EVALUATION OF

THE CATALYTIC ROLE OF MUMBAI PROJECT

WITH REGARDS TO POLICY CHANGES

OCTOBER 2021

This publication was produced at the request of Médecins Sans Frontières (MSF) - Operational Centre Brussels (OCB) under the management of the Stockholm Evaluation Unit (SEU).

This publication was prepared independently by external evaluators Ruth Sherratt and Sameer Sah of HEAD International.

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ACRONYMS

<u>ARO</u>	Annual Review of Operations
<u>Bdq</u>	Bedaquiline
<u>COVID-19</u>	Coronavirus Disease
<u>CSO</u>	Civil Society Organisation
<u>DOT</u>	Direct Observation of Treatment
<u>DR-TB</u>	Drug-Resistant Tuberculosis
<u>Dlm</u>	Delamanid
<u>DST</u>	Drug Susceptibility Testing
<u>HIV</u>	Human Immunodeficiency Virus
<u>MDR-TB</u>	Multidrug-Resistant Tuberculosis
<u>MoH</u>	Ministry of Health
<u>NITRD</u>	National Institute of Tuberculosis and Respiratory Diseases
<u>NGO</u>	Non-Governmental Organisation
<u>NTP</u>	National Tuberculosis Programme
<u>PSS</u>	Psychosocial Support
<u>RR-TB</u>	Rifampicin-Resistant Tuberculosis
<u>TB</u>	Tuberculosis
<u>UNHLM</u>	United Nations High Level Meeting
<u>WHO</u>	World Health Organization
<u>XDR-TB</u>	Extensively Drug-Resistant Tuberculosis

EXECUTIVE SUMMARY

PROJECT OVERVIEW

The MSF-OCB Mumbai Project aims to improve outcomes of patients with DRTB within targeted areas/facilities within Mumbai, India, working in collaboration with the Public Health Department of Greater Mumbai and the National TB programme. By providing DRTB patients with appropriate treatment and support, the project aimed to reduce DRTB-related mortality and morbidity. Through these interventions, the project ultimately aimed to demonstrate an effective and replicable model of care for DRTB patients which would influence relevant policies at national and global level, and thus achieve improved results for patients within and beyond the project area.

EVALUATION PURPOSE, APPROACH AND METHODOLOGY

The evaluation focused on reviewing the Project's relevance and appropriateness, coordination, efficiency, effectiveness and sustainability, all within the context of the extent to which the Project contributed to policy change. The evaluation utilised mixed methods, and primary and secondary data collection. The evidence base is summarised below:

EVIDENCE-BASE FOR EVALUATION:

39 Interview/ Focus Group Participants

- 16 MSF India based stakeholders (current/former)
- 6 MSF stakeholders based outside India
- 9 Government of India & affiliated organisations
- 3 WHO stakeholders
- 5 NGOs/ CSOs, Academic/ research organisations

135 Documents Reviewed

- 50 MSF documents
- 9 GoI documents
- 24 WHO documents

Findings and conclusions were presented to MSF and used as the basis to jointly identify actionable recommendations for any future phases of the Project.

FINDINGS

Given the Project's overall objective to influence policies in India in beyond, we outline below the key findings under effectiveness, which relate to the extent of the Project's success in this area:

- The Project's operational research activities directly influenced five WHO publications and indirectly influenced four GoI guidelines around the use of new drugs in children and the use of bedaquiline and delamanid in combination.
- The Project's contribution to the 2020 WHO DRTB treatment guidelines was significant, as patients from the Mumbai project comprised more than half of the cohort used by WHO to inform the use of bedaquiline and delamanid in combination.
- The significance of the Project's contribution to other WHO guidelines could not be established, but it did not appear to directly influence any GoI guidelines
- Stakeholders felt the Project could have done more to actively advocate for priority interventions at both a national and international level, and thus the Project's contribution was not as significant or catalytic as it could have been.

The overall theme which reappeared across each of the evaluation criteria was the limitations of the Project's advocacy approach, and the impact which this had on Project results as a whole.

CONCLUSIONS AND RECOMMENDATIONS

Evaluation conclusions were cross-cutting and are framed below against the evaluation criteria, with the related recommendation. We have indicated which criteria apply using the following coding:

R Relevance **C** Coordination **E** Effectiveness **E** Efficiency **S** Sustainability

CONCLUSION 1	The <u>Project's strategy and interventions</u> were seen <u>as highly relevant and adaptive</u> to the TB context in Mumbai, to MSF's experience and expertise, and <u>to the overall objective to influence DR-TB policy.</u>	**R**
Recommendation 1: Build on the Project's adaptability	Build on the Project's adaptability by making it an explicit part of future strategies; and ensure that robust M&E systems are in place to support timely adaptation by capturing contextual changes and preliminary results.	
CONCLUSION 2	The <u>approach to influencing policy was pragmatic rather than strategic</u>. There were <u>missed opportunities to identify and prioritize</u> the <u>guidelines</u> being targeted and the <u>stakeholders that could support influencing of those guidelines.</u>	**R** **C**
Recommendation 2: Develop a more strategic approach to advocacy	Utilise a more strategic approach to advocacy through a process which includes regularly updated stakeholder mapping, prioritisation of policy interventions in line with MSF's expertise and experience, and updated plans.	
CONCLUSION 3	The <u>advocacy approach</u> was <u>dependent</u> on demonstration of an <u>effective and replicable model of care</u>. The model of care <u>was effective</u>, but its ability to drive policy change was <u>constrained by its complexity, limited replicability</u> and thus <u>lack of sustainability.</u>	**E** **R** **S**
Recommendation 3: Ensure a balanced Model of Care	Regularly review the Model of Care to ensure that it considers the wider health system context in order to strike the right balance between providing an evidence base for new interventions, while demonstrating affordability, replicability and thus sustainability.	
CONCLUSION 4	There were <u>missed opportunities to build relationships</u> with other key internal and external stakeholders which <u>would have improved the Project's ability to advocate for policy change</u> and improved sustainability	**S** **E** **C**
CONCLUSION 5	The project <u>directly influenced key WHO DR-TB treatment policies</u> and <u>thus indirectly influenced DR-TB policies in India and beyond</u>, but there were <u>missed opportunities</u> to improve the catalytic effect through <u>improved advocacy and collaboration</u> with others.	**E** **C**
Recommendation 4: Develop more strategic partnerships	Forge new and leverage existing partnerships with government-affiliated institutes such as NITRD in order to magnify MSF's reach and influence and counteract the limitations of limited organisational size and government mistrust of NGOs	

