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| Date | 10/09/2020 | | | |
| **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 | **Evaluation of Mobile Clinics in the Somali Region, Ethiopia** | | | |
| Purpose of study | In Doolo zone, in the Somaliland region, Ethiopia, MSF is operating mobile clinics in order to provide access to the local and pastoralist population to primary health care, including sexual and reproductive health, nutrition, EPI, general OPD services and referrals to primary and secondary health care available in the zone  This study aims to provide a detailed description of the conception, implementation and lessons learnt from this mobile clinic approach, which will complement the existing body of research and will serve as a guidance to other MSF missions and other organizations when establishing mobile clinics in similar settings. | | | |
| Research question | **Are mobile clinics an appropriate, efficient and effective modality to deliver care for local and Pastoralist populations in the Somali Region, Ethiopia?** | | | |
| **Objectives** | **Primary objective**  *Evaluate whether mobile clinics are an appropriate, efficient and effective modality to deliver care for local and Pastorals populations in the Somali Region, Ethiopia.*  (see definitions of ‘appropriateness’, ‘efficiency’ and ‘effectiveness’ under the ‘Methods’ section of this concept paper)  **Secondary objectives**  *Assess the following evaluation domains of MSF mobile clinics in the Somali Region, Ethiopia:*   * *Connectedness/continuity* * *Perceived impact*   (see definitions of ‘coherence’, ‘connectedness/continuity’ and ‘perceived impact’ under the ‘Methods’ section of this concept paper) | | | |
| **Background/significance**  *1-2 paragraphs* | Is the study part of an OCA topical research agenda / strategy document?  No  Yes, namely:  The objective of MSF’s mobile clinic approach in the Somali Region in Ethiopia, is to increase access of local and pastoralist populations to health care services. Through the mobile clinics, the following health care services are provided: General medicine (Adults), General Medicine Paediatrics, Nutrition, Sexual and Reproductive health and EPI. In addition, the indicator-based surveillance is implemented in the mobile clinics, aiming to timely identify and respond to epidemic outbreaks (diseases under surveillance: suspected Acute Watery Diarrhoea (AWD), measles, Acute Jaundice Syndrome (AJS) and Acute Respiratory Tract Infections (ARTI) and, since March 2020 suspect COVID-19). Due to the population’s mobility, the target population of the mobile clinics has a large variation and is estimated to be 556,870 persons. The decision on where to locate the MCs follows a certain flexibility based on the population movements, remoteness of regions, difficulty of access etc resulting in a constant review of locations where they operate. This mobile clinic approach has been implemented by MSF since January 2019.  There is currently [very limited guidance or systematic reviews and evaluation available on mobile clinics](https://conflictandhealth.biomedcentral.com/articles/10.1186/s13031-020-0251-8#Tab1). There is no guidance or systemic evaluation available of the utilization of a mobile clinic modality to deliver health care for pastoralist populations. This study aims to provide a detailed description of the conception, implementation and lessons learnt from mobile clinics in the Somali Region in Ethiopia, which will 1) give insight to the project on how to strengthen their mobile clinic approach, 2) complement the existing body of research and 3) serve as a guidance to other MSF missions and other organizations when establishing mobile clinics in similar settings. | | | |
| ***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:  Evaluation of mobile clinic modality to deliver primary health care for local and pastoralist populations | 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  A mixed methods approach will be used for this evaluation. 1) Quantitative: Routine mobile clinic data will be used to evaluate some of the evaluation domains. In addition, a patient satisfaction survey will be implemented (see methods).  2) Qualitative: Focus Group Discussions or Individual interviews (if Focus Groups Discussion may not be appropriate considering social distancing measures) will be held to evaluate different evaluation domains (see methods). | | Mixed methods study  Qualitative research  Quality improvement study  Prediction model  Other | |
