| **Date** | 19/12/2022 | | |
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| **Proposed study title** | Needs Assessment: Exploring the demand for a Digital Therapeutic (DTx) for drug-resistant TB (DR-TB) and drug-sensitive TB (DS-TB) patient-centred support in Belarus. | | |
| **Purpose of study** | This needs assessment is intended to provide a comprehensive insight into the demands of patients engaged in MSF supported treatment for DR-TB and DS-TB in Belarus with a view to informing patient-centred operational improvement. | | |
| **Research question** | Hypothesis: Patients undergoing treatment for DR-TB/DS-TB supported by MSF in Belarus may benefit from the integration of a DTx intervention and/or adjacent patient-centred operational enhancements.  Needs assessment research questions:   * What are the needs of patients within the current model of care and how may these needs differ between patients on different treatment regimens? * To what extent would the integration of a DTx and/or adjacent patient-centred operational enhancements into the model of care better assist in meeting those needs? * What are the potential challenges or barriers to implementing a DTx intervention and/or patient-centered operational enhancements in the treatment of DR-TB/DS-TB in this population? | | |
| **Objectives** | The overall objective of this needs assessment is to assess and guide programme delivery in Belarus, in two parts:   1. To assess the needs and DTx perception of patients and clinicians in Belarus within the current model of care. 2. To assess the contextual feasibility of integrating a DTx intervention into the current model of care. | | |
| **Background/significance** | DS-TB and DR-TB:   * According to the [WHO World TB Report 2022](https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022) an estimated 10.6 million people were diagnosed with TB in 2021 representing an increase of 4.5% from 2020. The global burden of DR-TB was also associated with an increase of 3% during the same period. * Belarus was among the highest multidrug-resistant tuberculosis (MDR-TB) burden countries in the world accounting for approximately [49%](https://www.who.int/teams/global-tuberculosis-programme/tb-reports) of all notified TB cases in 2021. * Increased concentration of TB is often associated with complex social issues such as [substance use disorders (SUD)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3537245/), financial instability and the presence of [comorbidities](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3537245/) which may lead to suboptimal treatment outcomes. As highlighted by [Harrison et. al (2022)](https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08525-x) within the context of TB care in Belarus “person-centred, multi-disciplinary, psychosocial support helped patients in this setting to cope with these challenges and complete the treatment programme.” * A coordinated approach to providing patient-centred care for people with DS-TB and those on the updated outpatient DR-TB treatment regimen is required in Belarus and beyond. As the leading non-governmental provider of TB care globally MSF is well positioned to support this progress towards more patient-centred methods aligned with new approaches and insights gleaned from the [TB-PRACTECAL](https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-022-06331-8) study.   The DTx opportunity and challenge:   * [Digital therapeutics (DTx)](https://edps.europa.eu/press-publications/publications/techsonar/digital-therapeutics-dtx_en) are software-based interventions focused on supporting patients navigating treatment and management of chronic conditions such as TB, Diabetes, or mental health disorders. * Mobile-based DTx tools may be provided as an adjunctive intervention to encourage improved patient understanding and sustained behaviour change via multimedia education, goal setting, medication adherence and appointment reminders and remote monitoring of symptoms and side-effects. There is currently a deficit in understanding of the feasibility and impact of DTx approaches in low-resource and humanitarian settings such as Belarus despite the high prevalence of health demands. * In 2015, the Belarus Ministry of Health with Global Fund support, piloted video observed therapy (VOT) for TB patients in Minsk. Following a successful pilot project, VOT was expanded countrywide with the Global Fund support in October 2016. Treatment adherence was high, as treatment success was demonstrated in 97% of DS-TB patients and 87% of RR/MDR-TB patients ([Skrahina et al., 2020](https://erj.ersjournals.com/content/56/suppl_64/1590)). While VOT interventions focus on improving medication adherence through remote patient monitoring and input, there remains an opportunity to understand how a DTx intervention may be appropriate to provide a psychosocially supportive mechanism. | | |