CONCLUSION 6	The <u>lack of focus on efficiency</u> and <u>sustainability</u> in the Project resulted in <u>unintended consequences</u> and <u>affected overall Project results.</u>	S E E
<u>Recommendation 5</u>: Embed efficiency and sustainability in the Project design	Embed sustainability and efficiency in the project through ensuring transparency and effective communications over HR and strategic and operational decisions. In the longer term, outline the relative cost-benefit of different interventions, and ensure a timebound exit strategy is in place	

INTRODUCTION

TUBERCULOSIS IN INDIA AND MUMBAI[1]

India has the highest burden of tuberculosis (TB) and multi-drug resistant TB in the world with an estimated 2.6 million people with TB and 124,000 people with drug-resistant (DR-TB) or multi-drug resistant TB (MDR-TB) in 2019. It is estimated that 436,000 people died of TB in 2018, but only around 66,000 MDR-TB cases were diagnosed. This indicates that there are large numbers of people with undiagnosed MDR-TB, leading to onward transmission, further aggravated by low treatment success rates of 49% for MDR/DR-TB cases started on second line treatment. The First National Anti-Tuberculosis Drug Resistance survey conducted by the Indian Government in collaboration with the World Health Organization (WHO) and the United States Agency for International Development (USAID) showed that close to 23% of new cases show resistance to any drug, with MDR-TB detected in 3% of cases, and high levels of resistance to first line drugs among patients previously treated for TB. Mumbai in particular is a hotspot for TB and DR-TB, with an estimated 45,000 new TB and 4,500-5,000 DR-TB infections annually. High population density, over-crowded housing and inadequate access to safe water all contribute to the city's high TB burden.

CHANGES AND CHALLENGES IN THE GLOBAL DR-TB LANDSCAPE

The global landscape for diagnosis and treatment for DR-TB has seen several changes in recent years. The 2020 update to the WHO Consolidated Guidelines on Tuberculosis, recommended the use of bedaquiline in place of the injectable agent in the 9- to 12-month standardized regimen and supported the use of other bedaquiline-based shorter regimens[2]. Similarly, there have been advances in TB diagnostics with more options for rapid molecular tests[3] replacing sputum smear microscopy, including in India where cartridge-based nucleic acid amplification tests (CB-NAAT) are widely available.

Challenges though remain in the implementation of new technologies and treatment regimens. More recently, the WHO has also updated the definitions of TB treatment outcomes as well as the definition of pre-Extremely Drug Resistant (XDR) and XDR-TB based on the shorter treatment regimen for DR-TB. In addition to the challenges around poor availability of resources for diagnostics and drugs, there is often a lack of appropriate psychosocial support and treatment adherence counselling provided to people with TB, especially people with DR-TB. MDR-TB treatment is long and painful and adverse drug reactions are common in the treatment, yet many people with DR-TB must go through the treatment experience all alone without much support.

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[1] WHO (2020): WHO Global TB Report 2020; Chatterjee S, Poonawala H, Jain Y. (2018): Drug-resistant tuberculosis: is India ready for the challenge?; Parmar MM et al (2018): Unacceptable treatment outcomes and associated factors among India's initial cohorts of multidrug-resistant tuberculosis (MDR-TB) patients under the revised national TB control programme (2007–2011): Evidence leading to policy enhancement; (MSF, 2016 Project Document Mumbai 2016)

[2] https://www.who.int/publications/i/item/9789240007048

[3] For example, Truenat MTB/MTB Plus, GeneXpert Ultra/XDR module

PROJECT OVERVIEW

The MSF-OCB Mumbai Project aims to improve outcomes of patients with MDR- or XDR-TB within targeted areas/facilities within Mumbai, working in collaboration with the MCGM (Public Health Department of Greater Mumbai) and the national TB programme. By providing MDR/XDR-TB patients in the project area with appropriate treatment and support, the project aims to improve their quality of life. While these results within the project area are important, the project ultimately aims to demonstrate an effective and replicable model of care for MDR/XDR-TB patients, that can influence relevant policies (within MSF and, perhaps most importantly, within other key institutions at local, regional and national level) and thus reduce morbidity and mortality for patients within and beyond the project area[4]. The MSF model of care has several different components:

1. Upfront rapid diagnostics using the GeneXpert platform followed by culture/drug sensitivity testing to ensure that the person with DR-TB is diagnosed quickly and accurately
2. Providing an individualised treatment regimen to people with DR-TB based on results of DST and with the utilisation of new/oral drug regimens for improved treatment outcomes
3. Efficient management of co-morbidities and monitoring/management of adverse drug events
4. Providing community outreach, treatment adherence counselling, regular follow-up and referral services for a more patient centred approach
5. Conducting operational research to inform advocacy for policy change and improvements in diagnostic and treatment guidelines, which are integrated into clinical activities at the MSF clinic

Across all of these components, the Project worked in partnership with Government of India and other key stakeholders. The high-level conceptual framework in Figure 1 captures the Project and its model of care, and reflects the more detailed Theory of Change developed during inception based on preliminary document review and an interactive workshop (see later):

<u>Figure 1:</u> MSF Mumbai Project High-Level Conceptual Framework

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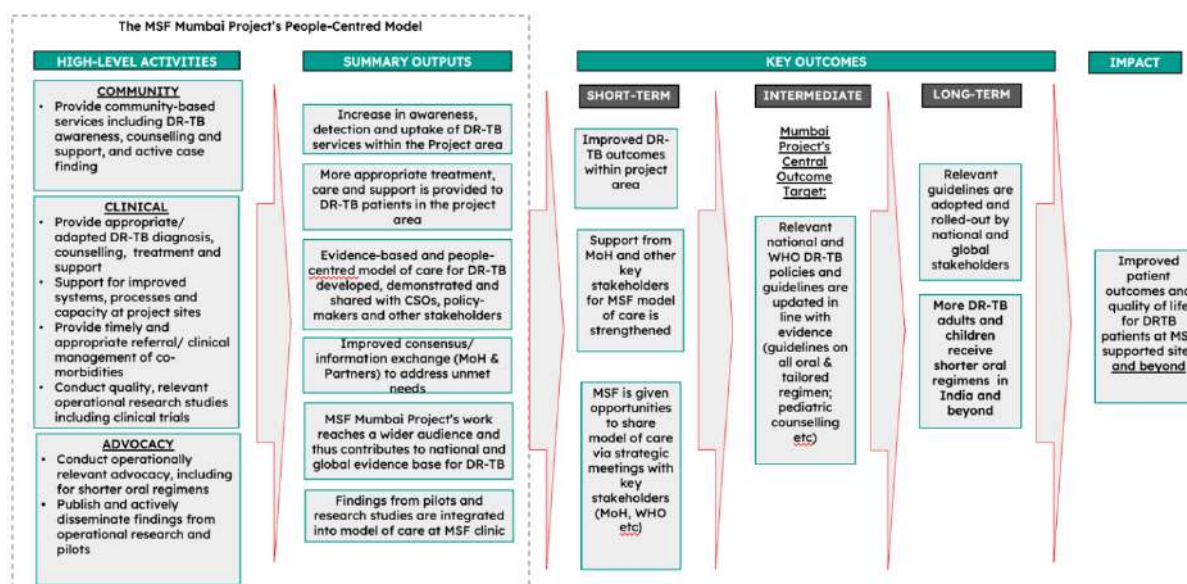
[4] (MSF, 2016 Project Document Mumbai 2016).

EVALUATION PURPOSE AND SCOPE

The evaluation covers the period January 2016 – December 2020, although it should be noted that MSF started working in Mumbai prior to 2016 and continue to work in the area.

The evaluation purpose as outlined in the ToR was "to document how catalytic (leading to change) the DRTB intervention in Mumbai is, and determine its relative value or significance in terms of achieving policy changes". From the ToR, document review and discussions held during the inception period, it was identified that while the focus of the evaluation is on the extent to which the project has achieved results related to policy change, there is a need to simultaneously understand the effectiveness of the Project's DRTB model of care, as policy outcomes are heavily dependent on success in this area. In line with this, the objectives of the evaluation from the ToR and an overview of how they have been addressed are as follows:

- To systematically describe the DR-TB project approach (the strategy, the model, and activities) and catalytic dimension and the expected outcomes
    - This was completed during the inception phase of the evaluation through the co-creation of a Project Theory of Change (See Annex 2)
- To evaluate results achieved in terms of policy changes and identify potential lessons learnt
    - Addressed through the findings, conclusions and recommendations presented in this report

The evaluation focuses on reviewing its relevance and appropriateness, coordination, efficiency, effectiveness, impact and sustainability, all within the context of to the extent to which the Project has contributed to the central intermediate outcome around policy change (see Figure 1). The evaluation seeks to provide clear evidence of what worked and under what circumstances and identify which elements should be continued and replicated. MSF[5] plans to utilise the findings and recommendations from the evaluation to inform future decisions and potential adaptations of the project. The complete ToRs of this evaluation are available as annex in this report, in Annex 1.

METHODOLOGY

In order to answer the evaluation criteria of relevance, coordination, efficiency, effectiveness and sustainability, the evaluation is theory-based, built around testing the Project's Theory of Change (ToC)[6] (see Annex 2), which lays out and unpacks the relationship between activities, outputs and outcomes of the MSF Mumbai Project. The ToC was developed in collaboration with MSF during the inception phase of the evaluation, to ensure that it was a fair reflection of the Project's logic, with sufficient detail for use as the basis for evaluative judgement. Prior to this, while the Mumbai Project did have logframes in place, there was no over-arching Theory of Change which outlined how change was expected to happen or the assumptions under-pinning the expected changes from activities to outputs, outcomes and impact/objective.