| **Methods - setting** | **Study location/setting:** *describe where you propose doing the study.* This study will be conducted in MSF-OCA’s Wardher project and its catchment area, in the Somali Region in Ethiopia.  **Conflict:** *Are any study sites located in a conflict setting?* No  **Context (1 paragraph):** *outline benefits/risks of using proposed study sites .*All sites are exclusively under MSF therefore,   1. There is generally a good representation/ proportion of the pastoralist population from our MCs OPD consultation numbers. 2. There is easy access to, and availability of historical data for all sites. 3. There is easy access to the proposed study sites therefore activities such as patient satisfaction survey are easy to conduct. 4. Operationally, the study does not so much interrupt the regular MC activities as a lot of the activities can easily be combined. 5. These are sites where MSF acceptance is high, therefore things such focus group discussions or patient satisfaction surveys will be easy to conduct. 6. There is no imminent security threat, but anything is possible, including land related and inter-clan fights that may make it difficult for our teams to access the proposed study sites though the chances are low.  * Covid-19 Phase of transmission can escalate to high caseload at any time making it difficult for us to conduct the study let alone the usual activities. * There is a tendency of exaggeration of humanitarian situations and needs by the community to attract more resources during focus group discussions. * Population movement from the selected sites especially the pastoralist.   Centralized data from when each MC started is available and accessible whenever needed. | | | |
| **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*** | A mix of quantitative and qualitative methods will be utilised for this evaluation.  Firstly, we will provide a **description of the mobile clinic modality in the Somali Region in Ethiopia** in terms of:   1. Definition of ‘mobile clinic’ for MSF and in Somali Region context specifically 2. Geographical area, population, coverage 3. Health services provided 4. Number of mobile clinics and mobility (where are they, criteria for choosing location of mobile clinics, criteria for closure of mobile clinics in an area, how often do mobile clinics visit areas, how is presence of mobile clinic communicated with community) 5. Components of the mobile clinics, data flow and frequency of reporting 6. SOPs or guidance documents 7. Data forms, data bases and outputs   For this evaluation, we will refer to evaluation domains that were identified by Organization for Economic Cooperation-Development Assistance Committee evaluation criteria (OECD-DAC), [adapted for humanitarian contexts](https://www.alnap.org/system/files/content/resource/files/main/eha-2006.pdf) by the Active Learning Network for Accountability and Performance in Humanitarian Action (ALNAP) and subsequently [further adapted](https://www.urban-response.org/system/files/content/resource/files/main/evaluation-manual-april-2013-online.pdf) by the MSF’s intersectional evaluation unit in Vienna.  The following evaluation domains will be assessed, utilizing quantitative and qualitative methods, in this evaluation:   1. **Relevance/Appropriateness** *(*[*Definition:*](https://www.alnap.org/system/files/content/resource/files/main/eha-2006.pdf) *“…Whether the project is in line with local needs and priorities (as well as donor policy) [and] appropriateness is the tailoring of humanitarian activities to local needs…”)* 2. **Efficiency** *(*[*Definition:*](https://www.alnap.org/system/files/content/resource/files/main/eha-2006.pdf) *“…the outputs – qualitative and quantitative – achieved as a result of inputs. This generally requires comparing alternative approaches to achieving an output, to see whether the most efficient approach has been used”)* 3. **Effectiveness** *(*[*Definition:*](https://www.alnap.org/system/files/content/resource/files/main/eha-2006.pdf) *“… the extent to which an activity achieves its purpose, or whether this can be expected to happen on the basis of the outputs [;] implicit within the criterion of effectiveness is timeliness”)* 4. **Connectedness/Continuity** *(*[*Definition:*](https://www.alnap.org/system/files/content/resource/files/main/eha-2006.pdf) *“…the need to ensure that activities of a short-term emergency nature are carried out in a context that takes longer-term and interconnected problems into account”)* 5. **Perceived impact** *(*[*Definition:*](https://www.alnap.org/system/files/content/resource/files/main/eha-2006.pdf) *“…perceived wider effects of the project – social, economic, technical, and environmental – on individuals, gender- and age-groups, communities and institutions. Impacts can be intended and unintended, positive and negative, macro (sector) and micro (household)”)*   In order to assess these evaluation domains, this evaluation will consist of three different components, which are set out in more detail below:   1. Retrospective analysis of routine data from mobile clinics (quantitative) 2. Patient satisfaction survey (quantitative) 3. Key informant interviews (qualitative)   **Quantitative component of the evaluation – retrospective analysis of routine data from mobile clinics**  Objective: The analysis of routine data from MSF’s mobile clinics in the Somali Region in Ethiopia will contribute the assessment of the following evaluation domains: relevance/appropriateness, efficiency and effectiveness. The definitions of these domains are set out above, the concrete ways in which these will be measured through the retrospective analysis of routine data is set out below under ‘data variables’.  