| **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  ☐ Mixed methods study  ☐Qualitative research  ☒ Quality improvement study  ☐ Prediction model  ☐ Other  Brief explanation for chosen study design:  These proposed quality improvement needs assessment will include the following components to answer the study questions and work towards the core objectives:     * Desk research * Aggregated demographic profiling of DS-TB/DR-TB cohorts accessing care from MSF and the NTP in Belarus (including socio economic status, literacy rates, distance from the clinic etc.) based on existing NTP and MSF data. * Context mapping of the cultural, technical, operational realities in Belarus based on existing secondary data sources and supplemented by NTP, MSF and patient interviews. * Literature review of digital and non-digital approaches for DS-TB/DR-TB patient support and their influence on improved outcomes and experience. * Technical landscape review and comparative analysis of existing tools and approaches for DS-TB/DR-TB patient support intended to provide insight into technical good-practices and their associated impact achieved to date.      * Stakeholders mapping and interviews * Semi-structured patient interviews (n=25-50) to understand patient perception of treatment and self-management challenges and gauge interest and reservations in potential digital therapeutic support intervention. Patients Interviews will be conducted until saturation of data is reached. [onsite] * Semi-structured medical team interviews/NTP interviews to develop understanding of current approach to patient support, patient education and counselling, challenges faced by clinicians and challenges at a systems level in addition to perceived opportunities for improvement and potential for digital therapeutic integration [onsite] * Persona development mapping core patient, clinician and stakeholder profiles to understand the potential interaction points with a patient-centred DTx platform and opportunities for other supportive system augmentations. * Clinical pathway mapping to represent the goals, needs, and behaviours of all relevant stakeholders identified through persona development in order to inform the design of DTx products and other patient-centred services. | | |
| **Methods - setting** | **Study location/setting:** describe where you propose doing the study.  The needs assessment is proposed to take place in Belarus with a primary focus on patients seeking care from the MSF supported clinic in Minsk. MSF has been supporting the Ministry of Health and NTP in four TB facilities across Minsk city and region for a number of years. Clinical studies and innovative treatment regimen upgrades associated with TB PRACTECAL and the EndTB trial have also been carried out with continued focus on this setting.  **Context (1 paragraph):** outline benefits/risks of using proposed study sites.    Benefits:   * The MSF team and the NTP in Belarus together expressed interest in exploring the adaptation of the DR-TB DTx tool that was tested in a small scale 28-person feasibility assessment in an MSF run clinic in Mumbai in 2022. * This needs assessment may serve to further strengthen the MSF/NTP relationship and care provided to patients through the review of the current system and opportunities for shared improvements strengthening ambulatory care. * Recently a 6-month all-oral MDR-TB regimen of bedaquiline, pretomanid, linezolid and moxifloxacin (BPaLM) has been rolled out in Belarus as an operational research project and is anticipated to be adopted at scale (both nationally and internationally). This underscores an opportunity to explore and contribute to new norms and standards for patient support which may include digital patient support systems and other patient-centred approaches which may be adopted in association with treatment regimen improvements setting a new standard for patient-centred care on multiple fronts.     Risks:   * Political instability in the region may present access challenges for in-person patient engagement during the intended interview period in the case of disruption to services. * Clinician and NTP representatives may not be readily available during the needs assessment interview period due to potentially high caseloads or political instability. | | |
| **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**: sampling strategy including where and how they will be found, over what time period, and inclusion/exclusion criteria; sample size (including sample size calculations if appropriate).  Patient Recruitment and Engagement:  Patients supported by MSF seeking care in Minsk and other regions of Belarus will be considered for participating in this needs assessment. A convenience sampling strategy will be adopted for patient interviews during the interview period of 3/4-weeks, during which the PI will be present in Belarus, including both patients being treated for DS-TB and DR-TB. While convenience sampling will be the primary method used for patient recruitment, the research team will also employ a purposive approach in order to gain representation insofar as possible. This purposive element will leverage selection criteria including TB type, treatment phase, age-range, ease of clinic access and gender.  