The evaluation utilised mixed methods, including primary and secondary data collection and a range of quantitative and qualitative analysis methods.

A set of reframed evaluation questions (EQs) under each of the above evaluation criteria were utilised, with data collection and analysis framed against the evaluation questions. From these evaluation

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[5] Operational management (Project, Mission, Cell) and technical staff within the support departments
[6] Which was developed collaboratively with the MSF team during the inception period of the evaluation

questions, a full evaluation framework was developed, outlining the analytical methods and judgement criteria for each of the EQs (see Annex 3).

DATA COLLECTION

The main data collection methods included secondary document review of MSF and wider stakeholder documentation, and key informant interviews (KIIs), with a small number of focus group discussions (FGDs). Secondary documentation was sourced from MSF (for internal documents particularly) and also independently by the consultants. A full list of documents reviewed can be found in Annex 4. Sampling of key informants for interviews was purposive, based on review of a list of stakeholders provided by MSF to include a suitably broad cross-section of stakeholders, and some use of 'snowballing', whereby initial informants suggested other potential informants and to be contacted. A list of key informants can be found in Annex 5. Interviews and focus group discussions were conducted with the aid of a semi-structured interview guide, structured around the evaluation criteria, but tailored for each category of informant. Due to COVID-19 travel restrictions and safety concerns, all KIIs and FGDs were conducted remotely.

SYNTHESIS AND ANALYSIS

Qualitative data was synthesised using a combination of deductive coding against the evaluation questions, followed by inductive coding against emerging themes. All findings were triangulated across sources and stakeholder types, with strength of evidence ratings provided in line with the degree of triangulation. The primary analytical methods used included standard qualitative analysis and triangulation; benchmarking of strategies against established good practice; temporal mapping of changes in Project strategy against wider policy changes; and contribution-inspired analysis to assess contribution towards the Project's central policy-related outcome.

ETHICS

The evaluation was conducted within the framework of the SEU Ethical Guidelines[7], with the respect and protection of all participants in mind. All interviewees were selected without discrimination on the basis or any protected or other key factors, including gender, age, ethnicity, disability, caste, religion, geographic location, ability, socio-economic status and hard-to-reach groups, and key informants are representative of the full spectrum of stakeholders involved in the Project. Prior to arranging and conducting all KIIs and FGDs, background information on the evaluation and its scope was shared with informants, to allow them to make an informed decision about participation and to make it clear that they were able to withdraw consent at any time. Verbal consent was again obtained at the start of each interview, and assurances provided on the anonymity and confidentiality of informants' responses. All the qualitative data was collected directly by consultants without the use of translators. The qualitative data was manually coded and, where necessary, translated from Hindi by our consultant who is an Indian national. In order to protect the confidentiality of key informants while being transparent about the strength of evidence of our findings, we refer to MSF key informants as either general "MSF staff" where we mean MSF staff from all geographies, "MSF India" for staff based in India (in Mumbai or Delhi), or "MSF International" for staff based outside of India, rather than referring to Missions or offices.

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[7] (MSF-SEU 2020)

LIMITATIONS

The key limitations were as follows[8]:

- **Potential bias as a result of primary data collection methods:** While key informant interviews (KIIs) went ahead smoothly for the most part, conducting interviews remotely did mean that it was harder to judge where informants may have been providing the answers that they felt we wanted to hear, i.e. confirmation bias. We consider this limitation minimal however as the findings presented were well triangulated across stakeholder groups.
- **Assessment of Project contribution to key outcomes:** Our evaluation methodology proposed the use of contribution-inspired analysis in order to assess the relative level of contribution by the Mumbai project to changes in policy outcomes (compared to other stakeholders working in the same landscape). This was not feasible as most stakeholders felt unable to ascribe any specific or relative level of contribution from the Project to policy results. Our analysis is instead based on review of cross-references to MSF research studies.

All of our findings are presented with a Strength of Evidence ranking in Annex 7.

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[8] Another limitation was that we were unable to talk to representatives of patient groups. As a result we were not able to gather any immediate feedback on the Project's support to patients, however as the evaluation is focussed on policy outcomes, this is not considered a major limitation.

FINDINGS

RELEVANCE

EQ1: How relevant and appropriate is the Project's strategy (including advocacy strategy) in terms of achieving the central policy-related outcome?
- EQ1.1: How relevant are the objectives of the Project as outlined in the Project strategy to achieving the central policy-related outcome?
- EQ1.2: Does the Strategy consider established knowledge around how to affect policy change and catalytic change in general?

Finding 1: Project objectives were broadly relevant to influencing DR-TB policies, but there were gaps in outlining how these objectives would be achieved.

The Mumbai DR-TB Project outlined the following general and specific objectives[9]:
- **General Objective:** To reduce mortality, morbidity and increase quality of life for DR-TB, HIV and HCV patients at MSF supported locations
- **Specific Objectives:** DR-TB, HIV and/or HCV patients make use of comprehensive, quality, patient centred and innovative services at MSF supported locations leading to wider policy and implementation improvements.

The general objective was highly relevant to the needs of the patients at the time and was based on MSF's thorough review and understanding of the DR-TB context within Mumbai at the time the project was planned, which included stakeholder analysis and preliminary discussions with local and national government[10]. The policy-focused specific objective was also seen as relevant, as it was deemed necessary to demonstrate that the Project's interventions were successful for them to be adopted into wider policies.

