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Assessing need for digital health technologies to improve TB patient support in Belarus

Needs Assessment Research Protocol | Version 1.3

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Acronyms and abbreviations

AUD Alcohol Use Disorder

BPaLM Bedaquiline, pretomanid, and linezolid plus moxifloxacin

DTx Digital therapeutic

DAT Digital adherence technologies

DOT Directly observed therapy

DOTS Directly Observed Treatment, Short-course

DR- TB Drug resistant Tuberculosis

DS- TB Drug sensitive/susceptible Tuberculosis

EECA Eastern Europe and Central Asia

ERB Ethics Review Board

HCP Health Care Provider

HIC High Income Country

HRQoL Health-related quality of life

IDI In depth interview

MDR- TB Multi-drug resistant Tuberculosis

MH Mental health

MM Medication monitors

MoH Ministry of Health

MSF Médecins sans Frontières

NCD Non communicable diseases

NTP National Tuberculosis Programme of Belarus

OCA Operational Centre Amsterdam

PCC Patient-centred care

PDP Personal Data Protection

PI Principal Investigator

PPE Personal protective equipment

QoC Quality of Care

QoL Quality of Life

RR-TB Rifampicin-Resistance Tuberculosis

RWE Real World Evidence

SIU MSF Sweden Innovation Unit

SMARRTT-OS six-month all-oral regimens for rifampicin-resistant tuberculosis treatment operational study

TB Tuberculosis

TGF Global Fund to Fight AIDS, Tuberculosis and Malaria

VOT Video observed therapy

WHO World Health Organisation

XDR-TB Extensive-Drug Resistant Tuberculosis

1. Abstract

The proposed needs assessment aims to provide a detailed understanding of the context-specific demand for digital health-enabled patient support to enhance the current model of care for DR/DS-TB patients in Belarus. This assessment is driven by a demand for increased operationalisation of integrated person-centred care to address the significant burden of TB globally – recognising TB as the second leading infectious disease in the world with an estimated 1.6 million deaths in 2021 alone. This model of care prioritises the preferences, lived-experiences and needs of patients and communities when designing and delivering health interventions. Digital health patient support platforms such as mobile apps offer one avenue of exploration to increase patient-centricity of TB care provided and expand the reach of current services. The achievement of the End TB target to eradicate the global epidemic of TB by 2035 has been recognized by the WHO and other global actors to require the exploration and validation of novel approaches including digital health interventions if the ambitious targets are to be met for a with patients and communities. While patient-facing digital health approaches have indicated early potential for supporting TB patients in these contexts this effort has been largely focused on medication adherence and remote monitoring. There is a gap in high quality information and evidence on context specific demand, acceptability, feasibility and efficacy of digital tools integrating comprehensive digitally delivered behavioural support for the potential improvement of TB patients treatment experience and health outcomes.

The Belarus National Tuberculosis Program (NTP) and MSF are committed to becoming increasingly person-centred in the provision of TB care, working with people as partners and supporting empowered health decision making. This was the result of different studies and projects that MSF and NTP conducted, realizing the that TB infection and treatment success rates are intertwined with social determinants of health and psychosocial wellbeing. One form of digital health technologies known as digital therapeutics (DTx) may offer one way to accelerate towards this ambition, however greater understanding of the Belarus context specific needs and realities of patients, are required for a contextualized approach. DTx are patient-facing platforms (typically a mobile application) offering evidence-based health behaviour change. By co-creating with patients and communities to leverage these DTx tools, patients will be able to more effectively access care and support, learn about their condition and treatment from a new perspective, and build improved practices to access better quality of life and health outcomes.

Three main research questions will guide the proposed needs assessment:

1. What are the self-management support and psychosocial needs of patients within the current model of care and how may these needs differ between patients on different treatment regimens?
2. To what extent may the integration of a digital health patient-support platform and/or adjacent person-centred operational improvements be feasible to enhance the model of care better assist in meeting those needs?
3. What are the key challenges and opportunities related to implementing a digital health patient-support platform intervention and/or patient-centred operational enhancements in the treatment of DR-TB/DS-TB in this population?

This research protocol delineates multiple methods to investigate these research questions. Firstly, the needs assessment will include the secondary analysis of existing data and a literature review, pre-emptively conducted to inform the current protocol design, to gain an understanding of current evidence and contextual realities. Secondly, primary research via semi-structured interviews involving patients and clinicians in Belarus will be conducted to explore their lived experiences and perceptions of the current model of care. Finally, building upon the previous methods outlined, a human-centred design approach will be used to map the current clinical and patient pathways and identify digital and non-digital opportunities for person-centred operational improvement. Through the combination of these methods, a comprehensive understanding of the TB model of care will be achieved, enabling understanding of the foundational requirements for potential digital health support. The needs assessment will ensure alignment and transparency on the demands and opportunities for digitally enabled person-centred care TB interventions in Belarus and shared understanding amongst decision makers (patients, NTP and MSF) on the potential for further digital health tools and other areas where person-centred care may be championed. It is also intended to contribute a degree of progress towards the EndTB targets.

1. Introduction
   1. *Global Burden of TB*

According to the WHO World Tuberculosis Report 2022 an estimated 10.6 million people were diagnosed with Tuberculosis (TB) in 2021 representing an increase of 4.5% from 2020 (1). This represents also an augmentation in the estimated incidence of TB for the first time in two decades, including the more difficult-to-treat form of this disease, drug-resistant TB (DR-TB). The WHO End TB Strategy launched in 2015, has a purpose to end the worldwide epidemic of TB by 2035 (2). Moreover, the SDGs (3) have a stated target within Goal 3[[1]](#footnote-2) to end the TB pandemic[[2]](#footnote-3)*.* By 2021, only a fraction of the targets has been reached for the various milestones (4). The progress was compounded by the COVID-19 pandemic, associated with gaps in access to TB diagnosis, treatment and sufficient patient support. It is critical for stakeholders to explore new approaches including integrated person-centred interventions, and digital health innovations to achieve the global TB targets.

All forms of TB treatment would benefit from innovative care strategies. Drug-susceptible TB (DS-TB) disease is treated with a standard 4-month or 6-month course of 4 antimicrobial drugs that are provided with support to the patient by a health worker (5). Drug- resistant TB (DR-TB) exists in three forms, including; rifampicin-resistance TB (RR-TB), multidrug-resistant TB (MDR-TB), and extensive-drug resistant TB (XDR- TB) (5). There is limited evidence on person-centred care in TB treatments, as these approaches are usually isolated to pilot projects (6,7).

* 1. *MSF Work in Ending the TB Pandemic*

MSF is one of the largest non-governmental providers of TB treatment and care globally. In 2021, there were 17,221 people in MSF’s care starting their TB treatment, including 2,309 with drug-resistant TB. MSF works on TB in many countries, especially the ones with a high burden such as India, South Africa, Central African Republic, Uganda etc. MSF has been a pioneer in TB treatment (largely focused on DR-TB) and research, focusing on patient-centred and innovative approaches to prevention, diagnosis, and treatment. These projects include the TB-PRACTECAL trial completed in Belarus, Uzbekistan, and South Africa. Using a 24-week regimen containing bedaquiline, pretomanid, and linezolid plus moxifloxacin (BPaLM)(8) for the treatment of DR-TB, against the standard of care using second-line drugs with up to 20 pills per day and with a duration of 9-20 months. The TB-PRACTECAL treatment regimen was found to be more effective and safer than the standard of care treatment, with a cure rate of 89% of DR-TB patients on the new ambulatory treatment, a significant departure from the previous 52% cure rate associated with the previous standard of care (8). In the long run it is estimated that it will also be cheaper (9). This DR-TB treatment regimen has been endorsed and approved by WHO at the end of 2022 (10). The introduction of new medications and treatments for TB is happening for the first time in 50 years with MSF and their partners efforts looking further ahead to keep on improving care for neglected diseases (11,12). This includes the EndTB project (13,14), targeting MDR-TB patients from all age groups (including adolescents) in 18 countries, through two clinical trials for new medications (15), observational research and advocacy efforts (16). Both trials are innovative as they introduce new medications to the TB treatment, and shorten the amount of time spent in treatment, which in turn will help in medication adherence, quality of life, and well-being for patients and their surroundings. The results for the trials will be available sometime in 2023 (15). MSF is not only focusing on TB treatment, but also on diagnosis, bringing the latest innovative technology to low resources and rural settings, such as GeneXpert (17), which can detect TB in about 2 hours. This will facilitate detection of TB, thus enabling prevention and treatment options. In terms of patient-focused care, MSF has been involved in learning from patients about the different barriers to accessing, adhering to, and succeeding in their TB treatment in different countries (18–20) to continuously refine programs and enhance patients' experiences. This aligns with MSF’s strategy where patients are considered partners in their treatments. Overall, such improvements in TB diagnosis, and treatment, making these interventions more accessible, and working with partners across the globe, will accelerate the cadence to reach the End TB and SDG goals in ending the pandemic, especially in low resources settings and among vulnerable populations.

* 1. *Approaches to TB Care*

Patient-centred care is the 1st pillar in the End TB strategy (2), with the 2019 WHO guidelines for the treatment and management of TB emphasising the involvement of people with MDR-TB in their care, and recommend shared decision-making between practitioners and patients regarding the choice of treatment option (21). Patient-centred care (PCC) or “person-directed care”, or “person-focused care” are common terms frequently used interchangeably. It can be defined as “providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions” (22). It supports the role of patients making informed and active choices, rather than remaining passive recipients of their care. Patients are partners with their health care providers, and providers treat patients not only from a clinical perspective, but also from an emotional, mental, spiritual, social, and financial perspective (23). This approach to health care decisions and its importance in quality of care is becoming increasingly accepted as playing a central role in healthcare delivery. Moreover, the achievement of the End TB target to end the global epidemic of TB by 2035 has been recognized by the WHO and other global actors to require the exploration and validation of novel approaches including digital health interventions (24). Digital health tools are directly relevant to all three pillars of the End TB strategy from integrated, patient-centred care, and prevention, bold policies and supportive systems, and intensified research and innovation. Digital health tools are being established as adequate practices for the shift towards more of a patient-centred approach. It is an intervention that enhances healthcare services delivery on the continuum of care from awareness, prevention, diagnosis, to care as described in Figure 1 ((25). It addresses issues related to barriers of access to essential healthcare (26). However, evidence of impact for such solutions is limited. This deficit of robust digital health evidence is particularly pointed out in low-resource and humanitarian settings and a core driver of the proposed assessment. The achievement of global targets TB and required changes, such as a move towards more patient-centred activities, to improve TB patients' health-related quality of life (HRQoL) and perceived quality of care (QoC) will not be sufficiently realized with current practices. As the TB pandemic continues worldwide, this disease is becoming more complex and invasive, the needs of TB patients during their treatment are not only confined to taking medications. It is about improving medication adherence for treatment success, accompanying them emotionally and mentally through the different phases, providing financial and social support as needed, and delivering educational sessions for better awareness and self-management, among other types of assistance. As such an integrated health services delivery is necessary. It is defined as an approach to strengthening people-centred health systems through the promotion of the comprehensive delivery of quality services across the life-course, designed according to the multidimensional needs of the population and the individual and delivered by a coordinated multidisciplinary team of providers working across settings and levels of care (27). Patient-centred interventions, integrated health service delivery and digital health tools are becoming increasingly popular strategies for TB treatment, yet they are rarely combined together. This approach to TB care can bring a holistic approach to treatment to ameliorate patients outcomes. Over the next sections, the main types of TB care and support will be described.

##### Figure 1: Examples of digital health tools on the continuum of care for TB (non-exhaustive)

Timeline

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* + 1. *The focus on medication adherence*

It is recognised that a highly detrimental issue in TB control is non-adherence to treatment which has led to a significant focus on alternatives to the directly observed treatment (DOT) and towards remote alternatives such as Video Observed Treatment (VOT). However, there are many factors associated with non-adherence, such as: financial, social, psychological, and personal realities (28). Patient adherence needs to be achieved by combining different strategies, as per the patient’s situation. The Directly Observed Treatment, Short-course (DOTS) is the internationally recommended non-digital strategy to improve medication adherence. However, its effectiveness and scalability have been questioned. Other forms of observed treatment emerged such as treatment observed by a family member, self-administered treatment, or more digitized tools such as VOT, trying to make up for the fallouts of DOTS (29). In terms of medication adherence, treatment success, and cure rates, DOTS is found to be better than self-administered treatment (30). From a systems perspective, DOTS places a high burden on healthcare workers who need to follow up with all their patients, instead of focusing on high-risk ones. This would lead to poor implementation, especially for community-based DOT (31,32). Other interventions tackled different factors involved with the non-adherence such as awareness, whereby, patients’ and their family members’ education and counselling, and staff education for lay health workers improved treatment outlook (30,33–37).

* + 1. *Digital health for TB*

The most prevalent digital adherence interventions launched in response to the shortcomings of DOT include SMS, VOT, and the Medication Event Monitoring System, and other electronic medication monitors (MMs). These technologies called “Digital adherence technologies (DATs)” allows for greater convenience of remote monitoring. Nevertheless, there is a lack of strong evidence of the integration of the psychosocial support elements in those interventions, which may have been more accessible in a DOT interaction. DATs systems typically function by reminding patients of their doses, addressing forgetfulness, a common barrier to adherence (38). They can also digitally observe or record dose taking, mimicking DOT, this could be asynchronous or synchronous VOT, the recording through automatic pillboxes, or ingestible sensors. DATs can also document patient dosing history, which allow for ‘real-time’ medication adherence monitoring, noting any missed medication just in time for clinicians to follow-up with patients (39), facilitating the work of healthcare providers, and their focus on non-adherent patients, thus improving effectiveness (39). Findings from one systematic review demonstrate that DATs resulted in higher rates of treatment success, medication adherence, sputum conversion after two months, and lower loss to follow-up, and development of drug resistance, with some variations as to what interventions are being compared and what type of TB (30). Specifically, MMs improved adherence and treatment success, and SMS reminders led to a higher treatment completion rate. The SMS reminders, in combination with MMs generated lower rates of loss to follow-up and higher rates of cure (30). This evidence supports treatment adherence for a low cost, prompting national TB programs to encourage their usages, such as 99DOTS[[3]](#footnote-4) or Digital pillboxes[[4]](#footnote-5) in India (40–42). VOT, which was first used for TB in 2007 in several clinical programmes in London, UK, as an alternative to in-person treatment observation (43) highlights a promising approach to remote medication adherence oversight, however, may be regarded as transactional in nature. It has been evaluated in a range of high-income countries (44,45), or low and middle-income countries (46,47) as well as low resources (48,49) settings with some promising results when it comes to medication adherence, and treatment success. This provided learnings for future iterations of remote adherence support. A number of countries have adopted VOT as part of their TB regimen, following the guidance published by WHO in 2017 (50) and after testing it in randomized trials, as in Belarus (49,51). In 2015, the Belarus MoH with Global Fund support piloted VOT for TB patients in Minsk. Following a successful pilot project, VOT was expanded countrywide with the Global Fund support in October 2016 (51). Treatment adherence was high, as treatment success was demonstrated in 97% of DS-TB patients and 87% of RR/MDR-TB patients (51).