The patient sample required for interviews is between 25-50 people or until saturation of information in these interviews is reached. Leading with convenience sampling for optimal patient ease, patients with existing medical appointments in the associated clinics will be invited by phone call to participate in a 30-45 minutes interview during their upcoming scheduled appointment. Full informed consent will be gained from patients who express an interest in participating in an interview. Patients who express provisional interest via phone will also have the opportunity to withdraw interest upon attending the clinic.  Patient inclusion: Individuals will be considered eligible for recruitment into the needs assessment patient interviews if they fulfil the following criteria:   * Patients on ambulatory DR/DS-TB treatment, * Patients 18 years and older - no minor patients will be included in the needs assessment interviews.   Patient exclusion: Individuals will be excluded from the needs assessment interviews based on the following criteria:   * Minor patients under the age of 18, * Severely ill that are not physically stable (i.e., requiring hospitalization and unable to communicate), * Patients an impairment or disability that may prevent full and informed consent or participation in interviews, * Patients not consenting to the full scope of activity.   Semi-structured interviews will also be conducted with the NTP representatives involved in MSF supported care and MSF clinicians and subject matter experts.  **Data variables (quant):**  The following information will be extracted from routine information and medical records already collected by MSF.   * Demographic * Age * Sex * Main language * Frequency of visits to MSF supported clinic      * Socioeconomic * Level of education (years spent in school) * Household size and income level * Occupation      * Lifestyle * Smoking * Alcohol consumption * Medical history * TB diagnosis and treatment information * Comorbid Diabetes * Comorbid Hypertension * Comorbid HIV * Other comorbid conditions * History of TB (self/family)   The following information will be collected from the needs assessment participants during the interview:   * Digital ownership * Ownership of smartphone and/or access to smartphone (no access, personal or shared device) * Phone model used * Internet and network access * Preferred social media networks     **Data sources and collection: how you will obtain your data, from what sources, how confidentiality and quality will be assured, training and supervision of data collectors, translation and transcription issues, how data will be transferred and stored safely**  OCA Data Protection Officer Taritha Sari will be closely consulted to ensure robust data collection, storage, and transfer practices at all stages of this needs assessment.  Primary Data: Insights on the current TB treatment regimen will be collected from patient interviews through semi-structured questionnaires administered by the PI of this project building on previous experience conducting needs assessments and leading data collection and analysis in other contexts.  During the informed consent process patients will be informed both verbally and via supporting documentation of the purpose of the needs assessment, the data being collected, how the data will be used, and any potential risks or benefits associated with participating in the study. Participants will also be given the opportunity to ask questions and decline to participate at any point in this engagement.  Provisional consent/withdrawal will be obtained from participants via phone before the interviews and full informed consent will be gained from those who have provided provisional consent before the interview in the clinic setting in addition to permission for accessing their medical and demographics data from MSF medical records. It will be clearly communicated that any choice to not participate in the interviews or choice to not answer certain questions is the right of the patient and will by no means affect the care provided by the NTP or MSF. Patient data will be fully anonymised.  The interview guide will be created and populated on Kobo within secure, password protected MSF OCA servers. Interviews will be conducted in a private room in the relevant clinic by the PI and supporting MSF translator. Additional information including phone ownership status of patients will also be gathered from the interviews.  Information on the current TB treatment regimen, patient education, opportunities and challenges faced by clinicians and at a systems level will be collected through interviews with MSF and NTP staff. With consent of participants, participant names and roles may be associated with collected insights. Those who do not consent to be identified in the needs assessment report will be anonymised in data collected and reported.  Secondary Data:  Demographic and medical data of patients will be obtained from the medical records at MSF, to learn more about the cohort of current TB patients. The data will also be linked to the patients being interviewed to be able to map the different personas.  