While these broad objectives were considered relevant, the Project strategy did not clearly outline how the planned interventions would contribute towards these objectives. Several "expected results" were outlined at the outset of the Project[11], but there was no explicit Theory of Change (ToC) or equivalent which laid out how it was expected that these output level results would contribute to policy change. As a result, there were some critical gaps in the causal logic, especially around how the Project's advocacy, clinical and community-based activities were expected to work together to influence policy[12], and an incomplete assessment of the risks and assumptions implicit in the overall Project strategy. More details on the main gaps in the causal logic in the initial Project strategy are provided in Annex 6. In our findings under EQ2 and Annex 7 we provide more details of the extent to which key assumptions in the causal logic held.

Finding 2: The Project strategy addressed two out of three key factors which support policy change: evidence of the DR-TB problem; and of possible policy solutions to the problem. It did not however sufficiently address the broader political context.

The Project strategy did not appear to explicitly consider established knowledge around how to affect policy change but did provide valuable evidence towards two factors which are widely seen as critical for this to occur: evidence of the extent of the particular **problem** that existed (DR-TB in Mumbai and

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[9] (MSF, 2016 Project Document Mumbai 2016)
[10] (MSF, 2016 Project Document Mumbai 2016); KIIs (MSF staff)
[11] (MSF, 2016 Project Document Mumbai 2016)
[12] Based on comparison with the ToC developed during the inception phase of the evaluation

India); and evidence which outlined successful **policy interventions** that could address the problem[13]. The project provided **valuable evidence of the extent of the DR-TB problem** in Mumbai, India and beyond prior to 2016 through its operational research activities[14]. This work laid the foundation for the current Project, and the Project continued to provide evidence of the nature and extent of the problem from 2016 onwards[15]. Through the approach of demonstrating an effective model of care, the Project strategy also laid out how it would share **effective policy solutions** to the problem that had been identified[16].
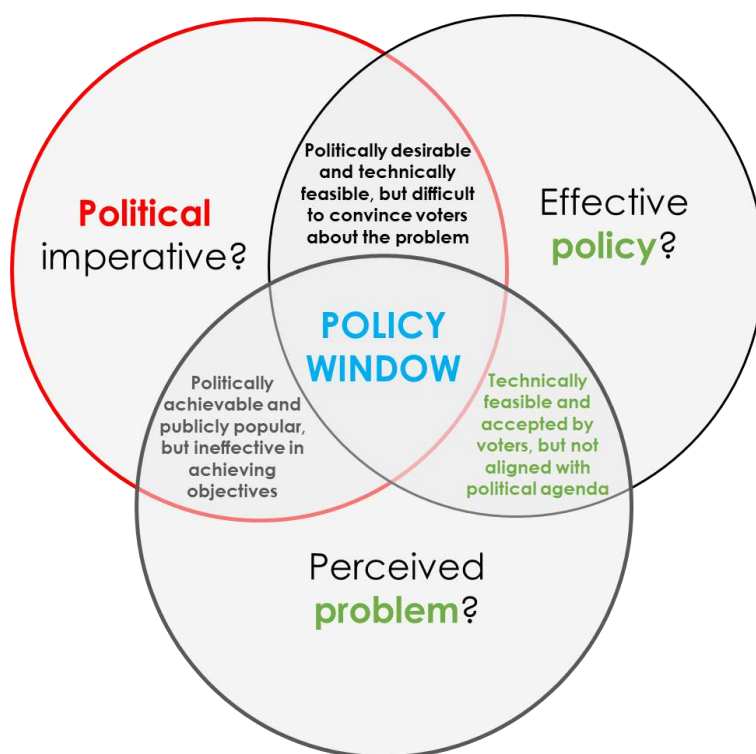
Figure 2: Kingdon's Multiple Streams Framework applied to the Project

The Project strategy did not sufficiently outline and address how the broader **politics** around TB and health in India[17] would affect the policy objectives[18]. The strategy acknowledged a resistance to enter into "direct conflict with the Department of Health (DoH)[19] but did not address how this would be mitigated. The need for stronger political leverage and to foster more strategic alliances to mitigate the challenges in advocating for policy change was clearly outlined at Mission level[20], but this was not carried through to the Project level strategy[21]:

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[13] We have framed our own analysis within the context of Kingdon's Multiple Streams Framework, which describes the need for three streams to converge in order for a policy window to open: the Problem stream, the policy stream and the politics stream.

[14] (MSF, 2016 Project Document Mumbai 2016); KIIs - MSF staff; WHO stakeholders; GoI stakeholders

[15] Ibid

[16] (MSF, 2016 Project Document Mumbai 2016)

[17] The political context incorporates broad national mood around the particular or broader policy issue, the influence of the media or special interest groups in addition to party politics.

[18] Based on application of Kingdon's framework

[19] (MSF, 2016 Project Document Mumbai 2016)

[20] Ibid

[21] (MSF, Country Policy Paper – India 2015 2015)

> "We have] limited political leverage to influence protocols and policy, which is inherent to Indian context. Advocacy: as a choice mission, contributing to changes in policy and practice is our objective (mostly in TB), however we aren't investing enough time and effort in advocacy to contribute to tangible change"
>
> MSF, Country Policy Paper – India 2015

As a result of the above-described failure to address the political context in its strategy and approach, the likelihood of achieving the desired policy changes was substantially reduced, as the Project was reliant on other stakeholders working towards similar objectives who were more actively engaging in this area.

- EQ1.3: Does the strategy and approach support adaptive management in line with contextual changes in the (policy) environment?