Nonetheless, it is clear while VOT tools are a step in the right direction to complement new medication regimens, findings with a patient-centred lens, such as the TB-PRACTECAL PRO sub study underscores the need to further prioritise quality of life and psychological factors of the TB lived-experience and potential to reduce stigma experienced by patients via integration of digital tools (52). There remains an opportunity to understand how new patient-centred ambulatory treatment regimens in combination with comprehensive digital health intervention, including psychosocial support, counselling, medication adherence measures, and context-specific and engaging education may work together for optimal experience and outcomes. Psychological support was found to be of great importance during protracted TB treatment to provide emotional support and reduce stigma (53). Mental illnesses and TB are highly comorbid conditions, such as AUD (as in Belarus (54)), depression (55,56) and anxiety (57). The comorbidity between TB and mental diseases, topped with the stigma that comes with having both illnesses (58), are resulting in delaying seeking TB care (59), poor TB treatment adherence, treatment failure, and thus increased mortality or emergence of resistant types of TB (56,60–62). Psychosocial interventions (including support group, counselling, and psychotherapy) during treatment, is essential to ensure adherence and success. Support groups, were linked to higher rates of treatment completion, and lower rates of loss to follow-up (30,63,64). Evidence on psychological counselling and educational interventions mainly looks at improved adherence to TB treatment (65–67) . Other benefits of integrating psychosocial support within TB treatment should be revealed. Such as the interventions mitigating stigma at the community level (68), are another way of intervening to prevent mental illnesses for TB patients. Psychosocial support packages need to be part of TB treatment, to guarantee the wellbeing of patients and their treatment completion (69).

* + 1. *Exploring an integrated patient-centered digital health approach for TB: DTx*

Digital therapeutics (DTx) may offer a framework to combine the demands of the new ambulatory regimens, with insights from DATs and evidence on the need for increased psychosocially supportive systems. DTx (70), typically bring together a bundle of digital and in-person health management components for long-term behaviour change associated with a chronic condition (figure 2). DTx are classified as a software-based intervention focused on supporting patients navigating treatment and management of chronic conditions such as TB, Diabetes, or mental health disorders (70). 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. Table 1 provides a comparison between the main tools used for TB treatment.

##### Figure 2: Description of a potential DTx

Graphical user interface, application, Word

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Currently, there are no DTx interventions for TB however some progress has been made for other chronic disorders in high-income contexts where contextual realities and patient needs are a significant departure from those faced by patients in low-resource and humanitarian settings (71). So far, they have been found efficient as a behaviour change platform with a comprehensive package of care (education, well-being and medical treatment) (72). This would potentially lead to improved outcomes in the overall quality of life of patients, not only because of the all-inclusive treatment. There is also the involvement of clinicians, counsellors and caregivers in real-time with minimal effort, as the DTx platforms have an interactive dashboard for the medical staff following up with the patients and educational content for both patients and caregivers. Given their improved health outcomes attainments and acceptance and validation by patients and physicians, for mental health and non-communicable diseases (NCDs), it might be time to explore the effect of DTx for chronic infectious diseases such as TB, especially in low resources and humanitarian settings. Such as solution could be an adequate plan for TB care combining a patient-focused approach, integrated health services and digital health. DTx solutions are enhancing the quality of care, well-being and patients' outcomes, through their comprehensive approach to encouraging patient understanding and empowerment with evidence-based behaviour change practices. Low- and middle-income countries and humanitarian settings with a high burden of diseases, and difficulties in accessing adequate healthcare services; are lacking such solutions. They could be essential to close gaps in the healthcare systems, in access to care, and in reducing the burden of disease. Deploying context-specific and carefully validated DTx solutions in low-resource and humanitarian settings may offer a tool to help close this deficit, through patient empowerment for a positive impact on population health at scale.

There is little doubt that the way forward for TB treatment is a comprehensive package of care, with a focus on psychosocial and behavioral interventions which will inevitably include digital health components in some form. What is yet to be determined is the precise context and cohort specific form of patient-facing digital health interventions to support TB patients.

##### Table 1: Comparative of DOT, VOT and DTx approaches to medication adherence and support

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Directly Observed Therapy (DOT)** | **Video Observed Therapy (VOT)** | **Digital Therapeutics (DTx)** |
| **Definition** | Directly Observed Therapy (DOT) includes health worker attended adherence oversight delivered in a range of settings including in-hospital, in a patient's home or in a local hub. | Video Observed Therapy (VOT) allows for a patient to record their medication intake via video for asynchronous review by a health worker. Intervention typically occurs if the video is not received by the health worker at a designated time. | Digital Therapeutics (DTx) are behavioural health interventions composed of a patient facing mobile application and corresponding clinician dashboard. DTx interventions include patient education elements, psychosocial support, medication adherence reminders and reporting and side-effect reporting mechanisms. |
| **Evidence Snapshot** | Established - Considered more effective than self-administration however there is a large diversity in approaches demonstrated in the published literature. Longstanding default recommendation from WHO | Developing - systematic evidence is building and a strong case growing for VOT. Need for more large scale and high-quality studies in LMICs | Nascent - fragmented evidence on varied approaches largely focused on HICs. |
| **Strengths** | Allows for integrated care approaches including counselling and social service support; in person intervention available in case of side-effects; home visit DOT provides easy access to patients in the comfort of their homes; home visits and local hub DOT reduces burden of commuting to a clinic | Convenient access to adherence support and care. | Potential for extending the continuum of care with increased focus on patients' psychosocial demands. Offers more patient centred opportunity for long term behaviour change and increased QoC/QoL and improved outcomes. Heavily focused on empowerment. |
| **Limitations** | Human resource intensive; requires patients to commute and wait for observation; challenging to deliver at scale; exposes patients to potential stigma during HCP home visits; requires HCP follow up | Psychosocial support elements may be neglected in favour of more transactional medication adherence reporting. | Evidence and developments to date have been predominantly focused on high income and stable contexts. Required investment of time and resources for highly context specific and evidence-based intervention. |

* 1. *TB in Belarus*
     1. *Burden of TB in Belarus*

The Eastern Europe and Central Asia (EECA) region, is one of the 10 constituencies representing implementing countries at the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF), it represents 22 countries (73). This region is particularly affected by high levels TB, notably DR-TB. MSF has been working in multiple countries in the EECA, bringing in new approaches to TB diagnosis, treatment, and prevention, and supporting countries to reach the needed targets to end the TB pandemic. Belarus is one of the 30 countries worldwide with the highest burden of MDR/RR-TB (4), one of the 8 in the EECA (73), and a high priority country for TB in Europe (74). It approximately accounts for 49% of all notified TB cases in 2021 (4). Belarus has one the highest previous cases returning back to treatment in Europe with 34.1% of its TB cases having undergone treatment, but either did not complete it, had a clinical failure, or were re-infected (74). When it comes to MDR/RR-TB this increases to 74.5% of cases having been previously treated; the highest in Europe (74). These figures further reinforce the demand to enhance the systems of care and support to improve the experience of patients. There is a need to refine the access and adherence to TB treatment, and advance the quality of care provided to ultimately ameliorate patient outcomes and limit the unnecessary morbidities, and loss of life. Adopting a person-centred approach within the TB response is an internationally recognised priority, especially for the EECA as the region is dealing with a high burden of DR-TB (75) . The WHO blueprint for the region on people-centred care published in 2017 (75), advises to move to models of care that can treat these strains of TB effectively through multidisciplinary models of care, acceptance of people-centred practices, cooperation between different care providers, enhanced clinical skills and high levels of staff motivation. None of these characteristics are traditionally health systems in the EECA region (75).

Nevertheless, the National Tuberculosis Programme (NTP) and Ministry of Health (MoH) of the Republic of Belarus have, in the face of one of the most challenging TB burdens globally, achieved some promising progress and demonstrated a strong commitment to person-centred care and innovation with a view to improved outcomes and experiences across their health system (76). Indeed, in 2021 Belarus reached the 80% target for the testing coverage set by WHO ((4) and the 35% target for the decrease in the mortality rate (74). However, it is recognised that as TB determinants are heavily rooted in social, economic, and health factors- such as undernutrition, diabetes, HIV infection, alcohol use disorders, and smoking (77); achieving the End TB and SDG targets in Belarus requires progress on these fronts beyond the introduction of improved medication regimens such as the TB-PRACTECAL treatment or the shy adoption of digital health such as Video-Observed Treatment (VOT) application (51). These innovations only treat part of problem, despite their crucial role, a health system integrated and patient centred approach is missing. With the already established evidence supporting person-centred treatment and care models, and NTP commitment to innovative approaches (54), Belarus is in a promising position to contribute to the accelerated impact of new approaches to TB patient support and care globally in LMIC and humanitarian contexts.

* + 1. *TB model of care and the role of MSF in Belarus*

In Belarus, the NTP under the MoH, provides treatments to all TB patients, supported by international donors and NGOs (MSF, WHO, TGF). Currently, there is a mixed model of TB care, whereby the majority of TB cases start their treatment in inpatient settings, stay there during most of the intensive phase, and then complete their course of therapy in outpatient settings. The sub-optimal management of TB cases in Belarus, is associated with the high rates of MDR-TB, in addition to late-stage diagnostics, and poor infection prevention and control (78). TB burden is also associated with complex social issues such as financial instability, the presence of comorbidities, and substance use disorders, such as high rates of alcohol use disorder (AUD) (78). In Minsk, 40% of people have comorbid MDR/RR-TB and AUD, and it is identified as one of the main barriers to adherence to treatment, and a principal reason for people being sent to hospital for involuntary isolation (79). In 2014, MSF opened a project to support the NTP to improve MDR/RR-TB treatment adherence, and outcomes by providing a psychosocial support and harm reduction intervention for people with MDR/RR-TB using a person-centred approach through a multidisciplinary team of counsellors-educators, nurses, doctors, social workers and health promoters (54). This PCC intervention encompassed support on multidisciplinary level and created a safe and trustworthy environment to the person/patient. This ensures that patient’s values and autonomy guide clinical decisions, and that the patient feels empowered and in control of choices determining their experience of care. Through the PCC approach of integrated psychosocial patient support recognising the importance of social and emotional variables, building patient’s self-management skills and building relationships with patients to make decisions the individual's ability to navigate the treatment pathway is improved. Through this project MSF supported the NTP to prioritise TB determinants through an integrated approach to lessen the burden of this disease, and meet the needs of TB patients through a patient-centred plan to achieve better treatment and health outcomes for patients with comorbid MDR/RR-TB and AUD. The support and guidance from a trusted practitioner team, and from reliable loved ones, helped patients navigate the complex treatment of MDR/RR-TB and other challenges faced in everyday life. Counsellor-educators built the relationships with patients to allow them to open-up about the entirety of their needs, and helped them meet these through other health providers, with the state or administrative bodies, or with relationships with family or friends.

On implementation level, this multi-disciplinary and patient-centred approach is not only focused on TB and AUD co-morbid patients. It is available for patients managing other substance use disorders. The multi-disciplinary package of care, includes general health and harm reduction education, group education sessions, adherence support groups, support groups, harm reduction interventions, anti-craving therapy, individual counselling and social support to improve adherence to TB treatment. The table 2 below describes the components of PCC on “minimum” and “comprehensive” package during the DR-TB treatment. MSF has established care guidelines on Patient Support, Education and Counselling[[5]](#footnote-6) and Mental Health and Psychosocial Support[[6]](#footnote-7). The patient education provided includes an e-learning course, brochures, leaflets, flipbooks and booklets, which are distributed to all patients, regardless of their level of knowledge about TB. The content is extensive including: TB infection information, peculiarity of TB (DS, MDR, XDR variants), treatment methods and medication, benefits of the therapy and consequences of not following the regimen or missing DOT’s, possible side effects and duration of therapy, infection control and rules to follow (patient and relatives), general health care instructions during TB treatment and available support during TB treatment in Belarus. Complementing the education package is the psychosocial support being offered, after having screened patients for any distress by a psychologist or social worker through validated test[[7]](#footnote-8). This quality counselling, and care from a multi-disciplinary group of health professionals was largely experienced as positive by study participants (54) as well as other patients. To this end, this approach has been subsequently expanded by the NTP.

Another main MSF project implemented in Belarus, is the roll out of the TB-PRACTECAL BPaLM treatment regimen as described in section 2.2. Implementation of this regimen in Belarus with the NTP has been active as of February 2022. The results demonstrated the patient reported outcome sub-study further indicates the psychological impact of new treatment and the potential to reduce stigma and deliver more person-centred care (52).

##### Table 2: Description of the “Minimum” and “Comprehensive” package of care during the DR-TB treatment in Belarus*[[8]](#footnote-9)*

|  |  |
| --- | --- |
| **Minimum package** | |
| Patient Education | Helps the patient to understand own disease and treatment; enables to acquire and maintain abilities that allow him/her to optimally manage his/her life with this disease |
| Patient Counselling | Aims to help patients find solutions to daily problems that have a negative impact on their adherence to treatment, and to provide emotional support in difficult situations |
| Adherence Counselling | Adherence counselling goal-directed, examination and resolution of ambivalence is central purpose, and counsellor is intentionally directive in pursuing this goal |
| Patient Tracing | Activities to support TB patients to return to care after disengagement from care |
| Support Groups | Patients share experiences in a safe environment, helping them to understand that they are not alone, create awareness on shared challenges, coping mechanisms, reducing sense of isolation; building sense of community |
| Identification and management of moderate-severe disorders | Identification: All team members shall be trained in identification of symptoms of moderate-severe disorders  Management: MH specialist, prescribing clinicians shall be trained in treatment and management of MH disorders |
| **Comprehensive package** | |
| Mental Health Care | Screening, diagnosing and treating mental health problems among HIV/TB infected patients   * MH counselling sessions: especially for sensitive and/or private issues the patient does not want to discuss anywhere else * Psycho-education group: aiming to raise awareness of psychological impact people may experience and services offered (linkage) |
| Social Support | Activities aiming to address the weak socio-economic support system like offering support for transport, food, accommodation, providing information and contact of local amenities, institutions, social initiatives and self-help groups in cooperation with local organizations and authorities. |
| Other health promotion activities | Raise awareness on TB, fight stigma and promote TB services among the general population or populations at high risk for TB |

The NTP in partnership with MSF has demonstrated leadership in TB treatment and care, with expertise and experience in researching and leading integrated, patient-centred and novel interventions. Recent progress in the current system and TB regimen associated with the TB-PRACTECAL trial indicates opportune timing to build on recent evidence and stakeholder motivation to further explore integrated person-centred care beyond medication regimen improvements. This would be an opportunity to be back on track to the set TB targets for Belarus. Approaches to patient support and care may be further refined and personalised with the help of digital interventions. Through evaluation of patient knowledge there may be an option to tailor support approaches to patients based on their needs and preferences. As currently patient knowledge it is informally evaluated within counsellor interactions. The following evaluations performed within the current care pathway in addition to digitally supported understanding of patient treatment and condition understanding may offer further insights into more tailored patient support packages. A number of components of this package stand to be enhanced via the exploration of the integration of a digital patient support tool (e.g., accessible and engaging multimedia patient education, digitised counselling support and communication, medication adherence reminders and reporting based on behaviour change evidence, side-effect reporting and early remote intervention and guidance). The areas of the current support package appropriate for digital adaptation and amplification will be determined via the needs assessment process and presented as recommendations in the final report. As such exploring a DTx tool as an option for a digital health intervention is needed to further improve TB care and patients support elements in Belarus, especially for DR-TB, and thus supporting their effort in reaching the necessary targets.

