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| Date | 24-07-2023 | | | |
| Proposed study title | Understanding the characteristics of survivors of sexual and gender-based violence and their utilisation of services in Cox’s Bazar (CXB), Bangladesh; a 7-year retrospective analysis of SGBV data from MSF CXB projects. | | | |
| Purpose of study | To describe the scale-up of MSF-OCA medical and humanitarian response for survivors of sexual violence and intimate partner violence and changes to SGBV care seeking behavior over time during 2017-2023. This internal descriptive analysis will help inform program approaches as well as advocacy. We will be able to highlight the gaps to include survivor participation in the advocacy plan. It may also add as useful data to triangulate with other knowledge generated from recent studies and assessments on survivor needs and care in the region. | | | |
| Research question | What are the characteristics of SGBV survivors visiting MSF clinics in Cox’s Bazar between 2017-2023? | | | |
| **Objectives** | *Primary objective:*  To describe the trends of SGBV services utilisation across MSF facilities over time, with an overall objective to guide program decision-making for adapted models of care.  *Secondary objectives:*   1. To describe the characteristics of survivors that visited the health facilities between 2017 and 2023, including:  * Consultation data and survivor demographic data * Episodes of sexual violence (including intimate partner violence) * Timeliness of access to care * Number and relationship to the perpetrators * Operational model of care adaptation  1. To assess risk factors for delays to care following SGBV events between 2017 and 2023. | | | |
| **Background/significance**  *1 paragraph* | Since August 2017, over 960,128 (according to population census by UN) Rohingya people fled violence from Myanmar to Bangladesh. This represents one of the greatest and most challenging humanitarians’ crises globally.  The refugees have limited access to healthcare, education, basic sanitation, and limited opportunities for employment. There have been concerns of growing instability in the camp, with potential negative consequences on the mental health and violence within these vulnerable populations with traumatic and unstable pasts.  MSF provides care for survivors of sexual and gender-based violence (SGBV) in the largest refugee camp in the world, where the Rohingya population faces sexual violence, sexual exploitation, abuse, intimate partner violence, and early and forced marriage. However, little is known about the survivor’s characteristics for the Rohingya population in Bangladesh. This retrospective data analysis is important to provide a complete overview of the last seven years of SGBV program in MSF clinics and outreach activities to create access for survivors seeking care and to inform the operational strategy for effective and targeted SGBV services for this population.  This analysis will provide a complete overview of all SGBV survivors in MSF clinics in Cox’s Bazar for the period since the start of activities until May 2023. | | | |
| ***Study topic***  *Check all that apply* | Is the study part of an approved OCA topical research agenda?  No  Yes, namely:  If yes, please provide a link to, or submit research agenda with this concept paper | | | |
| AMR  Cholera  Covid-19  Ebola  Environmental Health  Emergency  HIV  Leishmaniasis  Malaria  Nutrition  Other disease 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 (excluding Covid-19)  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  Brief explanation for chosen study design: | | Mixed methods study  Qualitative research  Quality improvement study  Prediction model  Other | |
| **Methods - setting** | **Study location/setting:** Kutupalong and Balukhali Settlements, Cox’s Bazar, Bangladesh  **Context (1 paragraph):** The proposed study population will include all patients seeking care for SGBV related incidents at MSF OCA facilities between 2017 and 2023.  In CXB, Médecins Sans Frontières (MSF) runs three health care facilities to provide, amongst other health care services, medical care and psychological support to survivors of SV and IPV. The clinics have been providing care for survivors and collected data on survivor’s demographics, episodes of sexual violence, medical care and psychological support, medical legal certificate, referral pathway and referrals to multi-disciplinary services. | | | |
| **Methods – participants, procedures, analysis**  *For retrospective analyses of routine data, if this section is sufficiently complete, this concept note will serve as the study protocol.* | **Study participants**: All SGBV survivors that visited MSF clinics from January 2017 to May 2023 will be included in this analysis.  **Data variables (quant):** Frequencies and proportions of characteristics of SGBV survivors will be described and stratified by age group, including (where data permits):   * Total number of SGBV consultations * Demographic data of survivor: age, gender, marital status, resident status (host community or forcibly displaced Myanmar national), place of residence (camp number or village name). * Type of violence * Type of perpetrator(s) * Time between incident and seeking care * Referral pathways * How survivors heard about the services * Barriers to accessing care services * Medical intervention * Intention to report to the police   **Data sources and collection**: Routine data on SGBV is collected in the patient file during the consultation and transcribed to a data collection sheet, which is then entered into the SGBV dataset in the MSF routine health information system also known as District Health Information Software 2 (DHIS2) as part of the MSF medical program. Data will be obtained from this server and a pre-existing excel tool for the earlier study years.  **Data analysis:** Data analysis will be performed in R and excel. Frequency and proportion tables will be generated for the categorical variables. For descriptive analyses, chi-square tests will be used to assess associations between categorical variables. Furthermore, we will assess the associations between potential risk factors and delays to care, defined as presenting to care services >72 hours following the SGBV event. This will be assessed using logistic regression analysis. | | | |