Finding 3: The Project continuously adapted in line with the needs of patients on the ground and the changing policy context, but changes were organic rather than based on a planned adaptive approach.

The overall and specific objectives and the specific expected results as outlined in the original Project documentation included a focus on both DR-TB but also HIV and HCV, in line with the needs and gaps identified by MSF at that time[22]. While the original project document clearly outlined the objective to change key policies in these areas, there was little explicit consideration within Project or wider Mission level documents of how and when the Project's objectives and expected results would change if policy or other key changes to the context took place during implementation[23]. Despite this, changes clearly did take place. For example, the Project's focus shifted away from HIV as government capacity increased in that area and towards other areas such as paediatric DR-TB[24], and the expected results of the Project were adjusted in line with these changes[25]. These changes ensured the Project's ongoing relevance, but changes appeared to be organic rather than based on any explicit adaptive approach[26] outlined in the Project strategy or elsewhere.

EQ2: How relevant and appropriate are the activities and outputs of the project with regards to leading to key policy-related outcomes and the overall project goal or impact, namely catalytic changes in policy which lead to improved DRTB outcomes beyond the project area?
- EQ2.1: Is the project aligned with and influencing the most appropriate and relevant policies (MSF, local, national, international)?

Finding 4: Relevant and appropriate policy gaps were identified in line with MSF's capacity and expertise, but there were missed opportunities to prioritize advocacy activities and potentially advocate for other areas where MSF could have influenced policy change.

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[22] (MSF, 2016 Project Document Mumbai 2016); (MSF, Country Policy Paper – India 2015 2015)

[23] One exception is an acknowledgement that many HIV activities are dependent on approval of MoUs, and outlines those activities and expected results would have to be updated if the MoUs do not materialise

[24] (MSF, 2016 Report Summary Operations Update 2016); (MSF, 2017 Medical Report final 2017); (MSF, Project monitoring: Mumbai Q4/Annual Report- 2020 2020) (MSF, Mumbai DR-TB/HIV Project Annual Report 2016 2016) (MSF, Project monitoring: Mumbai 2019 2019); (MSF, Concept note: Model of care for Drug resistant TB decentralization in MEW, proposal for MSF Mumbai project (2017) 2017)

[25] (MSF, 2016 Report Summary Operations Update 2016); (MSF, 2017 Medical Report final 2017); (MSF, Project monitoring: Mumbai Q4/Annual Report- 2020 2020) (MSF, Mumbai DR-TB/HIV Project Annual Report 2016 2016) (MSF, Project monitoring: Mumbai 2019 2019) (MSF, Project monitoring: Mumbai 2019 2019)

[26] Based on for example ongoing monitoring and evaluation and updated needs and gaps analyses

The key DR-TB policy gaps that were identified at Project initiation included delay in effective diagnosis due to challenges in drug susceptibility testing, long treatment duration with drugs that had higher toxicity, lack of interventions specific to paediatric DR-TB and near absence of psychosocial counselling and treatment adherence support for people with DR-TB[27]. WHO guidelines during that time classified anti-TB drugs into five main groups, based on safety and effectiveness considerations. At around the same time, two new drugs (bedaquiline and delamanid) were in confirmatory phase 3 trials, having received accelerated approvals for MDR tuberculosis based on phase 2 data in 2012, and 2014, respectively[33]. In such an environment, the Mumbai project was aligned with and influencing the most relevant policies nationally or globally, which included introducing upfront GeneXpert diagnostics, new/oral drugs for DR-TB treatment, focus on paediatric DR-TB and psychosocial counselling for clients. The Project's planned interventions to address these policy gaps were based on a detailed analysis of the identified needs, main gaps in DR-TB diagnosis, treatment and care at the time, the response by other actors, the areas where MSF was best placed to intervene, and all stakeholders interviewed agreed that the gaps identified were relevant [28].

While the policy gaps identified were relevant and appropriate, the Project did not attempt to influence policy in all of these areas, with advocacy and operational research focussed on specific DR-TB treatment regimens[29]. The rationale for focussing on influencing DR-TB treatment rather than the Project's other clinical or community interventions was not clear, and some stakeholders felt there were missed opportunities to prioritize which specific policy gaps advocacy activities should be influencing[30]:

> "[the Project] needed someone in the Mission, to … analyse the policies in place to see what we want to change. This basic step didn't take place. …[it's] not just about changing treatment [and] opening more clinics. If [we] don't know policies, we will end up with something that doesn't make sense" (MSF staff)
>
> MSF Staff

Due to the focus on advocacy activities related to treatment, several stakeholder groups felt there were missed opportunities to advocate for other areas where MSF could have influenced policy[31]. Key examples shared included providing data on use of rapid diagnostics; and the importance of psychological counselling, adherence support and socioeconomic support in improving DR-TB treatment outcomes.

- **EQ2.2: Are the project activities relevant in terms of influencing the desired policy changes at MSF, local, regional, and national level?**

Finding 5: Activities were seen as highly relevant and necessary for improving treatment outcomes and demonstrating an effective model of care which could influence wider policy changes.