Study participants: For this quantitative component of the evaluation no participants will be recruited, we will conduct retrospective analyses of routine data from the mobile clinics.  Data sources: Mobile clinic data collected in the Somali region by MSF-OCA between February 2019 and September 2020 (18 months). The mobile clinic data that will be analysed for this evaluation has been stored in a data base.  Data variables: The following evaluation domains will be assessed in this quantitative component of the evaluation:   1. Relevance/Appropriateness  * *Proportion of planned follow up consultations that are completed* * *Representativeness: break down of consultations by local/pastoralist population and by service* * *Proportion of deaths, proportion of referrals for hospitalization (severity of health outcomes)*  1. Efficiency  * *Human, financial and logistical resources needed to implement* * *Staff retention/turn over* * *Time efficiency – time mobile clinics spend travelling to reach destination*  1. Effectiveness  * *Proportion of referrals to other health facilities that are completed* * *Medical waste disposal* * *Comparison of seasonal variations in attendance, description of seasonal populations’ movements observed* * *Comparison of trends between outbreak prone diseases picked up by indicator based surveillance at mobile clinics and alerts picked up by Tea Team Surveillance* * *Stability: interruptions of services during 18 months of implementation of mobile clinics due to security or logistical issues*   Data collection procedures: Quantitative routine data that will be used for this evaluation has already been collected and will be analysed retrospectively. The data collection procedures of the mobile clinics will be described under the ‘description of the mobile clinic modality’.  Data analysis: Quantitative data analysis will consist of basic descriptive analysis including proportions and median calculations where appropriate. All analyses will be done using R software (R Core Team (2014). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. [http://www.R-project.org/.](http://www.r-project.org/))  **Quantitative component of the evaluation – patient satisfaction including a component on quality of care survey (cross sectional)**  Objective: The implementation of a patient satisfaction (with a component including standardised questions on quality of care) survey will contribute to the assessment of the following evaluation domains: relevance/appropriateness, effectiveness, and perceived impact. The definitions of these domains are set out above, the concrete ways in which these will be measured through the retrospective analysis of routine data is set out below under ‘data variables’.  Study participants: Patients that have completed a consultation at a mobile clinic will be asked whether they would like to participate in the patient satisfaction survey. There are currently 15 mobile clinics operational. Each day, on average, there are 55 consultations per mobile clinic. The number of consultations per clinic varies, therefore 10% of daily consultations will be asked to participate in the patient satisfaction survey. Patients will be selected with systematic random sampling (every 10th patient) to ensure that there is a balance between male and female patients, local and pastoralist population and to make sure that all services that the mobile clinic offers are represented (patients that visited OPD services, patients that visited SRH services, etc). Patient will be asked after the consultation and the voluntary nature will be emphasized.  Data sources: patients that have completed a consultation at an MSF mobile clinic during the data collection period.  Data variables: The following evaluation domains will be assessed in this quantitative component of the evaluation:   1. Relevance/Appropriateness  * *Care seeking behaviours/willingness to come to mobile clinic* * *Barriers/obstacles to go to mobile clinic* * *Facilitating factors to go to mobile clinic* * *Delay in care seeking*  1. Effectiveness  * *Perceived quality of care* * *Willingness to come to mobile clinics* * *Alternative places to go for health care, why (not) prioritized* * *Patient knowledge: ability of patients to repeat back health promotion messages* * *Does the patient know his/her diagnosis* * *Can the patient explain his/her treatment* * *Can the patient explain how to prevent the disease in the future* * *Does the patient have a written card with a diagnosis?* * *Did the patient receive the appropriate treatment?*   Data collection procedures: The patient satisfaction survey will be administered with patients that have completed a consultation at the mobile clinic, upon exit. The data will be collected on a mobile devices using KoBoCollect.  Data analysis: Quantitative data analysis will consist of basic descriptive analysis including proportions and median calculations where appropriate. All analyses will be done using R software (R Core Team (2014). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. [http://www.R-project.org/.](http://www.r-project.org/))  **Qualitative component of the evaluation – Key informant interviews**  Objective: The collection and analysis of qualitative data through key informant interviews will contribute the assessment of the following evaluation domains: relevance/appropriateness, effectiveness, connectedness/continuity and perceived impact. The definitions of these domains are set out above, the concrete ways in which these will be measured through the qualitative data collection is set out below under ‘data variables’.  Study participants: For the qualitative assessment key informant interviews will be conducted. MSF staff (including mobile clinic staff, CHWs, MTL), local informants, local leaders, women and elders will be selected based on their knowledge of the mobile clinics.  Data sources: Qualitative data will be collected through individual key informant interviews. Each interview will take 30-60 minutes following a semi-structured interview guide. A total of 15 interviews will be conducted (two per homogeneous key informant category as specified under ‘study participants’, or until saturation is reached. Interviews will be facilitated by a data collector (male or female depending on the participant). The interviews will be conducted with the help of a translator if needed (translating from Somali to English), who will receive training on detailed and real-time translation, body cues.  Data variables for key informant interviews: The following evaluation domains will be assessed in the qualitative component of the evaluation:   1. Relevance/Appropriateness  * *Are project objectives and priorities consistent with identified needs?* * *Were appropriate and timely adaptations made in response to changes in the environment?* * *Are mobile clinics perceived to be appropriate*  1. Efficiency  * *Human, financial and logistical resources needed to implement & time efficiency*  1. Effectiveness  * *Coverage: to what extent are the mobile clinics reaching the target population? Are there any factors that are hindering population to access the mobile clinics, is there any particular group excluded from having access to mobile clinic services* * *Perceived quality of care* * *Willingness to come to mobile clinics* * *Alternative places to go for health care, why (not) prioritized* * *Stability: interruptions of services during 18 months of implementation of mobile clinics due to security or logistical issues* * *Is there adequate coordination with other actors/MOH in the region*  1. Connectedness/Continuity  * *What would happen if mobile clinics were closed, where would you/people go* * *Is exit strategy designed, what does it consist of and which local capacities and resources were identified if any*  1. Perceived impact  * *What does catchment population perceive to be the effects of the intervention (mobile clinics)* * *What would happen/where would you go for health care if the mobile clinics were not there?* * *Has anything changed since mobile clinics were implemented* * *Do mobile clinics have any unforeseen (harmful) impact*   Data collection procedures: Transcripts will be prepared from key informant interview notes and will be password protected and stored on the secure MSF Network drive.  Data analysis: For qualitative data analysis, all hand-written notes will be transcribed. We will use a deductive approach for the analysis in line with the pre-structured themes for interviews, allowing for new themes emerging from the data. Transcripts will be reviewed and coded and the codes will be grouped under pre-identified themes using a framework approach to facilitate qualitative data synthesis and exploration of patterns across and within articles. An analytical plan will be developed to integrate any of the qualitative findings with the analysis of the quantitative data (including the retrospective analysis of routine data and the patient satisfaction survey). Qualitative data analysis will be performed with NVivo software (QSR International Pty Ltd, Australia). | | | |
| **Resources/costs:** | *List resources needed e.g. statistician, input from other specialists, field time. Include cost estimate if known.*   |  | | --- | | * 1 remote field epi for 8 weeks * 1 evaluation lead for 8 weeks (national field epidemiologist | | * 4 data collectors for 5 weeks (1 week training, 4 weeks data collection) | | * 1 driver for 4 weeks | | * 4 tablets and chargers and extension cords | | * 4 audio recorders, or install audio recorder app on abovementioned tablets | | * 5 clipboards, pens, pencils, rubbers, A4 paper sheet, MSF IDs, MSF aprons for surveyors | | * 1 cars plus fuel for 4 weeks | | | | |
| **Planned dates**  *List proposed* ***start/end date******[mm/yyyy]*** *of each stage and any time restrictions* | **Protocol development:** October/November 2020  **Ethics review:** Concept paper: September 2020, Protocol: October -November 2020  **Study preparation:** 2 weeks (recruitment of data collectors & training on qual methods and patient satisfaction survey)  **Data collection:** 4 weeks (qualitative data collection – individual interviews & quantitative data collection – patient satisfaction surveys)  **Data analysis:** 4 weeks  **Write up (report):** 1 week  **Write up (other study outputs):** 2 weeks | | | |