| **Resources/costs:** | Time of the epidemiologist team to analyse  Time of the research team to review research outputs | | | |
| **Planned dates**  *List proposed* ***start/end date******[mm/yyyy]*** *of each stage and any time restrictions* | **Protocol development:** August 2023  **Ethics review:** August 2023  **Study preparation**: N/A  **Data collection:** N/A  **Data analysis:** August/September 2023  **Write up (report):** September 2023  **Write up (other study outputs):** Abstract submission for Scientific Day Asia 2023 (takes place in October 2023) | | | |
| **Ethics** | **Benefits:** Since this is a retrospective analysis of routinely collected data, there will be no direct benefits to study participants. However, the findings have the potential to inform targeted awareness strategies, treatment and follow-up for SGBV survivors, which will benefit the population at large.  **Risks:** Since this is a retrospective study of routinely collected data, we expect this analysis to have minimal impact on study participants. However, we are cognisant of the fact that risk may depend on who the perpetrators and survivors are and how the findings are shared. For this reason, dissemination will be carefully planned by the study coordinator, who is a subject matter expert in this area and has experience balancing the risks and benefits of disseminating this type of scientific finding among similar vulnerable populations previously. Risks to completion of the study include staffing constraints and time limitations.  **Involvement of / collaboration with relevant local stakeholders:** the findings will be used as a tool for advocacy and communication with key local stakeholders such as local health services, community leaders and outreach teams. Findings/lessons learned may be used to encourage further discussions among key SGBV actors in the country.  **Obtaining informed Consent**: Since this is a retrospective study of routinely collected data with minimal impact to study participants, we are applying to waive the requirement of informed consent. In addition, the process of trying to seek consent would create additional risk and potential for harm for participants because unless the digitised data contains identifiers, the process would require retrieving paper records to re-identify people and find those individuals. This risk is not justified.  **Confidentiality and privacy:** All data will be stored on password-protected computers. Individual-level data will be made available only to the relevant persons involved in data analysis. Variables will be analysed with minimal personal identifiers such as name, contact details, addresses and identification numbers.  **How will the study demonstrate respect for study participants:** Where possible, findings will be disseminated bi-laterally with relevant actors and patient confidentiality will be maintained throughout. As this is a sensitive subject, a concerted effort will be made not to describe specific population groups in a negative light. Our subject matter expert will review all wording that is disseminated with external audiences.  **In-country permissions and regulatory 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:   Civil surgeon and RRRC health coordinator.   1. If not planned to be submitted to local committees please note why not, and which alternative permissions have been obtained:   **Do you believe your study meets MSF ERB criteria for exemption from full review?:**  Yes, because it is a retrospective review of routinely collected data. If so, it must meet all [criteria to qualify for exemption](https://scienceportal.msf.org/assets/7964) | | | |
| **Roles and responsibilities**  If responsibilities are split differently between the roles outlined below or held by other members of the research team, please describe clearly in the sections below. ReMIT responsibility must be held by an MSF staff member. | | | | |
| **Primary Investigator (PI)**  *Responsible for carrying out the study with support and consultation from research team. Will usually lead on all journal correspondence. TOR is* [*here*](https://msfintl.sharepoint.com/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%e2%80%8b%e2%80%8b/Research%20System%20Processes/Research%20Team%20ToR.pdf) | Name: Debbie Malden  Email address: cxb-epidem@oca.msf.org  Co-PI name: Partha Datta  Email address: [[cxb-data-manager@oca.msf.org](mailto:cxb-data-manager@oca.msf.org)](mailto:cxb-data-manager@oca.msf.org) | | | |
| **Study Coordinator (SC)**  *Overall responsible for study, must be MSF HQ staff, usually topic specialist. Responsible for: ensuring HA and PI have fulfilled their roles; ensuring everyone named in this CP is clear about their involvement; updating ReMIT, translating findings into impact, appropriately disseminating materials (see later section). TOR is* [*here.*](https://msfintl.sharepoint.com/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%e2%80%8b%e2%80%8b/Research%20System%20Processes/Research%20Team%20ToR.pdf) | Name: Meggy Verputten  Email address: Meggy.verputten@amsterdam.msf.org  Is the topic specialist / topic holder informed/involved? Yes: Meggy Verputten | | | |