Clinical and community-based activities were highly relevant in terms of influencing DR-TB treatment guidelines. MSF clients were people with DR-TB who were failing treatment with the regular two-year MDR-TB treatment utilising injectables in the public health system. These drugs had severe side effects, were painful for adults and children and the long duration of treatment meant that psychological

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[27] (MSF, 2016 Project Document Mumbai 2016)
[28] KIIs – MSF India and international staff
[29] (MSF, Operational Research Repository DRTB 2011-2021 2021)
[30] KIIs - MSF India and international staff, WHO, CSO/NGO stakeholders
[31] Ibid

counselling and adherence support was crucial[32]. Therefore, stakeholders reported that MSF's approach in utilising oral drugs with adequate counselling and adherence support was very relevant in tackling these challenges[33].

WHO guidelines on the programmatic management of DR-TB include early diagnosis, effective treatment, infection control, psychosocial support and palliative and end of life care. MSF activities were in line with these recommendations and thus relevant. Specifically, the Project implemented upfront rapid diagnostics combined with second line DST; use of a salvage regimen comprising of new/oral drugs; infection control demonstrated through the MSF clinic at Govandi; provision of psychological counselling and treatment adherence support and, to some extent, palliative care and support. Given that MSF's approach to influencing policy change was through leading by example, the activities were necessary to generate data that could contribute towards influencing policy outcomes in the form of new DR-TB treatment guidelines at the global level.

- **EQ2.3: Are activities: a) necessary, and b) sufficient to contribute to project outcomes and objectives and the intended catalytic change?**

Finding 6: Some key gaps were identified in terms of advocacy activities, which were seen as overly focused on production and sharing of operational research.

In comparison to other Project interventions, advocacy activities were less relevant. Advocacy in the project was not based on a situational assessment or felt needs of the clients that MSF Mumbai supports. While stakeholder mapping and review of power dynamics was done at the start of the project and reviewed in 2017[34]it was not clear how this was taken forward. Several key organisations, such as Global Fund, USAID and Bill and Melinda Gates Foundation, were identified but not considered in the power mapping and appear not to have been engaged with. Highly influential groups, including the Central TB Division and generic "policy makers" were identified but seen as being "strongly opposed" to MSF's work. This appears to have contributed to a decision not to directly lobby or advocate the government for policy change, due to concerns about government antagonism towards international NGOs and foreign influence in general and the legal situation. As a result, advocacy activities focussed on the sharing of operational research at national and international forums and utilising the voices of patients to indirectly influence the government. As a result, advocacy activities within India were necessary, but not sufficient, as they did not target or reach many of the key policy makers or other significant stakeholders within India[35][36].

Below are some specific examples of additional advocacy activities suggested by various interviewees including WHO, NITRD, Mumbai CTO and DFY[37]:
- Consultations with the Central TB Division on a regular basis for sharing of activities and outcomes would have been effective in gaining more acceptance with the MoH
- Position papers on challenges with managing TB, especially DR-TB in India, would have informed policy makers and provided a public image for MSF among 'people who matter'
- Information sessions with parliamentarians would have provided more political support to MSF locally

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[32] (WHO, Guidance for national tuberculosis programmes on the management of tuberculosis in children. Second edition 2014) (WHO, WHO treatment guidelines for drug resistant tuberculosis. 2016 update 2016)

[33] KIIs – MSF India and international staff; WHO, GoI and affiliated organisations

[34] (MSF, Advocacy and Communications strategy 2019 2019); (MSF, Advocacy and Communications strategy 2017 2017)

[35] For example, Global Fund

[36] KIIs – MSF India and International staff; WHO; GoI and affiliated organisations; NGO/CSO stakeholders

[37] KIIs – MSF India; WHO; GoI and affiliated organisations

- Briefings for bureaucrats/ministers in preparation for the Moscow Ministerial Conference on TB in 2017 or the UN High Level Meeting on TB in 2018 could have influenced the country's participation

  - EQ2.4: What assumptions underpin the intervention logic, and have they been upheld?

Finding 7: Project assumptions mostly held, with the exception of those related to advocacy, where assumptions were only partially upheld due to a lack of effective engagement with the key stakeholders starting at the activity level.

As part of the ToC development process during the Inception phase of the evaluation, a list of indicative assumptions based on document review and preliminary key informant interviews were drafted. A full qualitative analysis of the extent to which these assumptions held is provided in Annex 7. A majority of assumptions at the activity to output level held, but at the output to outcome level and beyond some of the assumptions only partially held. The main area of concern in terms of assumptions was those related to advocacy, which only partially held from activity level onwards, which had implications in terms of being able to ascribe the Project's level of contribution towards outcome level results (See Limitations and Annex 8).

COORDINATION

EQ3: To what extent does the MSF Project work complement and coordinate their work with other key stakeholders?
- EQ3.1: How effective is the Project's coordination with other actors, including wider MSF, civil society, TB treatment providers and Ministry of Health?
- EQ3.2: How sustainable is the collaboration with other actors?

Finding 8: MSF built successful relationships with institutions linked to the central government, such as NITRD and WHO, and was effective in influencing the Central TB Division through these partnerships.

The MSF project's association with institutions linked to the central government, for example the National Institute of TB and Respirator Diseases (NITRD), ensured that MSF activities and approaches were a part of discussions at the central level despite the fact that MSF was not in any of the technical working groups[38]. MSF was sharing its approaches and results with the local WHO office in New Delhi as well as with the NITRD. These organisations would then provide the MSF related evidence in the meetings of the technical working group on MDR-TB of which they were a part[39].

Finding 9: The Project built an effective partnership with the local government in Mumbai through the City TB Officer, which supported interventions and thus improved care and treatment outcomes for DR-TB patients in Mumbai, but this was not replicated at national level.

