entry and analysis process. We will not be recording any data that could be combined with other data sources to make individual records potentially identifiable. |
| * 1. What are anticipated harms? Ensure you acknowledge any that are relevant or state ‘no harms anticipated’. Can these be kept minimal?   Minor risk to communities of breach of confidentiality and/or stigmatisation. Using local staff and careful training on interview-techniques can mitigate this. |
| * 1. Describe potential benefits to the programme, community, and if publication is the goal, to a wider audience:   A better understanding of the vaccination coverage ratios and causes of non-vaccination in the area will allow more tailored programming and more efficient resource use. Accurate data on vaccination status are of tremendous importance for advocacy on a national and international level. |
| * 1. Describe any collaborative involvement and, if applicable, authorship from a local authority or partner (Ministry of Health, DHO, other NGO); if relevant and applicable, describe consultation with a body representing the community:   None |
| **2. Ethics Statement** |
| Once exemption has been granted by the OCA Research Committee, the authors can insert into their article the following statement that has been approved by the MSF ERB:  *“This research fulfilled the exemption criteria set by the Médecins Sans Frontières Ethics Review Board for a posteriori analyses of routinely collected clinical data and thus did not require MSF ERB review. It was conducted with permission from (Medical Director, Operational Centre) Médecins Sans Frontières.”* |