| **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:** By evaluating the current mobile clinic approach in the Somali region in Ethiopia, we are aiming to identify the strengths and weaknesses of the mobile clinic modality, and to identify lessons learnt and recommendations that will be operationalized. Further strengthening of the mobile clinic modality will help MSF to better meet one of its programs objectives in the Somali region, namely to ensure access to quality primary health care for local and pastoralist populations.  In addition, we will be contributing to the scarce evidence base of mobile clinic evaluation, which can be used by other MSF missions, governments, NGOs and other stakeholders when implementing mobile clinics, especially in similar settings.  **Risks:** We do not foresee any major risks for the implementation of the retrospective analysis of quantitative routine data from the mobile clinics, considering the retrospective character and that all data has been recorded without any identifiers. For the patient satisfaction survey and the population-based coverage survey, we do not anticipate any major risks either, as we will follow an informed consent procedure and will only collect data without identifiers. However we will observe appropriate IPC measures during the administration of the patient satisfaction survey as described in the following paragraph.  For the qualitative component, we do not foresee any major risks either. Considering the current COVID-19 pandemic and IPC practices we may have to decide to hold individual interviews as opposed to Focus Group Discussions. The individual interviews will be held in a location in the open air where privacy can be ensured. In addition, participant and interviewer will avoid all physical contact, keep 1 meter distance from each other, and wear a cloth mask. There is a risk that participants may feel that they have to give desirable answers. In order to mitigate this, prior to the individual interviews, all participants will be explained that they should feel free to answer honestly, and that their answers will not impact their access to MSF services in any way.  **Consent**: For the retrospective analysis of routine data from the mobile clinics, no consent procedure is needed. For the patient satisfaction survey and population-based coverage survey, we will ask prospective participants for their written consent to participate in the survey. Data collectors will be provided with an informed consent script in the local language that will be read to prospective participants, and clarified where needed. In the script, the data collector will clearly explain that participant’s answers will not impact their access to MSF services in any way and that they can withdraw from survey participation at any time.  For the qualitative interviews we will ask prospective participants for their consent to participate in the study with a clear explanation that their data will be anonymized and will only be used for this evaluation. In addition, the interviewer will explain that their answers and feedback will in no way impact their access to MSF services, and that participants are welcome to withdraw their participation at any point. Consent for the qualitative evaluation will be verbal, it will be explained that all data will be kept confidential, no personal identifiable data will be collected, there is no individual benefit associated with participation, participants can withdraw their consent any time.  **Confidentiality:** For the quantitative mobile clinic data, all data has already been collected as routine data and has been fully anonymized. The data is stored in DHIS2 that is password protected. The electronic database for entering the data associated with the patient satisfaction survey and the population-based coverage survey will be a secure web-based database in KoBoCollect, which will only be accessible to the Primary Investigator and Study Coordinator and the identified data encoder for this evaluation. The qualitative interview notes will be transcribed and translated by a translator, and will then be stored on a password protected computer. Only the Principal Investigator and Study Coordinator will have access to the transcripts, which will be fully anonymized. No personal identifiable data will be collected.  **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:   A research proposal will be developed based on Somali Regional Health Bureau (RHB) /Jigjig university IRB form and submitted to SRHB scientific and ethical review office (SERO) and approved by regional health bureau /Jigjig University . A support letter from RHB and Ethical clearance from JU will be granted and communicated to local administrative offices.   1. 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: Medco Assist and remote international field epidemiologist  Email address: [Ethiopia-medco-assist@oca.msf.org](mailto:Ethiopia-medco-assist@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  OCA Epidemiological Advisor  Email address: [Patrick.keating@london.msf.org](mailto:Patrick.keating@london.msf.org)  Is the topic specialist / topic holder informed/involved? Yes, Epi Advisor | | | |