* 1. *Rationale, Aim, Objectives and Research Questions*

The rationale for conducting this needs assessment is to better understand the extent to which digital patient support tools may further learnings from Belarus MoH, NTP, MSF and people living with TB regarding understanding complexities and improving outcomes of TB treatment, adherence, experience and quality of care. This needs assessment aims to provide an understanding of the profile of patients, their treatment, and self-management support needs, to identify areas for improvement which may include a digital health intervention. Furthermore, this needs assessment builds on the leadership of the Belarus MoH, NTP and MSF in Belarus in validating and scaling improved treatment regimens and models if care.

In summary, this needs assessment is grounded in the following research questions, aim and objectives.

**Aim:** The proposed needs assessment aims to provide a detailed understanding of the context-specific demand for digital health enabled patient support to enhance the current model of care for DR/DS-TB patients in Belarus.

**Research Questions:** To achieve the aim of this needs assessment the research team will strive to answer the following questions:

1. What are the self-management support and psychosocial needs of patients within the current model of care and how may these needs differ between patients on different treatment regimens?
2. To what extent may the integration of a digital health patient-support platform and/or adjacent person-centred operational improvements be feasible to enhance the model of care better assist in meeting those needs?
3. What are the key challenges and opportunities related to implementing a digital health patient-support platform intervention and/or patient-centred operational enhancements in the treatment of DR-TB/DS-TB in this population?

**Objectives: To achieve and answer the above the needs assessment objectives are as follows:**

1. Assess the needs, experiences, and perceptions of DS/DR-TB patients, clinicians and health system experts in the Belarus context with experience of the current model of care
2. Assess the feasibility of a digital support tool based on the current TB context in Belarus including information on demographic, epidemiological, technical, operational, cultural and political realities
3. Assess existing evidence, approaches and learnings from relevant patient-support initiatives
4. Assess the current TB care pathway and propose recommendations and requirements for augmented patient support and person-centred care

Through this needs assessment and its dissemination, the research team intends to provide transparent and explicable access to relevant decision makers on the concept of person-centred digital health tools for TB patients in Belarus to inform future activities

* 1. *Phase 1: Needs Assessment*

The needs assessment is intended to provide transparency and explicability to the usefulness of DTx as well as comprehensive insights into the requirements of patients engaged in MSF supported treatment for DR-TB and DS-TB in Belarus with a view to informing patient-centred operational improvement. The needs assessment considers the model of care more widely, not only focusing on the potential for a DTx in this setting but also adjacent operational improvements, which may benefit patients. The research assesses the model of care from a global perspective, including psychosocial support, TB knowledge, and education. However, the potential implementation of a DTx is a key driver of the research programme, therefore the contextual feasibility of implementing a DTx is explicitly considered within these wider needs assessment.

Further research activity in the subsequent phases will depend on and be guided by the results of the needs assessment. Phase 2 and phase 3 continuations of this research, not relevant to this protocol are documented in the Annex.

* 1. *Scope of this Protocol*

This protocol considers only “Phase 1: the needs assessment”. Potential future phases are dependent on the outcomes of the needs assessment. Any further work on developing, assessing feasibility, piloting and/or implementing a DTx in Belarus will require a more detailed subsequent concept note(s) and protocol(s) and approvals by both the MSF and Belarus ERBs.

1. Methodology
   1. *Study Design and Methods*

This needs assessment has been designed around the aim to provide a detailed understanding of the context-specific demand for digital health enabled patient support to enhance the current model of care for DR/DS-TB patients in Belarus**. A qualitative design** has been selected to understand patient, clinician and NTP perspectives on the demands for digital patient support interventions. Qualitative insights will be complemented with descriptive analysis of **secondary data** available providing the context within which these perspectives exist. Within this methodology human centred design approaches will also be used to synthesise the data and insights to provide recommendations on potential opportunities and challenges.

As outlined in Figure 3 below the proposed needs assessment uses a variety of research tools that are aligned with the areas of inquiry to deliver a flexible, participatory and exploratory benefit. Although each component of this design will be reported individually in the ultimate needs assessment report, there are cumulative dependencies between the components: the demographic profiling will be used as a pre-requisite to inform appropriately representative sampling for the semi-structured patient interviews. The stakeholder analysis components (persona development mapping, patient journey mapping, and clinical pathway mapping) will be developed in part using the data collected from interviews and existing information on the current model of care in place. Each of these components is described in further detail below.

##### Figure 3: Methodology overview

Diagram

Description automatically generated

* 1. *Demand and Experience: Primary Data Collection*

The key qualitative component of this needs assessment will be conducted to assess the needs, experiences, and perceptions of DS/DR-TB patients, clinicians and health system experts in the Belarus context with experience of the current model of care. This element will provide the basis for understanding the self-management support and psychosocial needs of patients within the current model of care and how may these needs differ between patients on different treatment regimens. **The primary data collection component** of this needs assessment has been designed to ensure that medical confidentiality and the privacy of patients are guaranteed. Further information can be found below, in the data protection section 4.6.

* + 1. Sampling

The patient **sample** projected to be required for interviews is between n=20-30 people or until saturation of information in these interviews is deemed to be reached, understood as the point in which new data gathered does not make any significant change to the coding generated (87) . This patient interview sample size may however be subject to a degree of reconsideration and adjustment based on the meaning generated through the interpretation of interview data (88). Approximately n=8 interviews with NTP and MSF experts are anticipated based on coverage of expertise associated with the investigation launch. This cohort with be engaged via a snowball sampling method. Again these interviews will be conducted until sufficient information has been gathered to assess the current model of care.

Patients supported by MSF who seek care in Minsk and other regions of Belarus will be considered for participation in the needs assessment. A **non-probability sampling method** will be used including **convenience sampling strategy** to ensure sufficient saturation can be achieved during the limited interview period of 3 to 4-weeks including both patients being treated for DS-TB and DR-TB. This convenience sampling strategy has also been selected to reduce the burden on patients and allow interviews to take place in line with pre-defined clinic interactions.

Within the convenience sample the research team aims to recruit a diverse range of patient participants to meet the study objectives for a complete view of the service. While convenience sampling will be the primary method used for patient recruitment, the research team will employ a purposive approach in order to gain a diverse sample of participants as possible. This purposive element will be guided via the demographic profiling as reference for the desired representation and include criteria including;

* TB type and treatment regimen (a diverse sample of DS-TB and DR-TB patients)
* Treatment phase (a diverse sample of early and later stage treatment)
* Age-range (reflective of diversity of clinic population)
* Ease of clinic access (ensuring a diverse sample includes participants who cannot physically attend the clinic)
* Gender (reflective of diversity of clinic population)
* Multimorbidities (NCDs, mental health disorders, SUD, physical impairment)
* Literacy (diverse range of literate and illiterate patients)

In order to achieve this purposive element, the study investigator(s) will regularly review the characteristics of already included participants from their medical record and will purposively seek participants with diverse characteristics for future interviews.

* + 1. Eligibility criteria of patients

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
* Patients living with a disability with ability to provide full informed consent and participate in an interview (89)

A pre-determined set of **exclusion criteria** will be applied when considering participants for semi-structured interviews. Patients meeting one or more of these criteria will not be eligible for participation:

* are not currently receiving ambulatory TB treatment; and/or
* are under the age of 18; and/or
* are severely ill that are not physically stable (i.e., requiring hospitalization and unable to communicate); and/or
* have an impairment or disability that may prevent full and informed consent or participation in interviews; and/or
* do not consent to the full scope of activity.
  + 1. Data Collection: Semi-Structured Interviews

The qualitative data collection element will be centred around in depth **semi-structured interviews with patients, NTP representatives and MSF staff.** Interviews will be conducted in a private room in the relevant clinic by the study investigator(s) in local languages with a supporting MSF translator. An outline interview tool for semi-structured interviews for both patients and MSF/NTP experts is included in Annex 2 and 3 respectively.

**Semi-structured patient interviews** will be used to understand patient perception and experience of treatment, self-management, general challenges and motivators related to their condition. Patient interviews while largely focused on the experience of patients, will also gauge interest and reservations in potential digital therapeutic support intervention.

**Primary data collected from the participants** through semi-structured interviews will broadly include the following:

* Living and working situation including literacy/education and existing family/friend support
* Daily routine, treatment regimen, and self-management practices,
* Actions taken to address condition related challenges
* Disease understanding and acceptance/motivation regarding condition, including confidence
* Perception/trust of care received from NTP/MSF
* Mental status/mental wellbeing
* Digital ownership (e.g., access to a phone / internet)
* Perception of existing information provided via NTP
* Perceptions of an outline patient support app
* Substance use (smoking, alcohol, other)

**Semi-structured medical team (MSF and others) interviews/NTP interviews** are 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.

* + 1. Data Collection: Patients’ characteristics

To provide an insight into the patient cohort who choose to participate in the semi-structured interview, and their representation in relation to the broader cohort's demographic composition, **consent will be gained from patients to report on aggregated demographic characteristics listed below**. This information will also be used during the coding of semi-structured interview data.

* *Demographic Characteristics*
  + Age
  + Sex
  + Main language
  + Frequency of visits to MSF supported clinic
  + Location where resident
  + Distance from clinic (where possible)
* *Medical Characteristics*
  + Treatment location/clinic
  + Treatment stage
  + Treatment regimen
  + TB diagnosis and treatment information
  + Comorbid Diabetes
  + Comorbid Hypertension
  + Comorbid HIV
  + Mental health comorbidities
  + Substance use disorder
  + Other comorbid condition
  + History of TB (self/family)

These **aggregated data will be anonymised** during and throughout data collection from the pre-existing sources and handled in a password protected database using Excel, which will also be used for analysis.

* + 1. Data Analysis

**Summary statistics** will be used (frequencies, mean, median and standard deviation depending on data type) to identify patterns in the characteristics of the patient cohort, alongside trends in these characteristics over time. Bivariate analysis will be conducted to make comparisons between aggregated demographic characteristics (age, sex, education...) looking for statistical evidence of different patterns within the patient cohort. This will include chi square tests and t-test for categorical and continuous variables as appropriate, for this analysis the R software[[9]](#footnote-10) will be used.

**Qualitative data** from patient and medical team interviews will be audio recorded, and transcribed and coded on excel. Qualitative insights will be analysed through **a grounded theory approach** to identify and search for meaning in data patterns and may also include elements of participatory action. Raw transcriptions will be considered in addition to observations made during the interview process to inform the thematic coding. This data will be stored on a secure, password protected MSF SharePoint. Consent will be gained for any anonymised collected and transfer of data. The interviews will also be analysed with consideration of the key demographic elements identified during desk research. Data management is detailed further below under confidentiality, privacy and data handling in section 4.6.

* 1. *Context: Desk Research/Secondary Data Gathering and Analysis*

Adding context to the qualitative element of this needs assessment the research team intends to assess the feasibility of a digital support tool via **secondary review of existing data on demographic, technical, operational and cultural factors.** In addition, this context building exercise will work towards the objective of assessing current evidence to learn from relevant patient support initiatives. This line of inquiry will allow the research team to understand and communicate the extent to which and in what form a patient support platform and/or operational upgrade may enhance the current model of care. The insight gathering desk research element includes a **quantitative data component** collating available descriptive demographic data sets on the patient cohort composition, which was already collected in the previous phase 3.2. It will be complemented to existing descriptive data sets on technical (e.g., internet and mobile phone ownership coverage), cultural (e.g., prevailing belief systems) and operational (e.g., geographical scope of current stakeholder activities) data sets which may be available via the NTP, MSF, WHO, TGF; and other relevant stakeholders. Altogether, this data will enable baseline orientation for the contextual analysis. Data collected for secondary analysis in the initial data gathering will specifically include routine programme data and existing aggregated demographic data publicly available on TB in Belarus for the purpose of demographic profiling of DS-TB/DR-TB cohorts in Belarus. Other sources which will be referenced to profile the Belarus demand and cohort will include the WHO Global TB Report (4) .

Furthermore, within the desk research insight gathering **literature review of digital and non-digital approaches** for DS-TB/DR-TB patient support and their influence on improved outcomes and experience will be conducted to further understanding of best practices. The literature review search strategy will include systematic and scoping reviews and original published research on interventions in TB care. Search terms will include: TB models of care, TB psychosocial support, patient centred TB care, digital health TB, digital therapeutics TB, and Tuberculosis care. Grey literature such as WHO reports, Global Fund resources will also be included. A first draft of the literature review is available in the Annex 4 of this protocol and will be updated for the final report as the research team’s understanding expands

**A technical landscape review and comparative analysis** of existing digital health tools and approaches for DS-TB/DR-TB patient support intended to provide insight into technical practices and their associated impact achieved to date will also be included. These digital tools may be developed by commercial entities, Governments, NGOs or international organisations. Tools developed or delivered to patients in therapeutic areas beyond TB may also be considered where relevant (e.g., medication adherence reminders for Diabetes or psychosocial support tools for mental well-being).

The **variables** to be included in this comparative landscaping exercise will include:

* Name of the intervention
* Associated organisations or entities
* Target population
* Therapeutic area
* Evidence of impact
* Location
* Features

Through the **triangulation** of the aforementioned desk research elements, it is anticipated a useful overview of both established standards of TB care and support and emerging approaches which may support improved patient experience and outcomes will be available to guide the subsequent insight generation and validation.

* 1. *Synthesis: Human Centred Design Pathway Mapping*

The final element of this needs assessment design will include **developing personas to represent the key stakeholders** (both patient and healthcare provider), **mapping patient and clinical pathways** and validating findings and results with a limited sample of patient, NTP and MSF representatives. This **human-centred design process** has been selected to support the synthesis of information from the preceding stages, demonstrating the recommendations and requirements for subsequent developments.

The purpose of this element of the needs assessment is to highlight the key characteristics and experiences of patients undergoing TB treatment supported by MSF and the NTP and the recurrent challenges and enablers faced by patients and supporting clinicians. The personas and pathways developed will be specific to the Belarus context and support robust understanding of where a DTx intervention, or other patient-support intervention, may be relevant and where challenges may be anticipated.

**Persona development** is a user-centred design technique that involves creating semi-fictional characters that represent the needs, goals, and behaviours of different groups of users within a health system (79) . The personas to be developed as a part of this needs assessment will be based on research and data on the cohort characteristics, attitudes, and needs expressed. Personas are used as a tool to help health system implementers and researchers to understand the perspective of those intended to benefit and use a health service and create more user-centred designs (80) . Personas are often used to aid teams to empathize with users and identify potential demands and opportunities for improvement in the design of a new health system or service or operational improvement.

**Patient journey mapping** in healthcare services is a process of understanding and documenting the different stages that a patient or other user goes through as they interact with a healthcare service, from their initial awareness of the service to their post-use evaluation. This includes understanding the emotions, pain points, and decision-making that takes place at each stage (81) . Journey mapping allows teams to identify areas where patients or other users may be experiencing frustration or confusion, and to design solutions to improve the overall experience of the service. Patient journey mapping is an increasingly popular approach to evaluating the experiences of individuals as they navigate complex and dynamic health services and systems (82) . The goal of journey mapping is to create a detailed map or visual representation of the patient experience, from the patient's perspective. Patient journey mapping methods are used almost always, placing individuals at the centre of the research in attempts to both understand and improve the experience of the individual and the systems that they navigate (83–86) .

**Clinical pathway mapping** is a process used to create a detailed plan of care for patients with specific conditions or undergoing specific procedures. The process involves identifying the most effective and efficient course of treatment for a patient, taking into account the patient's individual needs, as well as available resources and guidelines. The final outputs of this section will be refined in any subsequent research phases.

1. Ethical issues

The study will be conducted in accordance with the World Health Assembly of 1975 concerning ethical aspects in human tests, and with the Helsinki declaration.

