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| Date | 11 November 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 reactive mass vaccination campaign (MVC) against measles in Bentiu IDP Camp, Rubkona, Unity State, South Sudan. | | | |
| Purpose of study | The purpose of the study is to estimate the vaccination coverage in the target population in order to forecast future outbreaks in Bentiu IDP camp, 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 15 years in Bentiu IDP camp? | | | |
| **Objectives** | Primary objective   * To estimate the measles vaccination coverage among children aged 6 months – 15 years living in Bentiu IDP camp   Secondary objectives   * To provide recommendations for vaccination strategies and surveillance in this context and similar ones * To describe the reasons for non-vaccination during the vaccination campaign | | | |
| **Background/significance**  *1-2 paragraphs* | Is the study part of an OCA topical research agenda / strategy document?  No  Yes, namely:  Overall immunization coverage in South Sudan has been estimated to be around 50% according to the Ministry of Health. In 2022, there have been vaccination campaigns as response to outbreaks, namely in Central Equatoria and Upper Nile states, but Unity State has not had a catch-up campaign or reactive campaign since 2019.  The last national measles mass vaccination campaign in Bentiu IDP camp occurred in 2020, with an estimated coverage of 80%. The population movement is highly dynamic in Bentiu and the IDP camp, hence the coverage is expected to be low. In 2021, more population moved in to Bentiu Town due to the worst floods in a generation, and this has substantially changed the population and the vaccination coverage in Bentiu.  EPI coverage assumed to be low in this population, based on nationwide EPI coverage, but no information currently available at county level. No information on whether there are any vaccine refusals explaining in part the low EPI measles coverage. Vaccination cards are typically given out during EPI vaccinations.  According to MSF facility data, the first case was reported in September 2022 W39. Since then, the cases started increasing.  In response to the 2022 measles outbreak, The MSF OCA Bentiu Hospital decided on the following actions:   * Improve case management by providing inpatient care for complicated measles cases, and outpatient care for simple cases in ER * Reinforcement of the surveillance system in the district, community sensitization and active case finding * Plan a measles mass vaccination campaign in Bentiu IDP camp, targeting 85% of the population (age group 6 months – <15 years). MUAC for all children less than five and Vit A distribution * The mass vaccination campaign is planned for the 21st – 28th November   A vaccination coverage survey is required to determine the vaccination coverage following the campaign. | | | |
| ***Study topic***  *Check all that apply* | AMR  Cholera  Ebola  Environmental Health  Emergency  HIV  Leishmaniasis  Malaria  Nutritio  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:**  Bentiu IDP Camp, Bentiu, Rubkona County, Unity State, South Sudan  **Conflict:** Study sites are not currently in conflict-affected areas. The Bentiu Protection of Civilians (PoC) was established in December 2013 by the United Nations Mission (UNMISS) in South Sudan to offer safety and protection to civilians fleeing the civil war that erupted in the area in December 2013. Internally displaced population had sought protection in the camp. However, the status of the camp was changed to IDP camp in March 2021 after negotiations between UNMISS and the government of South Sudan.  **Context (1 paragraph):** The Bentiu IDP camp is divided into five sections (1-5). According to the last population count conducted by IOM (July 2022), the current population is 104,581 of which 25% are children under 5 years.Médecins Sans Frontières-Operational Centre Amsterdam (MSF-OCA) runs a secondary care hospital located in the humanitarian compound at Bentiu IDP Camp | | | |
| **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 design**  We will conduct a vaccination coverage survey among the population living in Bentiu IDP. We will use simple random spatial sampling methodology in this survey  **Study population**  All people living in Bentiu IDP camp (sectors 1-5) aged between 6 months and under 15 years will be included in this survey  **Study participants**:  The vaccination coverage survey will be conducted in Bentiu IDP camp where MSF will have conducted the mass vaccination campaign in late November 2022.  The target population for this mass vaccination campaign will be approximately 48,000 children aged 6 months – <15 years.  The household head (≥18 years) will be asked about the number of children in the household aged 6 months to <15 years and the vaccination status of one randomly selected child in the household in the target age range.  Inclusion criteria:   * A child between 6 months –15 years * Living in the household (see household definition below) selected based on simple geospatial sampling   Exclusion criteria:   * Person under 6 months or 15 years and above * Person not living in the GPS sampled household   Definition of household:  A household will be defined as a group of people who commonly live together and are under the responsibility of one person or head of household.  **Sample size**  The sample size was calculated using ENA SMART software (SMART, 2015) based on the following inputs:   * Average household size of 7 * 45% of children aged 6 months to 15 years * Estimated coverage of 85% * Confidence intervals of 95% * Precision of 5% * Design effect of 1 * Non-response rate of 10%   This returns a sample size of **265 children** in **96 households**.  Sampling plan  We will use simple random spatial sampling to select participants in the IDP camp. As vaccination status is likely to be clustered at the household level and the number of households in the sample is low due to the large household size and high proportion of the target age group in the population, we will use the number of children to be included to guide the number of households to be chosen and randomly choose 1 child in each household. This means sampling of **265 households**, instead of 96 (as seen in calculations above).  The 265 households will be selected using simple random sampling, using randomly generated GPS points (created using QGIS/R) imported into smartphones. Where data are available, probability proportional to size will be used to ensure that the households per sector are allocated proportionally to the population of the blocks within the sectors.  **Pilot survey**  Each team will visit 5 HHs in each sector of the IDP camp, 1 eligible child selected at random in these HHs will be chosen and questionnaire will be administered to the head of the HH.  Data will be entered into the KoBoCollect application. The survey manager and an experienced MSF technical adviser will supervise all stages of the pilot test. A feedback session, which will address the complete team, as well as individual surveyors, will be held in group for the whole day. The weaknesses will be corrected, and equipment improved, if necessary, before the beginning of the actual survey. Adjustments regarding team leaders/supervisors for various teams will be made afterwards.  Anticipated dates for data collection are 02 December – 09 December, 2022.  The household head will be asked to provide consent for the survey questionnaire, which will collect information on:   * Total number of persons aged between 6 months to <15 years in the household * Measles vaccination status for one random child from 6 months to <15 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 on household level: the total number of persons in the household aged between 6 months to < 15 years (eligible for inclusion). Variables collected for 1 child 6 months to <15 years chosen in the household: age, sex, vaccination status, previous measles diagnosis and reasons for non-vaccination if applicable.  **Data sources and collection**: Data collectors will use *KoboCollect* software on smart phones or tablets 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 or tablets 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. No personal identifiable information will be collected as part of this study.  **Data analysis:** Data cleaning will be done to check for inconsistencies in data entry and responses. Data analysis will be conducted using R 4.2.2. 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. Weights based on the total number of children in the eligible range in each selected household will be applied. | | | |
| **Resources/costs:** | * 12 data collectors (6 teams of 2 data collectors): * Training materials (office space, projector, flipboard, small notebooks) * Recording materials (pens, smartphones with KoBoCollect installed, paper questionnaires as backup, 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: Nov 07 2022**  **Protocol development:**   * **5 working days,** 07 Nov – 11 Nov , 2020   **Ethics review:**   * Not needed   **Study preparation:**   * **5 working days** 14 Nov -18 Nov, 2022: questionnaire programming, logistical planning, photocopies, recruitment of interviewers * **3 working days**, 29-01 Dec, 2022: training of surveyors and pilot survey day   **Data collection:**   * **5 working days,** 02 Dec – 07 Dec 2022 (assuming 10-20 households/team/day, working with 8 teams of 2; complete within 3-6 days.)   **Data analysis and write up**   * **5 working days,** 08-15 Dec - 2022   **End 15 December, 2022 (considering one non-working day per week)** | | | |
| **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: Iina Hiironen, Epidemiology Activity Manager  Email address: [ssudan-epidem@oca.msf.org](mailto:ssudan-epidem@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: Patrick Keating  Email address: [patrick.keating@london.msf.org](mailto:patrick.keating@london.msf.org)  Is the topic specialist / topic holder informed/involved? Yes | | | |
| **MSF research team** | **MSF OCA Epidemiology Activity Manager: Iina Hiironen**  Email address: [ssudan-epidem@oca.msf.org](mailto:ssudan-epidem@oca.msf.org)  Responsibilities: Concept paper and r  esearch protocol conception. Selection and training of data collectors and data encoders. Supervision of data collection in the field. Data analysis, interpretation, and survey report writing.  **MSF OCA HospCo Bentiu: Robert**  Email address: [bentiu-hospco@oca.msf.org](mailto:bentiu-hospco@oca.msf.org)  Responsibilities: Support of Field Epi and medical team during Bentiu intervention for successful implementation of VCS.  **MSF OCA Data Specialist: William Wiel Mathoat Kuony**  Email address: [ssudan-data@oca.msf.org](mailto:ssudan-data@oca.msf.org)  Responsibilities: Training of data collectors and data encoders. Supervision of data collection in the field.  **Deputy Medical Coordinator South Sudan: Ibrahim Barre**  Email address**:** [ssudan-medco-dep@oca.msf.org](mailto:ssudan-medco-dep@oca.msf.org)  Responsibilities: Overall Support of Field Epi and medical team during Bentiu intervention for successful implementation of VCS. Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results.  **Epi Advisor: Patrick Keating, MSF-OCA**  Email address: [**patrick.keating@london.msf.org**](mailto:patrick.keating@london.msf.org)  Responsibilities: Support in development of concept note and protocol. Remote support to Field Epi for survey implementation and report writing. Submission of concept paper to OCA research committee.  **Vaccine Advisor: Kartini Gadroen, MSF-OCA**  Email address: [Kartini.Gadroen@amsterdam.msf.org](mailto:Kartini.Gadroen@amsterdam.msf.org)  Responsibilities: Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results.  **Health Advisor: Agatha Bestman, MSF-OCA**  Email address: [agatha.bestman@nairobi.msf.org](mailto:agatha.bestman@nairobi.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): Agatha Bestman  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:** South Sudan MoH via Rubkona/Unity State MOH  **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: **Iina Hiironen**  Email: ssudan-epidem@oca.msf.org  Data management plan: Data will be entered into smart phones or tablets 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 South Sudan 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: A survey report will be prepared and shared with the project, coordination and HQ teams  Participants: Not applicable  Community: A summary of the study may be presented to the community after the vaccination campaign  In country partners (including MoH): The survey report or at a minimum, an executive summary, of the report will be shared with the MoH and other relevant stakeholders  International dissemination (including WHO and other agencies, scientific publication): No publication will be created on the basis of this vaccination coverage survey  **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 Bentiu IDP Camp, Bentiu, Rubkona County, Unity State, South Sudan. |
| ***Name of Primary Investigator (PI):*** Iina Hiironen (Epidemiology Activity Manager) |
| ***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 Bentiu IDP camp 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.”* |