A desk review on the healthcare system in Belarus, with a focus on TB care will take place. Cultural mapping for Belarus and technical landscape for existing digital tools for TB treatment in Belarus will be done.  Data will be completely anonymized when shared for analysis and any associated dissemination.  **Data analysis:** Qualitative data from patient, clinician and NTP interviews will be collected and downloaded from Kobo (connected to a secure OCA server) for coding on excel. Qualitative insights will be analysed leveraging a grounded theory approach and may also include elements of participatory action.  Quantitative variables (demographics and select details collected as a part of standard practice) will be described in frequencies, mean, median and standard deviation depending on its type. Univariate and simple analysis will be conducted using excel. We might be interested in comparing some variables by sex or age groups to understand better the patterns of the sample population. This will be done using R studio, through the statistical tests of chi square tests and t-test for categorical and continuous variables respectively. A statistical significance will be considered when a p-value is ≤0.05. | | |
| **Resources/costs:** | List resources needed e.g. statistician, input from other specialists, field time. Include cost estimates if known.     * Travel to Minsk and other regions (via SIU) * Needs assessment desk research, data analysis and interviews resourcing (via SIU) * In country travel (MSF Belarus) * Translation (MSF Belarus) | | |
| **Planned dates**  List proposed **start/end date** **[mm/yyyy]** of each stage and any time restrictions | **Estimated needs assessment timeframe subject to research committee approvals:** November 2022-June 2023  November 2022: Team alignment and concept note development  December 2022: Research committee review and feedback  December 2022-January 2023: Concept note edits and associated protocol development  January 2023: MSF and Belarus ERB submission  January-February 2023: Desk research elements (lit review, technical landscape analysis, context mapping, demographic profiling)  February/March 2023: MSF and Belarus ERB feedback/approval  March 2023: Interviews with clinicians, NTP representatives, and patients  April 2023: Interview coding, data analysis, needs assessment report write up  May 2023: Finalise needs assessment report, dissemination to direct stakeholders, and formulation of appropriate dissemination plan with HA input  June 2023: Move into the next phase as determined by needs assessment findings (e.g., further dissemination, intervention development/adaptation etc.) | | |
| **Ethics** | **Benefits:** Likely benefits to participants, projects, community, national.  Patient benefit: While no direct benefit to patients participating in the interviews is anticipated as a result of participating in this needs assessment, future TB patients in Belarus or elsewhere may benefit as the insights collected from this needs assessment will be used to inform patient-centred operational improvements. Patients may experience a perceived benefit by means of having the opportunity to contribute their perspective and experience to improve future treatment intervention.  NTP benefit: Opportunity to add to MSF and NTP operational understanding of DS-TB/DR-TB patient experiences in the current system. Adding to the understanding of how digital support interventions and other patient centred approaches may in the future be integrated with the new 6-month ambulatory treatment protocol for MDR-TB and supplement the established regimen for DS-TB.  MSF benefit: Opportunity to learn about patient feedback on the different TB regimens in Belarus, which leverage the opportunity to contribute to decision making on operational upgrades for TB cycle of care in Belarus and other countries supported by the MSF movement. This experience may also contribute to understanding of patient-centred opportunities supporting improved preparedness for vulnerable patients engaged in long-term treatment regimens.  **Risks:** Potential harms to patients/community and risks to study completion.  There is no likelihood of any physical risk as a result of participation in this needs assessment. Patients are not asked to perform any tasks that could result in physical harm.  Participants would be asked to provide information about their insights on their TB treatment, their experience, and socioeconomic information. These questions may be associated with emotional distress in the recall of challenges experienced. This will be mitigated as participants can decline answering some questions if they do not wish and can withdraw from the interview when they want. In addition, there may be a perceived risk among patients that participation in the needs assessment may impact the quality of health services they receive. This will be mitigated as patients will be assured that their participation is independent of the services being received in the clinics.  **Involvement of / collaboration with relevant local stakeholders: please describe the role that they will play**  **Obtaining informed Consent**: Describe how you plan to obtain consent. Oral and written consent will be obtained from patients, MSF, and NTP before each interview. Patients will also be informed of the interview in advance of their clinic appointments in order to ensure fully informed consent in advance of written commitment. Patients who express disinterest in participating in an interview will not be requested to participate when attending the clinic. Patients will also be clearly informed that refusal to participate will by no means impair the quality or access to care.  An MSF translator will be present during the patient interviews.  The NTP and MSF representatives will contribute to the development of the semi-structured patient interview guide.  **Confidentiality and privacy:** Describe how you plan to protect confidentiality.  A number of steps will be taken to protect confidentiality and privacy of all those involved in the primary data collection via interview:   1. Deidentification of data collected from participant interviews 2. Secure data collection and storage on Kobo and OCA servers 3. Interviews will take place in a private space in the clinic 4. Informed consent will be gained both in written and verbal formats from each participant with continued opportunity for refusal to answer questions or withdrawal entirely from interview 5. A confidentiality and privacy guidance will be agreed upon with the research team to ensure full understanding of best practices informed by the OCA Data Protection Officer   **How will the study demonstrate respect for study participants:** including how findings are shared with them.  The following steps will be taken to ensure participants are treated in a respectful manner:   1. Participants will be provided with multiple opportunities to learn about the scope of the needs assessment and ask any questions they may have to deepen this understanding 2. Participants will be informed of the timeline of the needs assessment and updated in case of any major changes to this timeline 3. Participants will be informed of the key findings of this needs assessment upon completion of the investigation 4. Participants may terminate or pause the interview at any time. 5. It will be made clear to participants that any information they are not completely comfortable sharing is not required.   **In-country permissions and regulatory review:**   1. Has a protocol been submitted to or approved by the 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: Yes, Belarus NTP associated committee 2. If not planned to be submitted to local committees please note why not, and which alternative permissions have been obtained: N/A   **Do you believe your study meets MSF ERB criteria for exemption from full review?:**   1. No. 2. Yes, because it is a retrospective review of routinely collected data. If so, it must meet all [5 criteria to qualify for exemption](https://fieldresearch.msf.org/handle/10144/618714) 3. Yes, because it is a survey that follows the MSF Intersectional Standardized Survey Protocol. If so, it must meet the [exemption criteria](https://scienceportal.msf.org/assets/6996) 4. Yes, for any other reason (please explain here): | | |
| **Roles and responsibilities**  If responsibilities are split differently between the roles outlined below or held by other members of the research team, please describe clearly in the sections below. ReMIT responsibility must be held by an MSF staff member. | | | |
| **Primary Investigator (PI)**  Responsible for carrying out the study with support and consultation from research team. Will usually lead on all journal correspondence. TOR is [here](https://msfintl.sharepoint.com/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%e2%80%8b%e2%80%8b/Research%20System%20Processes/Research%20Team%20ToR.pdf) | Name: Hanna Phelan  Email address: hanna.phelan@stockholm.msf.org | | |
| **Study Coordinator (SC)**  Overall responsible for study, must be MSF HQ staff, usually topic specialist or epi advisor. Responsible for: ensuring HA and PI have fulfilled their roles; ensuring everyone named in this CP is clear about their involvement; updating ReMIT, translating findings into impact, appropriately disseminating materials (see later section). TOR is [here.](https://msfintl.sharepoint.com/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%e2%80%8b%e2%80%8b/Research%20System%20Processes/Research%20Team%20ToR.pdf) | Name: Vera Vasilyeva (Patient Support Supervisor)  Email address: minsk-pss@oca.msf.org  Is the topic specialist / topic holder informed/involved? Yes | | |