| **MSF research team** | **Co-investigators:**  Md. Samiur Rahman Chowdhury, Epidemiologist, [cxb-epidem2@oca.msf.org](mailto:cxb-epidem2@oca.msf.org)  **Responsibilities:** Support analyses, as needed. Review report.  Sohana Sadique, OCA Kamrangirchar Epidemiologist, [kamrangirchar-research@oca.msf.org](mailto:kamrangirchar-research@oca.msf.org)  **Responsibilities:** Support analyses, as needed. Review report.  Dipali Gharami, BKL SGBV supervisor,[balukhali-sgbv@oca.msf.org](mailto:balukhali-sgbv@oca.msf.org)  **Responsibilities:** Review of the concept note and report.  Roksana Akter, SGBV supervisor  **Responsibilities:** Review of the concept note and report.  Patrick Keating, OCA Epidemiology advisor, [Patrick.keating@london.msf.org](mailto:Patrick.keating@london.msf.org)  **Responsibilities:** Data management and sharing,Support with data analysis (if needed), review of the concept note and report.  Maura Daly, Reproductive Health Specialist [Maura.Daly@amsterdam.msf.org](mailto:Maura.Daly@amsterdam.msf.org)  **Responsibilities:** Review of the concept note and report.  Raghda Sleit, Mental Health/Psychiatry advisor, [raghda.sleit@amsterdam.msf.org](mailto:raghda.sleit@amsterdam.msf.org)  **Responsibilities:** Review of the report.  Kalyan Krishna Velivela, Health Advisor, [Kalyan.Velivela@nairobi.msf.org](mailto:Kalyan.Velivela@nairobi.msf.org)  **Responsibilities:** Review of the concept note and report.  Meggy Verputten, SGBV advisor, [meggy.verputten@amsterdam.msf.org](mailto:meggy.verputten@amsterdam.msf.org)  **Responsibilities:** Writing of the concept note and report.  Saiful Islam Mohammad, Medical Coordinator, MSF-OCA  [Cxb-medco@oca.msf.org](mailto:Cxb-medco@oca.msf.org)  **Responsibilities:** Review of the concept note and report.  Rezwan Rahman Masum, Deputy Medical Coordinator, MSF-OCA  [Cxb-medco-dep@oca.msf.org](mailto:Cxb-medco-dep@oca.msf.org)  **Responsibilities:** Review of the concept note and report. | | | |
| **Field involvement** | Are national/other field staff informed/included as co-investigators?  No  Yes  Will protocol development include field team input?  No  Yes  If no to either of above, please provide explanation:  Please describe any planned capacity building activities for national staff: The current study will support the public health training capacity of local epidemiology staff. Moreover, staff who have been providing care to SGBV survivors on this project will be encouraged to attend the MSF Scientific Days conference to assist with the dissemination of this work to gain valuable skills and networking opportunities. | | | |
| **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): Kalyan Velivela  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:** Refugee Relief and Repatriation Commission (RRRC) including Camp In Charge (CIC) and Civil Surgeon (MoH). These external partners will assist in the study process by providing feedback on the final report.    Are **resource agreements in place**, e.g. Open Access publication costs?  No  Yes, namely: | | | |
| **Competing interests** | None | | | |
| **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](mailto:Patrick.keating@london.msf.org)  Data management plan: The data will be kept in a password-protected computer and will be accessible to the Primary Investigator, data manager and Study Coordinator with the secured ID. For data analysis, the data will be stored on local Research folders 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*](https://msfintl.sharepoint.com/:w:/s/Researchsystem/EUzjH4uorYtApQ2oduCHxO0BQXa7WT97eyajiqacMxr-1w?e=tnvzUh) *and submit for Medical Director signature.* | | | |
| **Opting out**  *All concept papers and/or (ERB approved) protocols are made available on ReMIT and the MSF Field Research website*. Questions about ReMIT? Email  *oca.research@london.msf.org* | This concept paper and/or accompanying protocol cannot be made available on:  ReMIT; because:  MSF Field research website; because: | | | |
| **Implementation/ impact and dissemination**  Responsibility of the Study Coordinator (unless otherwise noted in roles/responsibilities section) | | | | |
| **Implementation/impact** | This will first be used to guide MSF OCA’s operational activities in relation to the setup of the SGBV services in the camps. Second, the analysis will be used as a tool for advocacy and communication with key stake holders. Findings/lessons learned would be extended for further discussions (e.g. MSF Scientific Day Asia 2023) and where relevant, among key SGBV actors in the country. Thirdly, the analysis will support MSF’s catalyst for change role for SGBV care in Bangladesh at national level among MoWCA, MOHFW and other actors providing care for survivors of SV and IPV. | | | |
| **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/:b:/r/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%E2%80%8B%E2%80%8B/Publication%20and%20Dissemination/Publication%20and%20data%20advice.pdf?csf=1&web=1&e=lCVTiD) *on publication.* | **Dissemination of findings:**  **MSF – project, mission, headquarters:** An internal MSF report will be disseminated. MSF report will be disseminated and presentations will be done at project, country and HQ levels (e.g., block days).  **Community:** If feasible FGD’s can be organized to discuss findings and the way forward with the different target groups in the community.  **In country partners (including MoH):** Round table discussions with key stakeholders at the GBV cluster in CXB will be organised to discuss the recommendations and ways forward.  **International dissemination (including WHO and other agencies, scientific publication):** We plan to disseminate this work through MSF Scientific Days and potentially other conferences that will help us to disseminate our findings directly to relevant actors.  **Budget: Has budget been allocated for dissemination, including potential scientific editing costs?** Yes.  **Agreements**  Authorship: All study investigators.  Has the dissemination plan got 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) |