The fundamental ethical dimensions of non-maleficence, autonomy, justice, and beneficence will be closely considered and used to guide the methodology of this needs assessment and to guide resulting recommendations (80,81).

* 1. *Ethics and Regulatory Review*

The protocol is intended to be reviewed and approved via the MSF Ethics Review Board (ERB) and to a local ERB in consultation with NTP partners.

* 1. *Commercial Implications*

During assessment phase commercial implications are not anticipated for the DTx.

* 1. *Expected Benefits*
     1. Humanitarian Benefit and Benefit to the Community

While no significant 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 as they are used to inform person-centred operational improvements. Patients participating in the interviews may experience a perceived benefit by means of having the opportunity to contribute their perspective and experience to improve future treatment intervention.

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. There is also an 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.

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 study 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.

* + 1. Organizational Benefits

For the organisation, it is hoped the needs assessment will provide an 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 the 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.

Ultimately, successful implementation of a DTx will aim to improve clinical decision making, reduce complications, improve adherence and attendance (improving the efficiency of the service) and generate learning to be applied to other contexts and for other organisations to benefit from. The use of digital therapeutics offers an opportunity to deliver benefit to more patients, including those with poor access to care, within a context of low resources. Generating and sharing high quality learning from implementing innovative models of care can increase the organisations humanitarian and scientific credibility.

* 1. *Potential Risks and Harms*

This is a complex project and research process which gives rise to a range of potential risks and harms. The risk framework includes:

* Risks to participants and data collectors
* Risks to the project itself
* Potential harms arising from carrying out the project
  + 1. Risks to Participants and Data Collectors and Mitigations

Participation in the project may influence healthcare access and treatment course and duration. As with all MSF clinical operations, patients will be tested and treated as per clinical protocols and any sick individuals will be referred for health care through existing structures.

All relevant COVID-19 precautions will be implemented during the interviews and focus group sessions. Masks will be provided to the interviewer and the responder and appropriate distance will be kept between the two. For qualitative data collection ventilation and distancing will be used on top of personal protective equipment (PPE) measures for all participants and data collectors.

* + 1. Risks to Achieving the Project’s Objectives and Mitigations

|  |  |
| --- | --- |
| **Risk** | **Mitigation** |
| Other emergencies (higher likeliness: COVID-19, political instability, displacement and conflict, supply issues) could limit the resource the existing teams can dedicate to the project | Depends on the severity of the emergency and the main tasks to accomplish; for example, demands on staff time.   COVID-19-specific: Clinical operations/programmes have adopted appropriate measures to enable clinical management of patients in a way that is safe for both patients and staff. Data collection will be conducted with masks/social distancing if necessary and the maximum number of attendees with respect to COVID-19 restrictions will be respected. |
| Clinicians might feel overburdened with the addition of new data collection if proper support is not given | Details of the data collection will be shared with staff. It is not anticipated additional time will be required by staff not participating in the project. Clinical staff will be made aware of the needs assessment and asked for consent to participate. |
| Patients facing insecurity may be reluctant to engage with the needs assessment | Participants will be given information in advance on the requirements of participation and will be supported throughout by the project team. |
| Inability or unwillingness of MoH or other stakeholders to engage in a collaborative effort | Stakeholders will be approached for collaboration at the outset of the project, including the MoH through ERB submission, and communication will be maintained throughout. It is hoped strong local links with MoH and other local stakeholders will be leveraged to improve collaboration, including with NTP. |
| Changing patterns of healthcare access reduce the ability of the clinics to complete the needs assessment | The MSF presence in Belarus is well established, and any operational changes that impact the project will be notified to the project team. |
| Interview fatigue due to treatment, condition, workload or previous requests to participate in similar interviews. | During the interview invitation process and consent process participants will be informed that they may pause or discontinue the interview at any stage. |

* + 1. Potential Harms Arising from Carrying Out the Project

The research programme following needs assessment, ultimately seeks to develop a DTx to enhance the existing NCD model of care and improve patient outcomes, however this protocol relates only to information collection during the needs assessment phase. As part of this, Patients are not asked to perform any tasks that could result in physical harm.

Participants will be asked to provide information about their insights on their TB treatment, their experience, and socio- economic information. These questions may be associated with emotional distress in the recall of challenges experienced. This will be mitigated as participants can decline answering questions they do not wish to answer and can withdraw from the interview at any time. 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.

Conducting the needs assessment requires resources, including financial and staff time, for which there is an opportunity cost, and this will be closely monitored. It is not expected that the implementation of the research elements of the project will divert staffing or resources away from the existing service. As a healthcare provider for these vulnerable populations, MSF has a responsibility to maintain the provision of care and will be careful to ensure the needs assessment does not impact on this delivery.

The introduction of a new way of delivering health promotion, education and monitoring may not align with other initiatives, such as those being delivered in the area by other stakeholders or MoH, creating duplication or confusion. This will also be closely monitored, and communication will be maintained with other stakeholders throughout the project.

Assessing the model of care and communicating the results in this setting carries an organisational risk, including a harm to the organisation’s reputation through the publication of reports of a poorly conducted study or through local reputation as a healthcare provider of choice. Communication with stakeholders and the community about the experimental nature of the research programme will be paramount.

* 1. *Obtaining Informed Consent*

Informed consent will be gained from participants in all relevant phases of the project, and written consent will be obtained from patients, MSF staff, and NTP staff before each interview as a pre-requisite. Routinely collected baseline clinical data will only be accessed with explicit consent. The participant information sheet and consent form are provided in Annex 1. Consent will be sought for all stages of the research programme, and participants will be offered the option to withdraw at any stage, at which point their information will be deleted.

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. It will also be made clear to staff members that participation will not jeopardise their employment or participation in the service in any way. It will be made clear to participants that any information they are not completely comfortable sharing is not required.

With consent of staff member participants, participant names and roles may be associated with collected insights, however this will only be with explicit consent for a particular insight (data from staff interviews will otherwise be anonymised).

* 1. *Confidentiality, Privacy and Data Handling*

Information about participants will be handled in accordance with established MSF protocols, and accessible only to project administration staff for the purposes of conducting the study, and written consent will be required for this. A data sharing agreement will be formulated as appropriate with guidance of the NTP, MSF project team and OCA Data Protection Officer. An MSF translator will be present during the patient interviews. The relevant translator will sign an NDA to ensure full protection of patient acquired information.

A number of steps will be taken to protect confidentiality and privacy of all those involved in the primary data collection via interview:

1. To create a database for storage with limited access provisioning and specific data retention schedule.
2. Deidentification of data collected from participant interviews
3. Secure data collection e.g., 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

Data collected from quantitative and qualitative components will be anonymised and coded to be handled anonymously throughout the analysis and reporting stages. The transcripts will be stored on MSF servers for the duration of the project after which they will be deleted. Measures to identify and modify individual datasets upon request are in place. Participants can access their own health data at all times. According to Belarus Law on Healthcare (LoH, 18 June 1993 2435-XII), data transfer can only be done on the basis of consent. The relevant consent forms include notification that transfer outside Belarus might take place and that participants can decide to opt-out based on informed preference.

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. Data will be handled in accordance with local regulation in Belarus, including but not limited to the Personal Data Protection (PDP) Law. A number of legislations may be applicable, some of which overlap with the basic principles of GDPR. One legislation relevant for continued consideration is the Belarus e-Health concept, which is currently under development – intended to regulate information technology for remote interaction between healthcare specialists and patients. Guidance will be sought from local NTP partners to support the interpretation and implementation of local data protection regulations.

* 1. *Collaborative Approach and Involvement of Stakeholders*

All participants in the needs assessment will be informed of the objective of the study to achieve informed consent. Participation in the study will be voluntarily end to end. 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

The project will be conducted in collaboration with the NTP. The NTP and MSF representatives will contribute to the development of the semi-structured patient interview guide. Established relationships between the MSF team in Belarus and local partners will be leveraged to communicate proactively about the intervention, the nature of the research programme, and to update on findings or changes to models of care as appropriate.

1. Project Team

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1. Timeline

* 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 preparations
* January-February 2023: Desk research elements (literature review, technical landscape analysis, context mapping, demographic profiling)
* February/March 2023: MSF and Belarus ERB feedback/approval
* April 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 Health Adviser input
* June 2023: Move into the next phase as determined by needs assessment findings (e.g., further dissemination, intervention development/adaptation etc.)

1. Dissemination Plan
   1. *Internal to MSF*

The 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.

* 1. *Community*

The 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.

* 1. *External to MSF*

The NTP who is a part of the immediate project team will have access to the reported and summarized findings of this needs assessment, to enable collaboration towards indicated operational upgrades.

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.

1. Security

Political instability might cause the project to be delayed, interrupted or postponed; conflict and instability cannot be predicted in advance. This will be monitored and responded to appropriately, following established MSF security protocols. If the project is delayed or cancelled due to insecurity, the MSF Project Coordinator/Medical coordinator will communicate this to the PI. The Project Coordinator will also communicate this to the project team working in Belarus.

1. Funding

This needs assessment will be funded via MSF [Transformational investment Capacity](https://msf-transformation.org/) incubator funding allocated from 2022-2024. This funding is also available for potential phases continued on from the needs assessment findings including resources required for research, technical development, patient education materials and publications.

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# Annex 1 – Participant information sheet and consent form

Participant information sheet and consent form

**Assessment team:**

**Hanna Phelan, Médecins Sans Frontières (MSF) Sweden Innovation Unit**

**Translator TBC**

Dear [Name],

You are being presented with the option to take part in this assessment because you are a current patient being treated for Tuberculosis (TB) via the National Tuberculosis Programme of Belarus with support from MSF. Before you decide whether you want to be a part of this interview, we would like to share more information and give you the opportunity to ask some questions and make an informed decision on your participation.

This consent form gives you information about this assessment, which will be done at the clinic you visit for your regular consultations. Please feel free to ask questions and discuss any concerns you may have with the assessment staff. If you agree to take part in this assessment, you will be asked to sign this consent form.

If you do not know how to sign, you may provide verbal consent. Please note:

* Your participation in this needs assessment is entirely voluntary. You may decide not to participate in the assessment, and it will not affect your medical care at any point
* If you do decide to participate in an interview you can choose to withdraw your participation and any information already provided at any point
* You may be asked some follow up questions during subsequent visits to the clinic or over the phone. By signing this consent form, you agree to be re-contacted for the purpose of this assessment. You may deny any follow-on participation at any point.
* If you have any questions while taking part in this assessment, you should contact the MSF team on the contact provided

**Why is this assessment being done?** This assessment is being conducted to gain a better understanding of the experience and needs of TB patients receiving NTP/MSF supported care in Belarus. We would like to explore your opinions regarding your health, daily routine, challenges you face, and the care provided in order to TB services and ensure they are favourable for patients. One potential use of this information is to guide the development of mobile health application for treatment support and understanding. If you agree to participate, we will use your answers from this assessment, on your experience of your condition and your preferences for treatment and support, to design and develop the features and content of an improved patient support service and to consider how the services provided may be improved generally to support patients.

**What is involved in this assessment?** This assessment will consist of a 30 minute to 45-minute interview with questions relating to your health, care provided and your preferences for how we may be able to improve TB services in the future. This interview will take place in the location you typically receive your care. The person conducting the interview is Hanna Phelan from MSF. You will also be joined by an MSF translator at the clinic to allow for the interviewer to understand your responses. With your permission the conversation will be audio recorded for the research team to listen back to after the interview to ensure no insight you share is missed. This audio file will only be accessible to the direct research team and will contain no identifiable information. Once the information has been gathered from this audio recording the file will be deleted.

**What are the risks of the assessment?** We do not anticipate any risks. Please take care not to disclose information you are not comfortable sharing, and please note that you can withdraw from this assessment at any point should you wish to do so. Whether or not you participate in the assessment, and if you later decide to withdraw, this will not impact your care or your right to receive treatment.

**What about confidentiality?** You will be assigned a unique participant code number, and answers given throughout the assessment will be linked to that code and separated from your name or any other information that could identify you. No identifiable information will be shared following the interview.

Transfer of anonymised data collected to a location outside of Belarus may be required during the process of analysis and reporting. You can choose to opt-out of this if you are in any way uncomfortable with this.

**The assessment, including the above information, has been described to me orally. I understand what my involvement in the assessment means and I agree to be re-contacted for the purpose of this assessment.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Participant**  **Signature of Participant**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date:**  **Date:**

**Verbal record of Participant,** **Witness**

**only if unable to sign** **if verbal record is taken**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of MSF staff**  **Signature of MSF staff**  **Date:**

MSF/NTP staff information sheet and consent form

**Assessment team:**

**Hanna Phelan, Médecins Sans Frontières (MSF) Sweden Innovation Unit**

**Translator TBC**

Dear [Name],

You are being presented with the option to take part in this assessment because you are a current stakeholder [mention if with MSF or NTP] working on TB in Belarus. Before you decide whether you want to be a part of this interview, we would like to share more information and give you the opportunity to ask some questions and make an informed decision about your participation.

* Your participation in this needs assessment is entirely voluntary. You may decide not to participate in the assessment, and it will not affect your medical care at any point
* If you do decide to participate in an interview you can choose to withdraw your participation and any information already provided at any point
* You may be asked some follow-up questions at a later stage. By signing this consent form, you agree to be re-contacted for the purpose of this assessment. You may deny any follow-on participation at any point.
* If you have any questions while taking part in this assessment, you should contact the MSF team on the contact provided.

**Why is this assessment being done?** This assessment is being conducted to gain a better understanding of the experience and needs of TB patients receiving NTP/MSF supported care in Belarus. We would like to explore your opinions regarding the challenges, and barriers, as well as the benefits of the TB care, services and activities provided. One potential use of this information is to guide the development of mobile health application for treatment support and understanding. If you agree to participate, we will use your answers from this assessment, on your experience to design and develop the features and content of an improved patient support service and to consider how the services provided may be improved generally to better support patients.

**What is involved in this assessment?** This assessment will consist of a 30 minute to 45-minute interview with questions relating to the stakeholders and TB services and care in Belarus, and your preferences for how we may be able to improve TB services in the future. This interview will take place in the location of your choice (either relevant clinic or your office space). The person conducting the interview is Hanna Phelan from MSF. You will also be joined by an MSF translator to allow for the interviewer to understand your responses. With your permission the conversation will be audio recorded for the research team to listen back to after the interview to ensure no insight you share is missed. This audio file will only be accessible to the direct research team and will contain no identifiable information. Once the information has been gathered from this audio recording, the file will be deleted.

**What are the risks of the assessment?** We do not anticipate any risks. Please take care not to disclose information you are not comfortable sharing, and please note that you can withdraw from this assessment at any point should you wish to do so.

**What about confidentiality?** You will be assigned a unique participant code number, and answers given throughout the assessment will be linked to that code and separated from your name or any other information that could identify you. No identifiable information will be shared following the interview.

Transfer of anonymised data collected may be required during the process of analysis and reporting. You can choose to opt-out of this if you are in any way uncomfortable with this.

**The assessment, including the above information, has been described to me orally. I understand what my involvement in the assessment means and I agree to be re-contacted for the purpose of this assessment.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Participant**  **Signature of Participant**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date:**  **Date:**

**Verbal record of Participant,** **Witness**

**only if unable to sign** **if verbal record is taken**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of MSF staff**  **Signature of MSF staff**  **Date:**

# Annex 2 – Semi-structured interview tool (patients)

**Patient Interview Semi-Structured Guide**

**Topics covered in this interview include:**

* Living situation
* Condition understanding
* Family support
* Friends support
* Work situation
* Perception/trust of care received from MSF/NTP
* Literacy level/time spent in education
* Acceptance/motivation of patient regarding condition
* Mental status/mental wellbeing
* Phone ownership/connectivity etc.