| **MSF research team** | Name(s) and email address(es):  Dr Ekaterine Garsevanidze - Project Medical Referent: [minsk-med@oca.msf.org](mailto:minsk-med@oca.msf.org)  Sarwat Al-Attas - Medical Coordinator: [Belarus-medco@oca.msf.org](mailto:Belarus-medco@oca.msf.org)  Vera Vasilyeva - Patient Support Supervisor: minsk-pss@oca.msf.org  Dr Dzmitry Zhurkin - National TB Programme Lead: dmitry\_zhurkin@yahoo.com  Dr Alena Skrahina-Deputy National TB Program Manager: alena.skrahina@gmail.com  Dr Dzmitry Viatushka – Medical Lead: da\_vetushko@bk.ru  Dr Norman Sitali - Medical Operations Manager: Norman.Sitali@berlin.msf.org  Francesc Galban - Medical Innovation Lead: cesc.galban@london.msf.org  Dr Animesh Sinha - HIV/TB/HEP Advisor: Animesh.Sinha@london.msf.org  Ghinwa Hayek - DTx Project Support: ghinwa.hayek@stockholm.msf.org  Marpe Tanaka – SIU Innovation Lead: Marpe.Tanaka@stockholm.msf.org  Lindsay Bryson - SIU Medical Innovation Lead:[Lindsay.Bryson@stockholm.msf.org](mailto:Lindsay.Bryson@stockholm.msf.org)  Hanna Phelan - DTx Project Lead: [hanna.phelan@stockholm.msf.org](mailto:hanna.phelan@stockholm.msf.org) | | |
| **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: N/A  Please describe any planned capacity building activities for national staff:   * Collaborative design of the semi-structured interview guides * Presentation of the literature review insights relevant to the project operations and potential DTx intervention * Presentation of digital health landscape exercise with methodology associated with review of digital health tools and services * Workshop and resources on persona development and systems mapping | | |
| **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): Dr Norman Sitali (Medical Operations Manager)  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:** N/A  **Local:** e.g. Ministry of Health, NGO  National Tuberculosis Program (NTP)  of Belarus - Dr Dmitry Zhurkin, Dr Alena Skrahina, Dr Dzmitry Viatushka  Are **resource agreements in place**, e.g. Open Access publication costs?  ☐ No ☐ Yes, namely: | | |
| **Competing interests** | Declare any competing interests of the research team, or collaborators. Note if this work will contribute to an academic qualification for any of the research team.  N/A | | |
| **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: Taritha Sari, OCA Data Protection Officer  Email: [taritha.sari@amsterdam.msf.org](mailto:taritha.sari@amsterdam.msf.org)  Data management plan: describe how data will be managed and stored. Data will be collected using the KoBo tool associated with OCA servers. The OCA Data Protection Officer, Taritha Sari, will be consulted throughout the needs assessment to ensure fully in accordance with MSF’s Health Data Protection Policy and GDPR.  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: N/A  ☐ 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** | How will findings be implemented in MSF or externally?  Findings of the proposed needs assessment will be primarily used to inform patient-centred operational upgrades in the context of MSF supported NTP care in Belarus. Specifically, the demands and contextual information included in the needs assessment will inform adaptation and development of patient support interventions including a DTx system and multimedia patient education. These insights may also be used to contribute to external understanding of patient-centred support approaches for people being treated for DS-TB/DR-TB in other relevant MSF supported settings. | | |
| **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:** Describe how findings will be disseminated: including translation of research into booklets or other advocacy materials as appropriate.  MSF – project, mission, headquarters: Needs assessment findings may be documented in a report and summarised within the parameters of ethical best practices, confidentiality and privacy for MSF only access. Findings of this needs assessment will be shared with the immediate Belarus project team and may also be presented to others working in environments with similar demands (e.g., MSF South Africa project team, TB working group). The insights gained from this needs assessment may result in the adaptation of patient education materials recalling de-identified and generalised feedback highlighting the general process of patient co-creation used.  Community: Needs assessment findings will inform the adaptation of patient education materials to further support patients to more confidently self-manage between clinic visits with aggregated and anonymised recall to the needs assessment conducted.  In-country partners (including MoH): The NPT who are a part of the immediate project team will have access to the reported and summarized findings of this needs assessment in order to enable collaboration towards indicated operational upgrades.  International dissemination (including WHO and other agencies, scientific publication): Consent will be gained from patients for the publishing and dissemination of anonymous aggregated and individual use cases to allow for potential dissemination of actionable insights and relevant publication.  **Budget: Has budget been allocated for dissemination, including potential scientific editing costs?** No  **Agreements**  Authorship: list possible authors (at least 1st and last): TBC  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. | | |

| **\*Study Reporting Guidelines**  To assist authors in writing up their studies to meet scientific journal criteria | |
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| 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) |