| **MSF research team** | * MTL Somali Region Project * HES Somali Region Project * HP Somali Region Project * Medical Coordinator Ethiopia Mission * Deputy Medical Coordinator Ethiopia Mission * Medical Coordinator Assistant Ethiopia Mission * Jade Pena – Health Advisor * Prince Alfani – Health Advisor * Anne Freedman – Quality of Care Advisor (for patient satisfaction survey) * Beverley Stringer – Social Science Lead * Elburg van Boetzelaer – Epidemiology Advisor | | | |
| **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: The national staff field epidemiologist will be the Principal Investigator on this study/evaluation. The national staff field epidemiologist will be supported by the Epidemiology Advisor. The aim is that the evaluation of the mobile clinics will be repeated periodically to ensure that the program’s objectives are continued to be met, and that the mobile clinic approach is continuously further improved. One of the objectives of this evaluation is to train the national staff field epidemiologist on how to conduct an evaluation of mobile clinics, so that he can take the lead on further evaluations in the future. Finally, for the qualitative component, different national staff will be trained on qualitative research methods. | | | |
| **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:**  **Local:** Mohammed Osman (M&E and HMIS officer Somali Regional Health Bureau (RHB)  **Community**: *if relevant, describe consultation with a body representing the community.*  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: Patrick Keating  Email: Patrick.keating@london.msf.org  Data management plan: The routine mobile clinic data is stored in a password protected data base and confidentiality will be maintained through the standard procedures in project for such files. The electronic database for entering the data associated with the patient satisfaction survey will be a secure web-based database in Kobo collect, which will only be accessible to the Primary Investigators and Study Coordinator and the identified data encoder for this evaluation. The qualitative data (interview transcripts) will be kept on a password protected computer. The quantitative routine data and qualitative data will be kept for 5 years, after which they will be destroyed.  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** | Findings of this evaluation will be used by the MSF-OCA Somaliland project in Ethiopia to further strengthen their mobile clinic approach to delivering primary health care and other services to local and pastoralist populations. In addition, findings of this evaluation can be used by other MSF project and missions that are working in similar contexts to inform their decision making around the mobile clinic modality. Finally, findings of this study offer a unique evaluation on different evaluation domains of a mobile clinic modality. This will be useful for the broader community of MOH, governments and NGOs to inform decision making around the implementation of mobile clinics in humanitarian settings based on a scientifically sound evaluation and data. | | | |
| **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:**  MSF – project, mission, headquarters: Study report will be prepared and shared  Participants: Findings will not be shared directly with participants, but will be shared to the larger community which includes the participants, by incorporating key messages from the study findings into ongoing HP activities.  Community: Findings will be shared to community leaders in the local by MSF HPs. Key advocacy messages identified through the work, if any, will be translated into the local language and shared with the local community through ongoing health promotion activities.  In-country partners (including MoH): After data analysis is complete, an external report will be prepared and shared with the local and state government.  International dissemination (including WHO and other agencies, scientific publication): If appropriate, an abstract will be submitted to a local and/or international conference and a manuscript will be drafted for journal publication.  **Agreements**  Authorship: TBD  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):*** |
| ***Name of Primary Investigator (PI):*** |
| ***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:***  *Please name the various ERCs.*  ***If not planned to be submitted to local committees please note why:*** |
| **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? |
| * 1. What are anticipated harms? Ensure you acknowledge any that are relevant or state ‘no harms anticipated’. Can these be kept minimal? |
| * 1. Describe potential benefits to the programme, community, and if publication is the goal, to a wider audience: |
| * 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: |
| **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.”* |