1. **Can you please share some detail on your background?**
2. Name
3. Age
4. Education/work background
5. Family
6. When were your diagnosed with TB?
7. When did you start working with this clinic to treat your condition?
8. Did you have any personal experience with TB before you started your current treatment? If so, what was this experience?
9. **What is a typical day like managing your health?**
10. What actions do you do to manage your condition?
11. What changes have you made in your daily life since the start of your treatment? What was the most difficult? What was the most satisfying?
12. What is most challenging about managing your health each day?
13. What TB medications do you take? How often? Is this something you find challenging to keep track of?
14. Can you please list any other diagnosed comorbidities you may have? What medications do you take for them?
15. What is your living situation?
16. How do you travel to the clinic when required? What does this journey entail?
17. How does your home environment impact how you manage your health?
18. Are there any specific challenges or obstacles you face when it comes to maintaining your diet, exercise or sleep?
19. Is there anything in your home environment that makes it easier or harder to manage your health?

**III.** **We want to know a bit more about your physical health and emotional journey since you were diagnosed**

1. What have you found most challenging since you started treatment?
2. Is there something you can feel proud of or a success you achieved since your treatment started?
3. How do you feel about your health-condition?
4. What are your thoughts and feelings about the treatment plan you are on?
5. What concerns do you have about managing your condition?
6. Are there any specific goals or motivations that you have or plan to achieve during your treatment?
7. Are there any additional resources (such as social support) that you believe will be or currently are helpful while managing your condition?

**IV.** **How useful have you found the information provided to you in managing your health?**

1. What resources or information did the NTP and/or MSF provide to you during your appointments?
2. What information or types of information did you find most interesting or useful?
3. What kinds of resources or information were you given to bring home after the appointment?
4. What kind of information would you most like to receive from your medical team?
5. Was there anything that you thought was missing?
6. How challenging do you find it to remember what has been recommended to you by your medical team?

**V.** **How many appointments per month do you have? How confident do you feel managing your health between appointments?**

1. If you feel you need help, more support or information what do you do?
2. Where do you get most of your information about your condition? Do you search the internet about it?
3. Do you currently have a way to connect with the NTP/MSF or a healthcare professional if you need help or support?
4. Please describe the distance you have to travel to the clinic for your appointments and means of travelling that you typically use to get there.

**VI.** **We are exploring launching a mobile app to support you to manage your health between clinic visits:**

1. What is your initial reaction to this idea?
2. To what extent would you be interested in a mobile application to support your health management?
3. If we were to develop a mobile app for you and other patients in Belarus undertaking treatment, what would you like this to help with?
4. Is there anything that you would be concerned about if we did launch an app like this?
5. What kind of content would you like on here e.g., video, voice, animation?
6. Where do you currently find information on your condition?
7. Do you currently use, or have you previously used, any mobile tools to manage your condition e.g. video observed therapy?
8. How do you currently remember when to takes your prescribed medications?
9. What motivates you to manage your condition?
10. If you feel demotivated or overwhelmed, what do you do?

**VII.** **How comfortable are you with navigating the internet and using a mobile phone or a computer?**

1. Do you have access to the internet? (Examples: mobile data, wi-fi, broadband) at home? How do you access the internet?
2. Do you have a smartphone or tablet? Do you have a computer or laptop? (If not: how do you navigate the internet?)
3. How often do you experience connectivity issues?
4. How confident, comfortable do you feel navigating the internet?
5. Do you use mobile apps? (If yes: could you mention some that you use?)
6. Do you use social media platforms like Facebook, YouTube, Twitter, Instagram, TikTok? Which platforms? from the ones mentioned, what do you usually use those platforms for?

**VII.** **Anything else you would like MSF to think about as we work to improve how we help to support patients like you?**

1. Any questions we didn’t ask that you think we should have?
2. Are there any questions you have about this assessment or your condition or care received?

# Annex 3 – Semi-structured interview tool (NTP/MSF staff)

1. **Overview of current reality of NTP/MSF TB services**
2. Who are the key stakeholders or roles involved in the care and support of TB patients?
3. From your experience how would you describe the current quality of treatment and support for TB patients in Belarus?
4. How is quality of care measured for these patient cohorts?
5. From your perspective what works particularly well in the current system?
6. What is is/are the greatest pitfalls or challenges in the current system?
7. What are some of the most important data points collated to understand a patient's health status and the progression of their condition over time?
8. Tell me about the typical referral systems and channels of communication that are necessary for TB patient care?
9. **Understanding the Patient Pathway**
10. Please describe the typical way in which you commence a treatment plan with a new TB patient.
11. How are TB patients supported to manage their condition in the clinic?
12. When patients are at home how are they encouraged and/or supported to self-manage their condition?
13. What information is provided to TB patients by their NTP/MSF medical team and how is this information typically communicated?
14. What type of information does a TB patient usually report back to their NTP/MSF care team or point of contact?
15. What is the typical frequency of interaction between the NTP and a TB patient and their caregivers?
16. What do you think is the greatest challenge when supporting a TB patient?
17. What works particularly well in the current system?
18. What information would you like to have more access to in managing TB patients?
19. How do you encourage a healthy lifestyle for TB patients?
20. How do you support mental wellbeing for TB patients?
21. **TB Digital Health and Innovation**
22. Are you familiar with any TB digital health or innovative approaches to TB management?
23. If MSF was to launch an app to support TB patients, what should this look like?
24. What are the key self-management tasks that you would like to further support patient with between clinic appointments?
25. What would you be most concerned about if this was to happen?
26. What element of a potential app would be most interesting to you?
27. Are you aware of any exemplary models of care integrating patient apps for TB that MSF may benefit from emulating?

# Annex 4 – Draft of the literature review of the Needs Assessment

**Introduction**

The literature and desk review are part of the data collection part of the needs assessment. The below section details the literature search done on the epidemiology of TB globally and in Belarus and the digital and non-digital approaches for DS-TB/DR-TB patient support and their influence on improved outcomes and experience. It highlights the need to challenge the current model of care into a more comprehensive treatment regimen. This would include a holistic and patient-centred approach coupled with a digital tool, to improve patients' outcomes and support in reaching the EndTB and SDG targets. The literature review compiled so far offers an overview of the current gaps existing in health systems, and how innovative approaches such as integrated patients centred designs and digital health can support in enhancing the current models of care. Then it examines the burden and social determinants of TB globally and in Belarus specifically, providing evidence to the demand for innovative approaches in TB care. This will be confirmed with the results and analysis from the stakeholders (patients, healthcare providers and others) interviews. The literature review will be continually updated throughout this needs assessment and will be complemented with the technical landscape review and comparative analysis of existing digital health tools and approaches for DS-TB/DR-TB patient support intended to provide insight into technical practices and their associated impact achieved to date will also be included as mentioned in section 3.1. This section complements the background information presented in the introduction (Section 2).

The methodology used was a literature review done by first searching the scientific literature for peers reviewed original articles, systematic and scoping reviews, as well as looking into the grey literature such as WHO reports, Global Fund resources, DTx alliance website and other TB related sources. Additionally, searching for the theory behind the concepts relevant to our intervention such as the patient-centred approach, innovation and digital tools in healthcare, was done. The main search terms used are TB social determinants, TB epidemiology, TB interventions, digital health TB, digital therapeutics TB, and Tuberculosis care.

**Literature review body**

**Gaps in current healthcare systems and the need for integrated patient-centred care**

Health outcomes remain unacceptably low across much of the developing world, especially in low resources and conflict settings. This can be attributed to the persistence of deep inequities in health status across and within countries. At the centre of this human crisis is broken health systems in many countries (82), which has been yet again demonstrated during the COVID-19 pandemic. Health systems resilience are beyond achieving certain goals or pre-set outcomes, rather describing the ability to adapt and transform in responding effectively to unanticipated or chronic crises (83). Much of the burden of disease can be prevented or cured with known, affordable technologies. The problem is getting drugs, vaccines, information and other forms of prevention, care or treatment – on time, reliably, in sufficient quantity and at reasonable cost – to those who need them. In too many countries the systems needed to do this are on the point of collapse, or are accessible only to particular groups in the population (82). This is exacerbated by the worldwide shortage in healthcare workforce especially in low and middle-income countries (84). Health gaps can have a range of consequences not only undermining the health of individuals, families and communities while failing to reach the SDGs, but global security and economic development are at risk (84).

Current healthcare systems are for the most single disease–oriented, with inadequate response to patients with complex care needs. Those needs are not only relative to the morbidity(ies) of the patient, but are on the continuum of social, financial, mental and wellbeing aspects of their lives. This results in additional burden on patients and their caregivers, often related to adverse patient outcomes, lower quality of life and well-being (85), less satisfaction with care, and eventually a greater risk of mortality and increased healthcare utilization and cost (86). Patient-centred care (PCC) or “person-directed care”, or “person-focused care” are common terms frequently used interchangeably. Such concept has the potential to make care more tailored to the needs of patients. It can be defined as “providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions” (22). This concept integrates the preferences, values, and beliefs of the person into the process of decision-making, producing a treatment plan that is both appropriate and meaningful for the patient. It supports the role of patients making informed and active choices, rather than remaining passive recipients of their care (85). Patients are partners with their health care providers, and providers treat patients not only from a clinical perspective, but also from an emotional, mental, spiritual, social, and financial perspective (87). This approach to health care decisions and its importance in quality of care is becoming increasingly accepted as playing a central role in healthcare delivery. This concept is now at centre stage when it comes to high quality health care delivery, especially in factors such as enhancing patient satisfaction, greater job satisfaction among healthcare professionals, increased quality and safety of care, and greater quality of life and well-being of patients, reducing admissions, readmissions, and length of hospital stay. Previous studies have investigated patients’ perspectives on PCC and distinguished eight dimensions: (1) patients’ preferences, (2) information and education, (3) access to care, (4) emotional support, (5) family and friends, (6) continuity and transition, (7) physical comfort, and (8) coordination of care (88). An additional layer to patient centred care is the co-creation of care with patients, which goes a step further in establishing a productive, timely and accurate interaction between patients and healthcare professionals (89). Making care for chronic conditions more patient-centred is expected to enable patients to manage their own health and quality of life, thereby improving their physical and social well-being and satisfaction with care (90). There is not a one-size-fits-all approach to person-centred care, rather, approaches should be grounded in the reality of how people navigate the pathway from symptoms to cure (91). Figure 4 below shows the different elements of patient centred-care. From a health systems perspective patient-centred care is intertwined with integrated health care. Integrated care is often contraposed to fragmented and episodic care, and it is used synonymously to terms like coordinated care and seamless care, among others. However, there is no unifying definition or common conceptual understanding of integrated care, which is most likely a result of ‘the polymorphous nature of integrated care itself’ (92). In effect, the perspectives that construct the concept are likely to be shaped by views and expectations of various stakeholders in the health system (Figure 5) (93). Based on the variety of perspectives and concepts, three principal definitions can be distinguished from the literature (93), all of which are centred on the needs of individuals, their families and communities:

1. A process-based definition used by many national governments in order to understand the different components of integrated care. It is a set of methods and models on the funding, administrative, organizational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors. This definition is rather a mechanistic one, as integrated care is seen as a set of interconnecting processes rather than something that has a specific meaning or value to the end user.
2. A user-led definition that supports a defining narrative and purpose for integrated care strategies at all levels of the system. It highlights the importance of population and individual needs in design, implementation and evaluation of integrated care models. The definition has been accepted nationally as the narrative for cross-governmental efforts by the Government of England.
3. A health system-based definition as used by WHO Regional Office for Europe. Integrated health services delivery is defined as an approach to strengthen people-centred health systems through the promotion of the comprehensive delivery of quality services across the life-course, designed according to the multidimensional needs of the population and the individual and delivered by a coordinated multidisciplinary team of providers working across settings and levels of care (93). This definition adopts a health system perspective and uses the term ‘integrated health services delivery (IHSD)’, acknowledging that integrated care is achieved through the alignment of all health system functions and effective change management.

Figure 4: Patient-Centred Care: Patient at heart of care continuum. Patient goals & values top priority. Family involved at every stage (87)

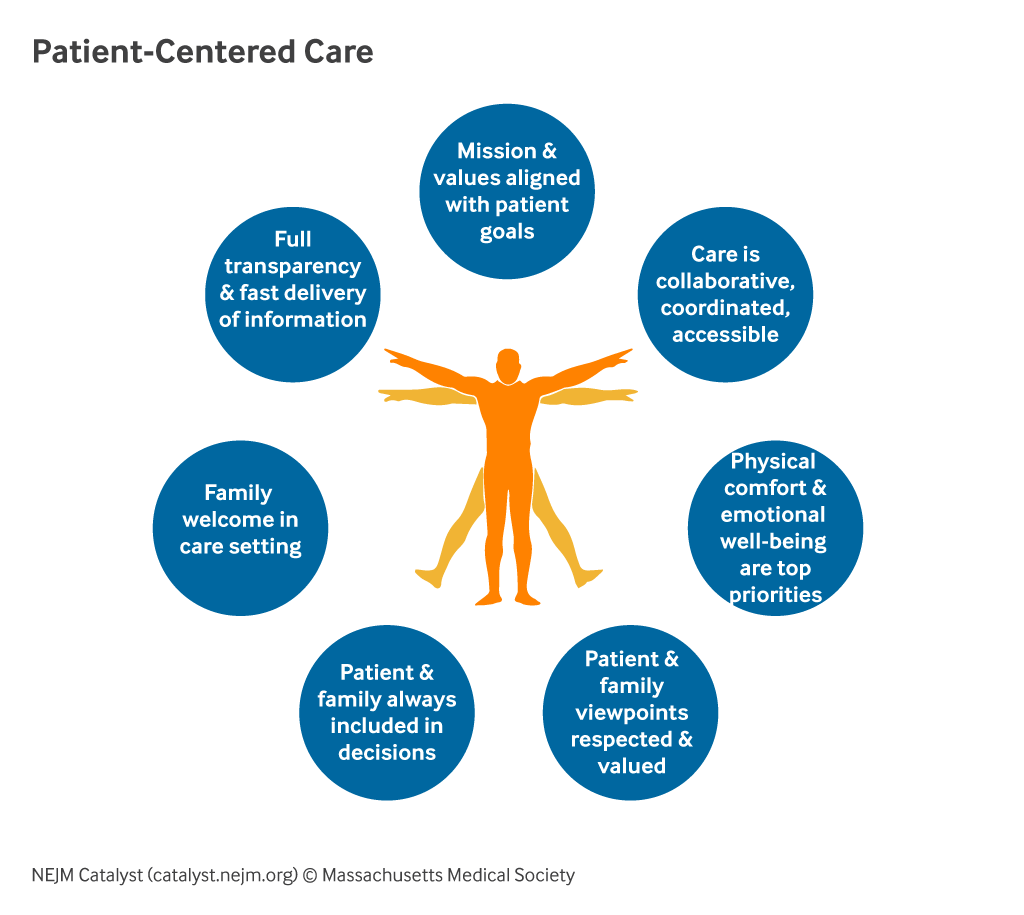
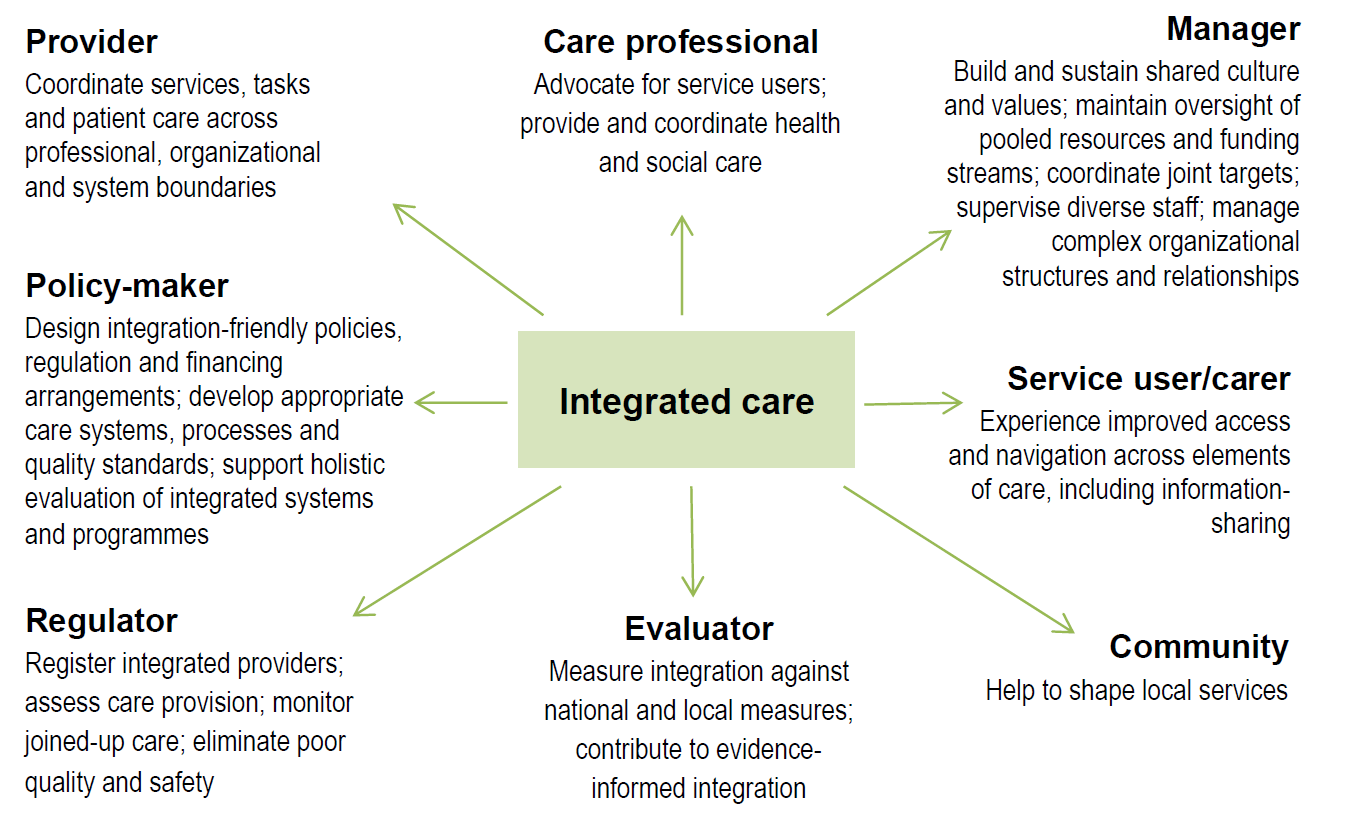


Figure 5: Perspectives shaping integrated care (93)



In many health systems, integrated care is seen as a possible solution to the growing demand for improved patient experience and health outcomes of multimorbid and long-term care patients (93). Therefore, both Person-Centred and Integrated Care (PC-IC) as central components of quality of care are identified as the way to go for treating multi-morbidities and patients with chronic diseases and complex care needs (93–95). A PC-IC process is believed to enhance both technical and patient-experienced quality of care to produce the triple aim (94) of improved care experience, health, and function, as well as cost-benefit ratios. The successful reorientation of health services will most likely be a long journey and will need sustained political commitment (96). Ultimately, each country or local jurisdiction needs to set its own goals for integrated and people-centred health services, and develop its own strategies for achieving these goals. The strategies must respond to the local context, existing barriers and the values held by people within the State or area, and should be achievable given the current health service delivery system and the financial and political resources available. Efforts should primarily concentrate on improving access to services for underserved and marginalized populations, on placing increased emphasis and resources on promotive, preventive and public health services and on strengthening district-level health services, among others (96). While such a transformation is a long road the role of humanitarian and non-governmental organizations, and development partners is to advocate for more people-centred and integrated health services, seek to integrate their support to health service delivery into countries’ own health systems, and share technical knowledge about different approaches to promoting more people-centred and integrated services (96). Albeit the role of such organizations could be to start implementing PC-IC as part of their programs to support and encourage governments in this road all while enabling patients.

**The need for digital health interventions for integrated patient centred care**

With the shift towards a more PC-IC models of care and health systems care providers are increasingly adopting information and communication technologies (ICT), i.e digital health tools, in their practices (97). Digital health interventions are not a replacement for existing health systems, but enhance healthcare services delivery on the continuum of care from awareness, prevention to care (25). It is a component in a multipronged approach to address issues related to barriers of access to essential healthcare (26). It has been established as a valuable tool for a more inclusive and PC-IC care model, supporting patients' goals and improving health outcomes (98). Digital health services aim to also improve the effectiveness and efficiency of healthcare through innovative approaches and strengthen the opportunities for self-care, self-management, and patient participation. These services span different tools from access to health information online, solutions for awareness, prevention, and health promotion, and electronic medical health records that can be shared with patients and accessed by different health care providers. There is also the component of self-monitoring and self-management tools that allows patients to collect a wide range of health-related data outside the clinic, while educating them about their health, and helping them manage their illness with quick actionable insights from their caregivers. Moreover, online consultations and telemedicine has been gaining popularity (26). The digital health environment offers a plethora of approaches relevant to different conditions, yet the tools seem fragmented as it focuses on one component of healthcare (awareness, promotion, teleconsultation...) and often one morbidity. This disregards the fact that digital health tools are to supplement integrated and patient-centred approaches. This is where Digital therapeutics (DTx) emerged encompassing all those components, as patient support platforms used to encourage long-term behaviour change associated with chronic conditions. DTx incorporates health promotion and educational materials, self-managing and monitoring components, and to the team of healthcare providers. It is made to address complex cases and multi-morbidities cases. It brings together a bundle of digital (patient facing mobile platform and clinician dashboard) and in-person health management components including clinic appointments and community based and peer support. It can also exist as a standalone intervention not associated with formal clinical care. The COVID-19 pandemic has been a driver of implementation for the use of digital tools, which served society and supported the sustainability of healthcare systems during a crisis (26). Many patients and healthcare professionals who were hesitant to use eHealth[[10]](#footnote-11) services, now see the need to learn, implement and adapt. Nevertheless, many patients choose not to use them (99). eHealth services can increase the digital divide (100) for lack of inclusiveness in the design process. Therefore, to increase the acceptability and feasibility of digital health initiatives, a co-design approach is crucial. Co-design is defined as the “collective creativity as it is applied across the whole span of a design process” (101). In the design process, diverse experts such as researchers, designers or developers and potential users work closely together to understand the needs and preferences of end users (102). A co-design approach is likely to increase scalability and dissemination of the initiative(102). This process coupled with an IC-PC model of care would empower patients, their caregivers and result in better health related outcomes.

**DTx role in MSF and focus on TB**

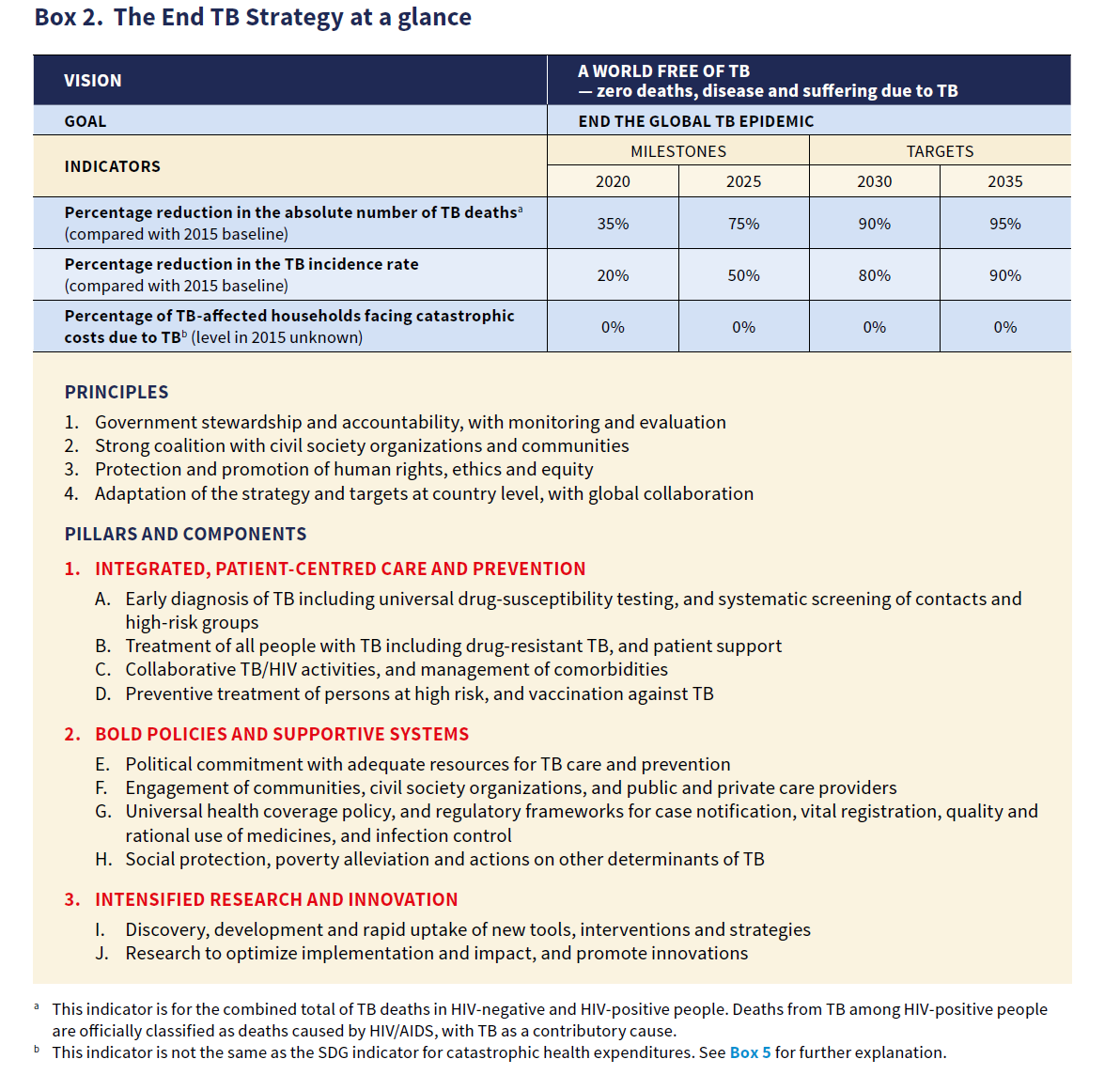
MSF is one of the largest non-governmental providers of TB treatment and care globally. In 2021, there were 17,221 people in MSF’s care starting their TB treatment, including 2,309 with drug-resistant TB. MSF works on TB in many countries, especially the ones with a high burden such as India, South Africa, Central African Republic, Uganda etc. MSF has been a pioneer in TB treatment (largely focused on DR-TB) and research, focusing on patient-centred and innovative approaches to prevention, diagnosis, and treatment. These projects include the TB-PRACTECAL trial completed in Belarus, Uzbekistan, and South Africa. Using a 24-week regimen containing bedaquiline, pretomanid, and linezolid plus moxifloxacin (BPaLM)(8) for the treatment of DR-TB, against the standard of care using second-line drugs with up to 20 pills per day and with a duration of 9-20 months. The TB-PRACTECAL treatment regimen was found to be more effective and safer than the standard of care treatment, with a cure rate of 89% of DR-TB patients on the new ambulatory treatment, a significant departure from the previous 52% cure rate associated with the previous standard of care (8). In the long run it is estimated that it will also be cheaper (9). This DR-TB treatment regimen has been endorsed and approved by WHO at the end of 2022 (10). The introduction of new medications and treatments for TB is happening for the first time in 50 years with MSF and their partners efforts looking further ahead to keep on improving care for neglected diseases (11,12). This includes the EndTB project (13,14), targeting MDR-TB patients from all age groups (including adolescents) in 18 countries, through two clinical trials for new medications (15), observational research and advocacy efforts (16). Both trials are innovative as they introduce new medications to the TB treatment, and shorten the amount of time spent in treatment, which in turn will help in medication adherence, quality of life, and well-being for patients and their surroundings. The results for the trials will be available sometime in 2023 (15). MSF is not only focusing on TB treatment, but also on diagnosis, bringing the latest innovative technology to low resources and rural settings, such as GeneXpert (17), which can detect TB in about 2 hours. This will facilitate detection of TB, thus enabling prevention and treatment options. In terms of patient-focused care, MSF has been involved in learning from patients about the different barriers to accessing, adhering to, and succeeding in their TB treatment in different countries (18–20) to continuously refine programs and enhance patients' experiences. This aligns with MSF’s strategy where patients are considered partners in their treatments. Overall, such improvements in TB diagnosis, and treatment, making these interventions more accessible, and working with partners across the globe, will accelerate the cadence to reach the End TB and SDG goals in ending the pandemic, especially in low resources settings and among vulnerable populations.

MSF has been committed to becoming an increasingly person-centred organization, working with people as partners and supporting more empowered health decision-making within an integrated model of care for the different healthcare programs, they engage in. By co-creating with patients and communities will leverage the use of digital health, notably DTx tools, patients will be enabled to have an effective access to care and support, learn about their condition and treatment from a new perspective, and build improved practices for better quality of life and health outcomes. MSF SIU is exploring developing DTx for TB in Belarus, where the health burden is substantial compounded by a low resources and complex political, financial and economical setting. The below sections of the literature review will analyse the burden of TB globally and in Belarus, highlighting the need for integrated patient centred approaches and explore the adjunction of digital health in the model of care.

**TB Burden– Global overview**

TB is a disease caused by a bacteria Mycobacterium tuberculosis, which spreads by airborne transmission (lungs or throat coughs, sneezes, speaks, or sings). It is the 2nd leading infectious cause of death in the world, only after COVID-19 with 1.6 million estimated deaths in 2021 (4). An estimated 10.6 million people fell ill with tuberculosis worldwide in 2021, including 1.2 million children. It is a global public health issue with about 25% of the world population infected with Mycobacterium Tuberculosis. The WHO End TB Strategy (Box 1) was launched in 2015, with a target to end the worldwide epidemic of TB by 2035(2). The milestones to reach by 2025, are 50% reduction in the incidence rate, 75% reduction in number of TB death, and 0% patients with TB facing catastrophic costs. What has been achieved so far by 2021, is 10%, 5.9% and 48% of those milestones for incidence reduction, number of TB death reduction and facing catastrophic deaths respectively (4). The progress to achieve these set targets was compounded by the COVID-19 pandemic, whereby there was gaps in access to TB diagnosis, and treatment, whereby global TB targets are mostly off-track for most countries (103).  In 2020, the number of people dying from TB increased, and far fewer people were diagnosed and treated for TB or provided with TB preventive treatment compared to 2019. Also, spending on essential TB services fell (103).  The consequence of the large drop in the number of people newly diagnosed with TB in 2020 and the increase in the number of people dying from TB at all levels: global, regional and country; reversed years of global progress in reducing the number of people who die from TB, with the first year-on-year increase (of 5.6%) since 2005 and the total number of deaths in 2020 returning to the level of 2017 (103). In parallel to the End TB strategy, there are the SDG, with a clearly stated target within Goal 3 to end the TB pandemic *“Ensure healthy lives and promote well-being for all at all ages”* to end the TB pandemic *“Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases”*(3)*.*

Box 1: The EndTB Strategy at a glance



**TB treatment - Global Overview**

People infected with TB bacteria, Mycobacterium Tuberculosis, have a 5–10% lifetime risk of falling ill. Those with compromised immune systems, such as people living with HIV, malnutrition, or diabetes, or people who use tobacco, have a higher risk of falling ill(5). The most common presentation of tuberculosis is the pulmonary TB that affects the lungs and is contagious (Active TB). It can also affect other parts of the body, such as the brain, the kidneys, or the spine (104). Child and adolescent TB is often overlooked by health providers and can be difficult to diagnose and treat(104). When a person develops active TB disease, the symptoms -such as cough, fever, night sweats, or weight loss- may be mild for many months. This can lead to delays in seeking care and results in the transmission of the bacteria to others. People with active TB can infect 5–15 other people through close contact over the course of a year (104).

TB is present in all countries and age groups, and it is curable and preventable; however, people with TB can die if they do not get proper treatment (104).  In the case of TB infection (where the patient is infected with TB bacteria but not ill), TB preventive treatment can be given to stop the onset of disease. This treatment uses the same drugs for a shorter time (105).  After the second World War, a medically oriented TB control model emerged (106). Hope was initially placed on mass vaccination with BCG (107), which were later shattered when it was demonstrated that the protective effect and epidemiological impact were limited (106). When effective chemotherapy for TB became available in the end of the 1940 and beginning of 1950s, the control model switched to an almost completely curative focus. ‘‘Prevention starts with cure’’ became a slogan for the global role out of effective treatments. It was predicted that good coverage of effective treatment would result in a rapid decline in TB incidence (106). Yet this did not happen, and the quest for new vaccine and treatment regimen started.

The most common form of TB is DS-TB. It stands for Drug-Sensitive TB (meaning that all TB drugs work) and its treatment is shorter than other forms of TB.  DS-TB disease is treated with a standard 4-month or 6-month course of 4 antimicrobial drugs that are provided with support to the patient by a health worker or trained treatment supporter. About 85% of people who develop DS-TB disease can be successfully treated with the 6-months and 4 antibiotics regimen. Drug resistance (DR-TB) emerges when TB medicines are used inappropriately, through incorrect prescription by health care providers, poor quality drugs, and patients stopping treatment prematurely (5). DR-TB exists in three forms, as follows; rifampicin-resistance TB (RR-TB), which is resistant to rifampicin, the first-line drug that is very effective for treating TB. Secondly, multidrug-resistant TB (MDRTB) is the form resistant to rifampicin and isoniazid, the two most effective first line TB drugs(5). MDR-TB is treatable and curable by using second-line drugs. However, the options are limited and require extensive chemotherapy between 9-20 months, with medicines that are expensive and toxic, and close monitoring for adverse events. Only about one in three people with drug resistant TB accessed treatment in 2020(5). Thirdly, extensive-drug resistant TB (XDR- TB) is the form resistant to fluoroquinolones and aminoglycoside(5). In 2020, WHO recommended a new shorter (9–11 months) and fully oral regimen for patients with MDR-TB. By the end of 2021, 92 countries started using shorter MDR-TB treatment regimens and 109 had started using bedaquiline, in an effort to improve the effectiveness of MDR-TB treatment(21).

**TB social determinants**

Historically, TB has been used as a prime example of a ‘‘social disease’’, the control of which requires social, economic and environmental interventions. There is an evident relationship between social determinants of health and tuberculosis (106). Furthermore, the need to control TB has often been used as an argument for improving living conditions and reduce inequity (108,109). To improve the main epidemiological indicators for the TB pandemic to attain the targets of the EndTB strategy (2), actions addressing the social determinants of TB, as well as the more proximate risk factors (the physical and biomedical factors that directly influence the mechanisms that govern exposure to tuberculosis, risk of acquiring tuberculosis infection, and risk of progression from tuberculosis infection to active tuberculosis disease) are needed. The TB burden follows a strong socio-economic gradient between countries, within countries, and within communities, and the poorest have the highest risk (110–112). TB tends to be concentrated in groups with complex health and social issues, for example homelessness, imprisonment, high rates of alcohol and substance misuse, HIV, and lack of entitlement to welfare (Craig, Daftary, Engel, O’driscoll, & Ioannaki, 2017). This called the proximate risk factors, which includes those that directly increase exposure to infectious droplets. A necessary risk factor for TB infection is contact with a person with active disease. The likelihood of having such a contact is determined by the underlying disease burden in the community. People living or working in environments where TB prevalence is particularly high are obviously at high risk of infection, for example prison staff and inmates (Bobrik et al., 2005) and certain health care workers (Menzies, Joshi, & Pai, 2007). The risk of exposure is also determined by the physical environment in which the contact takes place, including aspects of crowding, air flow and humidity (Rieder, 1999). Proximate risk factors also include those that impair the host defence against infection and break-down to disease, such as HIV infection (Corbett et al., 2003), malnutrition (Cegielski & McMurray, 2004), tobacco smoke (Lin, Ezzat, & Murray, 2007, Slama et al., 2007), indoor air pollution caused by burning of solid fuels (Lin et al., 2007; Rhefuess, 2006), silicosis (Corbett et al., 2000; Rieder, 1999), diabetes (Stevenson et al., 2007), malignancies, a wide range of chronic systemic illnesses, and immunosuppressive treatment (Rieder, 1999), as well as alcohol abuse (Lonnroth, Williams, Stadlin, Jaramillo, & Dye, 2008). Indeed, alcohol is considered one of five key risk factors for TB and estimates that 0.72 million cases of TB are attributable to alcohol disorders annually (World Health Organisation, 2020).  There is some evidence that outdoor air pollution is a risk factor for TB (Cohen & Mehta, 2007; Tremblay, 2007). While, depression and stress can have negative effect on the cell mediated immune system and could therefore in theory increase the risk of TB (Prince et al., 2007).

In an analysis applied to the 22 High TB Burden Countries (countries that together suffer 80%of the estimated global TB burden), the population attributable fraction for selected TB risk factors for impaired host defence was roughly estimated suggesting that malnutrition (PAF, 27%), smoking (23%), HIV (19%), diabetes (6%), harmful alcohol use (13%) and indoor air pollution (26%) are all important risk factors globally (though the evidence base for indoor air pollution is still weak). Their relative importance depends on the prevalence of exposure and is therefore different for different countries and regions. For example, a regionalized PAF analysis suggests, as expected, that HIV is a much more important risk factor in Africa (PAF,>50%) than elsewhere due to the high prevalence of HIV. Links between socio-economic status and proximate risk factors exists. It is reasonable to assume that the higher risk of TB among people in low socio-economic status groups is largely an effect of their greater exposure to some or all of the risk factors discussed above. A recent multi-level analysis of TB risk factors from South Africa found an association between the risk of TB and smoking, alcohol and under-nutrition. These factors partly explained the underlying association between low SES and TB risk, suggesting that these proximate risk factors are on the causal pathway between poverty and TB risk (Harling, et al., 2008). People from low SES groups have on average: more frequent contact with people with active TB disease; higher likelihood of crowded and poorly ventilated living and working conditions; limited access to safe cooking facilities; more food insecurity; lower levels of awareness and/or less power to act on existing knowledge concerning healthy behaviour (e.g. safe sex, smoking, diet and alcohol use); and limited access to high quality health care (FAO, 2006; Gilson, Doherty, Loewenson, & Francis, 2007; Kjellstro¨m et al., 2007). Malnutrition and indoor air pollution are direct markers of poverty (FAO, 2006; Rhefuess, 2006). Smoking prevalence is consistently higher among the lower SES groups than among higher SES groups in all regions of the world and smoking prevalence is increasing rapidly in low-income countries, while it is decreasing in high-income countries (WHO, 2008b). For HIV, alcohol and diabetes, the picture is more complex. On average, HIV prevalence is higher in poor countries than in rich countries and the prevalence is higher in countries with more unequal wealth distribution. However, there is wide variation in national HIV prevalence across countries with similar level of national wealth (Piot, Greener, & Russell, 2007; Reidpath, 2008). Furthermore, on an individual level the association between SES and HIV prevalence is less clear (Humphrey, Nathoo, & Hargrove, 2007; Mishra et al., 2007, Wojcicki, 2005). Prevalence of alcohol dependence is higher in rich than in poor countries. However, within countries, at least for men, harmful drinking patterns and alcohol related morbidity and mortality follow a reversed socio-economic gradient: those with low SES are at highest risk (Schmidt, Ma¨kela¨ , Rehm, & Room, 2008). The association between SES and diabetes is also complex. Economic development, reduced poverty and improved food security can lead to increased diabetes prevalence. The prevalence is generally higher among the better off than among the worse off in poor countries. However, in middle- and high-income countries the reverse is true. Here, people from low SES groups have higher prevalence, and this is probably linked to a less healthy diet and less physical activity (Irwin & Whiting, 2008; Smith, 2007). the role of urbanisation Rapid urbanisation can create ideal conditions for TB epidemics to flourish, unless accompanied by good urban planning, social reforms, environmental protection, and a strong and well-coordinated urban health system (Kjellstro¨m et al., 2007). TB incidence is generally higher in urban than in rural areas (Lo¨nnroth, Zignol, & Uplekar, 2006), and, as discussed above, there are signs that urban TB control is particularly challenging (Dye et al., 2007; Watt et al., 2008; WHO, 2007). The tendencies for the burden of TB to be higher in urban than in rural areas may be due to high population density, crowded living and working conditions, as well as lifestyle changes associated with urban living. Exposure to certain TB risk factors such as smoking, alcohol abuse, unsafe sex, and unhealthy diet, may increase when absolute poverty falls at the same time as rapid socio-cultural transitions lead to changed health behaviour patterns (Kjellstro¨m et al., 2007). Such changes are partly the result of globalization (Raviglione, 2007). For example, globalization of nutrition makes food with high calorific value but a low nutritional value available at relatively cheap prices (Labonte´ , Blouin, & Chopra, 2007). Changed nutritional patterns combined with less physical exercise due to poor urban planning and lack of health promoting policies can explainwhy diabetes can coexist with malnutrition in poor urban settings (Kjellstro¨met al., 2007). HIV prevalence is on average 1.7 times higher in urban than rural areas (UNAIDS & WHO, 2006), and this is linked to various social determinants of unsafe sex. The potential increase in risk increase due to clustering of these TB risk factors is often further augmented by fragmented health care systems in urban areas, and poor health care access among urban slum dwellers (106).

**TB in humanitarian contexts | TB in low resource settings | TB and displacement**

Refugees and other populations in humanitarian settings face substantial threats to health and survival, such as poverty, crowded living conditions, undernutrition and poor access to health services – all conditions in which TB transmission thrives (113). TB has a disproportionate burden on the world’s poorest populations and people who are most disadvantaged. For the years 2021-2025, the 30 countries on the high burden TB countries list are either in conflict, undergoing political and economic turmoil, have large inequalities within their populations, or have limited resources to attend to the TB pandemic (4). It is in those countries where the TB pandemic is mostly concentrated. Following the realization that the COVID-19 pandemic offset the milestones of the EndTB and SDG targets, the United Nations General Assembly has urged for more ambitious investments and actions to accelerate global progress towards these goals. The World Health Organization and the Global Fund to Fight AIDS, Tuberculosis and Malaria and other agencies created a group to work together to accelerate progress towards the health-related SDGs through the Global Action Plan for Healthy Lives and Well-being for All. There are many actors in the TB sphere, contributing the to the awareness, prevention, treatment and eradication of TB. Since 2002, the Global Fund has disbursed more than US$50 billion across more than 155 countries to help communities most in need for HIV, Malaria and TB. Over the last years it scaled up its programs that remove human-rights related barriers to services – discrimination, gender inequality and violence, criminalization and socioeconomic marginalization. This work, coupled with increased investments in health services for the most under-served, will benefit the national average, bringing countries closer to achieving goals and targets. The Global Fund provides 77% of all international financing for TB, in country with high TB burden and low resources (114).

**TB model of care**

One of the most detrimental problems in TB control is non-adherence to treatment, as such several interventions -digital or not- are mostly focused on tackling this matter. There are many factors associated with non-adherence, such as: financial, social, psychological, and personal realities (28). Accordingly, patient adherence needs to be achieved by combining different strategies, as per the patient’s situation. Patient adherence needs to be achieved by combining different strategies, as per the patient’s situation.

**DOT**

The Directly Observed Treatment, Short-course (DOTS) is the internationally recommended strategy to improve medication adherence. However, its effectiveness has been questioned(33). Other forms of observed treatment emerged such as treatment observed by a family member, self-administered treatment, or more digitized tools such as the video-observed therapy (VOT), trying to make up for the fallouts of DOTS(29). There has been many systematic reviews and meta-analysis comparing the different interventions that could address non-adherence to treatment. In terms of medication adherence, treatment success, and cure rates, DOTS is found to be better than self-administered treatment(30). Yet, there was no difference when it comes to comparing DOTS with health facility-observed treatment, or family-observed treatment versus health facility ones(33). Patients with TB stated that DOT may be associated with perceptions of low autonomy, inadequate confidentiality, and stigma (115). From a systems perspective, DOT is poorly implemented placing a high burden on healthcare workers who need to follow up with all their patients, instead of focusing on high-risk ones. This would lead to poor implementation, especially in the community DOT (31,32).

**Digital Health**

The achievement of the End TB target to eradicate the global epidemic of TB by 2035 has been recognized by the WHO and other global actors to require the exploration and validation of novel approaches including digital health interventions (24). However, evidence of impact for such solutions is limited. This deficit of robust digital health evidence is particularly pointed out in low-resource and humanitarian settings and a core driver of the proposed assessment. The achievement of global targets TB and required changes already evidenced, such as a move towards more patient-centred activities, to improve TB patients' health-related quality of life (HRQoL) and perceived quality of care (QoC) will not be sufficiently realized with current practices.

Digital health interventions may be leveraged across the TB continuum of care for surveillance, diagnosis, prevention, clinical management, patient care, treatment, and support as highlighted non-exhaustively in Figure 6. Digital health tools are also directly relevant to all three pillars of the End TB strategy from integrated, patient-centred care, and prevention, bold policies and supportive systems, and intensified research and innovation. Digital interventions are gradually being integrated into practice, and are evaluated in field trials largely focused on TB care (26) . The successful development and integration of validated digital interventions across this continuum may allow for greater scalability of diagnostic efficiency, improved patient outcomes and experiences, augmented access and improved population-level awareness and understanding.

One sub-segment of the TB continuum prime for digital health investigation is treatment and self-management support. While there is currently a clear opportunity identified in the literature for supporting patient care and self-management with digital health systems many interventions explored to date have focused heavily on medication adherence reminders and reporting via SMS, medication monitors, or video observed therapy (VOT) (27) . These approaches do not sufficiently address the opportunity to build on existing evidence of the benefits of more integrated psychosocial and behavioral approaches for improved programme performance and patient experience.

Figure 6: Pathfinder Digital Health Products and Their Link to the End TB Strategy

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**DATs**

The most prevalent digital adherence interventions launched in response to the shortcomings of DOT include SMS, VOT, and the Medication Event Monitoring System, and other electronic medication monitors (MMs). These technologies called “Digital adherence technologies (DATs)” allows for greater convenience of remote monitoring. SMS and other technologies, which can communicate via phones, smartphone or internet networks, such as VOT and the Medication Event Monitoring System and MMs, are currently the most in use to remind patients of their medications. These technologies called “Digital adherence technologies (DATs)” are at the interface of digital health integration in the TB treatment regimen. They have the potential to provide patient centred TB treatment approaches covering for the gaps of DOTS. Their roles are comprehensive in the TB treatment, from reminding patients of their doses, addressing forgetfulness, which is a common barrier to adherence (38). They also digitally observe or record dose taking, mimicking DOT, this could be asynchronous or synchronous VOT, the recording through automatic pillboxes, or ingestible sensors. DATs can also record patient dosing history, which allow for ‘real-time’ medication adherence monitoring, noting any missed medication just in time to follow-up with patients(39). Dosage history is helpful for triaging patients, facilitating the work of healthcare providers and their focus on non-adherent patients(39). Their addition to TB treatment regimen resulted in higher rates of treatment success, medication adherence, sputum conversion after two months, and lower loss to follow-up and development of drug resistance, with some variations as to what interventions are being compared(30). SMS reminders, pillbox and electronic medication monitors specifically, generated lower rates of loss to follow-up and higher rates of cure(30). The evidence that such initiatives supporting treatment adherence for a low cost, prompts national TB programs to encourage their usage, such as 99DOTS or Digital pillboxes in India(40,41). 99DOTS consists of TB medications issued in blister packs wrapped in an envelope. On dispensing a dose, a hidden phone number is revealed on the inner envelope flap, prompting the patient to place a toll-free call to indicate a dose taken. It also reminds patients of their doses via SMS. Healthcare providers can receive SMS text notifications regarding potentially non-adherent patients and monitor patients’ adherence in real-time through an online portal accessible on computers or smartphones. Similarly, Digital Pillboxes, store TB medications and have preprogrammed audiovisual reminders embedded in the pillbox. Opening and closing the box to access medications serve as a proxy indicator of a dose taken(42). This information is transmitted via a SIM card to create a real-time dosing history accessible by HCPs(116). Another recommended intervention is VOT, which was first used for TB in 2007 in several clinical programmes in London, UK, as an alternative to in-person treatment observation(43). It has been also evaluated in other countries, whether high income countries (44,45), or low and middle-income countries (46,47). VOT has even been tested in low resources (48,49) settings with promising results when it comes to medication adherence and treatment success. Some countries have adopted VOT as part of their TB regimen, after testing it in randomized trials, including Belarus (51) and other countries with high TB Burden, following the guidance published by WHO in 2017(50).

**Psychological Support/MHPSS**

There is a lack of strong evidence of the integration of the psychosocial support elements in those interventions, which may have been more accessible in a DOT interaction. Psychological support is of outmost need during the long duration of the TB treatment to provide emotional support and reduce stigma (65). Mental illnesses and TB are highly comorbid conditions, such as high alcohol intake (as in Belarus (54)) or depression(55,56). The comorbidity between TB and mental diseases, topped with the stigma that comes with having one or both illnesses (58), are leading to poor TB treatment adherence, treatment failure, and thus either increased mortality or resistant types of TB emergence (56,61,62,117). Psychosocial intervention (support group, counseling, psychotherapy…) during treatment, is essential to ensure its adherence and success. This has been studied, especially in low and middle-income countries(63,64). Support groups, were linked to higher rates of treatment completion and lower rates of loss to follow-up(30). Psychosocial support packages need to be part of TB treatment, to guarantee the wellbeing of patients and their treatment completion(69).

**Other interventions to tackle lack of medication adherence**

Other interventions tackled different factors involved with the non-adherence such as awareness, whereby, patients’ education and counseling increased adherence to treatment, treatment completion(30) and cure rates(33,34)in addition to – of course- improving knowledge on tuberculosis disease course(35). Nevertheless, the magnitude of the benefit is likely to vary depending on the nature of the intervention and the setting. Staff education for lay health workers was also associated with a higher rate of treatment success and a lower rate of loss to follow-up (30). In terms of incentives, financial incentives, preferably immediate cash payments, are deemed to be successful at decreasing default rates during treatment, while food incentives had no effect on success nor default or mortality rates(33,118,119).

**Case study TB in Belarus**

The Eastern Europe and Central Asia (EECA) region, is one of the 10 constituencies representing implementing countries at the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF), it represents 22 countries (73). This region is particularly affected by high levels TB, notably DR-TB. The estimated incidence of TB in 2020 in Belarus, is 26/100 000 (i.e. 2,500 cases)(103).  Belarus is one of the 30 countries worldwide with the highest burden of MDR/RR-TB, one of the 8 in the EECA(74), and a high priority country for TB in Europe(74). Nevertheless, in 2021 it has reached the required testing coverage by WHO, of more than 80%(4) and the decrease for mortality rate of 35% has also been met(4). The country has one the highest previous treatment cases returning to treatment in Europe with 34.1% of its TB cases having undergone treatment, but either did not complete it, or had a clinical failure, or were re-infected(74). When it comes to MDR/RR-TB this increases to 74.5% of such cases having been previously treated; the highest in Europe(74). There is a gap between the number of TB cases diagnosed, particularly MDR-TB and XDR-TB, and the treatment coverage of these cases, whereby, some cases were not accessing nor seeking treatment(74). The overall high rates of MDR-TB may be associated with late-stage diagnostics, sub-optimal management of cases, poor infection prevention and control(78).

The National TB program (NTP) in Belarus under the Ministry of Health (MoH), provides treatments to all TB patients supported by international donors and NGOs (MSF, WHO, Global Fund)(76). Currently, there is a mixed model of TB care, whereby the majority of TB cases start their treatment in inpatient settings, stay there during most of the intensive phase and then complete their course of therapy in outpatient settings. This model has resulted in unnecessarily high hospitalization rates, as well as hospitalizations of excessively long duration, including for patients with a low degree of or no infectiousness. Moving away from a model of TB care centred on hospitalization also has a positive effect on: continuity of treatment, integration with the primary health care sector, TB contact tracing, actions to encourage patients to follow up treatment and capacity to re-engage them in adequate care(76).

In 2021 Belarus reached the 80% target for the testing coverage set by WHO ( (4) and the 35% target for the decrease in the mortality rate (6) . The National Tuberculosis Programme (NTP) and Ministry of Health (MoH) of the Republic of Belarus have, in the face of one of the most challenging TB burdens globally, achieved some promising progress and demonstrated a strong commitment to person-centred care and innovation with a view to improved outcomes and experiences across their health system (7) . However, it is recognised that as TB determinants are heavily rooted in social, economic, and health factors- such as undernutrition, diabetes, HIV infection, alcohol use disorders, and smoking- achieving the End TB and SDG targets in Belarus requires progress on these fronts beyond the introduction of improved medication regimens despite their crucial role (8) . With the already established evidence supporting person-centred treatment and care models, and NTP commitment to innovative approaches (9) , Belarus is in a promising position to contribute to the accelerated impact of new approaches to TB patient support and care globally in LMIC and humanitarian contexts.  In 2014, MSF opened a project to support the NTP to improve MDR/RR-TB treatment adherence, and outcomes by providing a psychosocial support and harm reduction intervention for people with MDR/RR-TB using a person-centred approach through a multidisciplinary team of counsellors, educators, nurses, doctors, social workers and health promoters (9) . Through this project MSF targeted TB determinants to lessen the burden of this disease, and meet the needs of TB patients to achieve better treatment and health outcomes for patients with comorbid MDR/RR-TB and AUD. The support and guidance from a trusted practitioner team, and from reliable loved ones, helped patients to navigate the complex treatment of MDR/RR-TB and other challenges faced in everyday life. Counsellor-educators built the relationships with patients to allow them to open-up about the entirety of their needs, and helped them meet these through other health providers, with the state or administrative bodies, or with relationships with family or friends. This quality counselling, and care from a multi-disciplinary group of health professionals was largely experienced as positive by study participants (9) . To this end, this approach has been subsequently expanded by the NTP. Another main MSF project implemented in Belarus, is the roll out of the TB-PRACTECAL BPaLM treatment regimen. Implementation of this regimen in Belarus with the NTP has been active as of February 2022.

TB determinants are rooted in social and health factors, as risky alcohol intake in Belarus has been identified as one of the main barriers to adherence to TB treatment, and the main reason for patients being sent for enforced hospitalisation. Indeed, the country has one of the highest alcohol consumption rates in the world(79). In Minsk, approximately 40% of MDR/RR-TB patients present with Alcohol Use Disorder(54). Additionally, the lack of sufficient consolidation with other required treatments for co-morbid TB conditions such as HIV/AIDS also presents a challenge for addressing TB in Belarus(78). The Red Cross Belarus offers psychosocial support and social assistance to TB patients as needed. This intervention is seen as helpful by patients(120). A recent MSF study done with TB patients and counselors enrolled in a program providing to patients with MDR/RR-TB a person-centred, multi-disciplinary psychosocial support and harm reduction approach (PCMPS program) addressing the psychosocial needs of people living with drug-resistant tuberculosis who have harmful alcohol use. The main findings were that patients with MDR/RR-TB and harmful use of alcohol faced complex issues during treatment. The person-centred, multi-disciplinary, psychosocial support offered, will help them cope with the challenges and complete the treatment program(54).

**Conclusion**

The proposed needs assessment aims to provide a detailed understanding of the context-specific demand for digital health-enabled patient support to enhance the current model of care for DR/DS-TB patients in Belarus. This assessment is driven by a demand for increased operationalisation of integrated person-centred care to address the significant burden of TB globally and in Belarus. This model of care prioritises the preferences, lived-experiences and needs of patients and communities when designing and delivering health interventions. Digital health patient support platforms such as mobile apps offer one avenue of exploration to increase patient-centricity of TB care provided and expand the reach of current services. The achievement of the End TB target to eradicate the global epidemic of TB by 2035 has been recognized by the WHO and other global actors to require the exploration and validation of novel approaches including digital health interventions if the ambitious targets are to be met for a with patients and communities. While patient-facing digital health approaches have indicated early potential for supporting TB patients in these contexts this effort has been largely focused on medication adherence and remote monitoring. There is a gap in high quality information and evidence on context specific demand, acceptability, feasibility and efficacy of digital tools integrating comprehensive digitally delivered behavioural support for the potential improvement of TB patients treatment experience and health outcomes.

The Belarus National Tuberculosis Program (NTP) and MSF are committed to becoming increasingly person-centred in the provision of TB care, working with people as partners and supporting empowered health decision making. This was the result of different studies and projects that MSF and NTP conducted, realizing the that TB infection and treatment success rates are intertwined with social determinants of health and psychosocial wellbeing. One form of digital health technologies known as digital therapeutics (DTx) may offer one way to accelerate towards this ambition, however greater understanding of the Belarus context specific needs and realities of patients, are required for a contextualized approach. DTx are patient-facing platforms (typically a mobile application) offering evidence-based health behaviour change. By co-creating with patients and communities to leverage these DTx tools, patients will be able to more effectively access care and support, learn about their condition and treatment from a new perspective, and build improved practices to access better quality of life and health outcomes.

Three main research questions will guide the proposed needs assessment:

1. What are the self-management support and psychosocial needs of patients within the current model of care and how may these needs differ between patients on different treatment regimens?
2. To what extent may the integration of a digital health patient-support platform and/or adjacent person-centred operational improvements be feasible to enhance the model of care better assist in meeting those needs?
3. What are the key challenges and opportunities related to implementing a digital health patient-support platform intervention and/or patient-centred operational enhancements in the treatment of DR-TB/DS-TB in this population?

Through the combination of various research methods, a comprehensive understanding of the TB model of care will be achieved, enabling understanding of the foundational requirements for potential digital health support. The needs assessment will ensure alignment and transparency on the demands and opportunities for digitally enabled person-centred care TB interventions in Belarus and shared understanding amongst decision makers (patients, NTP and MSF) on the potential for further digital health tools and other areas where person-centred care may be championed. It is also intended to contribute a degree of progress towards the EndTB targets.

Subsequent phases of the research will be conducted if this first phase is successfully completed and a consensus on an integrated patient-facing DTx solution is reached and developed to be piloted. These potential phases may include:

* Potential Phase 2: Feasibility Assessment and Pilot Implementation

Dependent on the findings of the needs assessment, phase 2 would be designed to develop, and pilot a first version of the DTx platform with a limited sample of patients as part of the TB model of care in Belarus. Based on this limited feasibility assessment exploring the patient perception and usage of the tool, clinician perception and use of the tool and other factors to be defined, the intervention and surrounding approach would be adjusted for subsequent investigation in phase 3.

* Potential Phase 3: Outcomes and Impact Assessment

Determined by the feasibility assessment findings, and using the updated tool, a final phase would be designed to involve wider implementation for and with patients in Belarus. In addition to further investigating the feasibility, acceptability and viability of the DTx platform in this context phase 3 would also increase focus on the measurement of impact on patient outcomes.

These will be subsequently completed and separate protocols will be submitted.

1. SDG Goal 3: *Ensure healthy lives and promote well-being for all at all ages* [↑](#footnote-ref-2)
2. *Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases* [↑](#footnote-ref-3)
3. 99DOTS consists of TB medications issued in blister packs wrapped in an envelope. On dispensing a dose, a hidden phone number is revealed on the inner envelope flap, prompting the patient to place a toll-free call to indicate a dose taken. It also reminds patients of their doses via SMS. Healthcare providers can receive SMS text notifications regarding potentially non-adherent patients and monitor patients’ adherence in real-time through an online portal accessible on computers or smartphones. [↑](#footnote-ref-4)
4. Digital Pillboxes, store TB medications and have pre-programmed audio-visual reminders embedded in the pillbox. Opening and closing the box to access medications serve as a proxy indicator of a dose taken. This information is transmitted via a SIM card to create a real-time dosing history accessible by healthcare providers [↑](#footnote-ref-5)
5. (MSF, internal document, 2018 Edition) [↑](#footnote-ref-6)
6. (MSF, internal document, 2021 edition) [↑](#footnote-ref-7)
7. PHQ-9 (Patient Health Questionnaire - screening of depression), or GAD-7 (General Anxiety Disorder – screening of anxiety), or AUDIT/ASSIST (Alcohol Use Disorders Identification Test/ Alcohol, Smoking and Substance Involvement Screening Test - screening alcohol or substance use disorder) [↑](#footnote-ref-8)
8. The package is offered after the diagnosis of patients, and monthly checks by TB-Doctors through the following tests:

   * Clinical examination including screening for visual acuity and peripheral neuropathy
   * AE/SAE checking
   * Sputum (smear and culture)
   * Full blood count
   * Biochemical blood test
   * ECG
   * X-ray examination only at the end of the treatment

   [↑](#footnote-ref-9)
9. https://www.r-project.org/ [↑](#footnote-ref-10)
10. Can be used interchangeably with Digital health [↑](#footnote-ref-11)