MSF also coordinated very well with the Mumbai City TB programme through the office of the City TB Officer and the District TB Officers. This ensured that; a). some of the approaches from the MSF clinic, for example infection control measures, were taken on by the TB programme locally; and b). prevented duplication of efforts through coordination meetings where all actors working on TB in the M East Ward, which is MSF's operational area, attended.

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[38] KIIs – MSF India staff; WHO; GoI and affiliated organisations
[39] Ibid

At the national level, there was limited interaction with the Central TB Division, which other partners saw as a missed opportunity for MSF since it could have helped MSF influence the MoH[40]. The government in general is sensitive to NGOs, especially international NGOs with foreign staff, and their activities and has in the recent past taken steps to monitor their activities, e.g., through making FCRA regulations more stringent. Therefore, it is wrong to assume that engagement with the government would have guaranteed acceptance of MSF or changes in policy.

<u>Finding 10</u>: Partnerships with CSOs were limited, with little sharing of practices especially in counselling and psychosocial support, which could have ensured continuity of support for patients in the longer term.

MSF partnered with local non-governmental organisations (Foundation for Medical Research and Doctor's for You) who were highly appreciative of the work that MSF implemented and saw their partnership with MSF as an opportunity to learn. MSF also partnered with local private sector actors, especially for drug susceptibility testing. MSF however failed to share and learn in partnership with the Tata Institute of Social Sciences (TISS) project that was also providing psychosocial counselling which was perceived by the government as being more efficient and cost effective and hence replicable.

At the local level there was also a gap in partnering with local civil society and non-governmental organisations in Mumbai. People with DR-TB undergoing long periods of treatment require long term support, sometimes even after the person has been cured. GoI and CSO stakeholders felt that local NGOs/CSOs that implement projects to improve the social and economic situation of poor people, especially in the area of nutrition and vocational training and support, would have been good partners for MSF to support so that MSF clients receive long term support[41].

<u>Finding 11</u>: There were several missed opportunities to collaborate with advocacy-focused NGOs, with the MSF Access Campaign, or with other influential stakeholders such as the Global Fund.

A broad range of stakeholders felt that MSF could have partnered with and supported local/national activist and advocacy organisations which would then have passed on the responsibility for actions seen to be anti-government to these organisations/activists that would not be perceived as controversial[42]. It was reported that activism by the Access campaign led to mistrust by the Ministry of Health, which appears to have affected the extent to which the Project subsequently worked with the Access Campaign and its overall approach towards advocacy[43]. It was also seen by some as a missed opportunity that MSF also did not engage with the Global Fund through the Country Coordinating Mechanism[44], or other influential stakeholder referenced in GoI guidelines such as USAID or CHAI[45].

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EFFECTIVENESS

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EQ4: Has the DRTB model of care effectively supported the central policy outcome the project?
- **EQ4.1**: Does the model of care align with established good practice and latest evidence?

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[40] KIIs – MSF India staff; WHO; NGO/CSO stakeholders
[41] KIIs – GoI and affiliated organisations; NGO/CSO stakeholders
[42] KIIs - MSF India and international staff; WHO; NGO/CSO stakeholders
[43] KIIs – MSF India and international staff
[44] KIIs – MSF India and international staff; WHO
[45] (Government of India/Central TB Division, Guidelines on Prevention and Management of TB in PLHIV at ART Centres 2016); (Government of India/Central TB Division, Guidelines for Programmatic Management of Drug Resistant Tuberculosis in India 2021); (Government of India/Central TB Division 2021); (Government of India/Central TB Division 2021); (Government of India/Central TB Division 2017)

- **EQ4.2:** Have the results, in terms of DR-TB treatment outcomes, supported effective advocacy for policy change?

Finding 12: The model of care effectively supported changes to relevant DR-TB guidelines by demonstrating best practice in improving treatment outcomes for 'complex' DR-TB clients and aligned with good practices at that time.

The MSF model of care targeted clients who had failed the old MDR-TB treatment regimen in the public health system and were thus 'complex' DR-TB clients. The components of the model of care included effective upfront diagnosis using GeneXpert, individualised treatment regimens using new/oral drugs, adverse drug surveillance and management, community outreach for counselling and adherence support; operational research and cross-cutting use of partnerships, especially with state actors[46]. These are as per good practice outlined in the Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis and now also outlined in the 2021 Guidelines for Programmatic Management of Drug Resistant TB in India[47].

Finding 13: Areas for improvement included improved provision of palliative care and long-term support to address socio-economic and psychological factors.

Key informants, especially from within MSF and from TISS, outlined areas of improvement in the model of care. These were palliative care for people on long term treatment for DR-TB as well as people on DR-TB treatment where the treatment is not effective, including those with co-morbidities and severe adverse drug reactions. This is substantiated through latest evidence of good practice in palliative care which requires compassionate care and a psychosocial assessment of people requiring palliative care. This includes understanding of the diagnosis, information needs, hopes, fears, anticipated loss, social support system, coping strategies, selfcare activities etc[48].

The other area where feedback pointed towards need for improvements was addressing longer term socioeconomic needs of people on DR-TB treatment. DR-TB treatment can be debilitating and prevent people from working. This can affect the economic security of the family and in many cases, lead to loss to follow up. Stigma attached to TB can result in loss of employment and social isolation. In the longer term, some people have lasting adverse effects of treatment long after treatment has been successfully completed.

Finding 14: Treatment outcomes were mostly positive, and thus did support advocacy for policy change.

Treatment outcomes of people on DR-TB treatment at the MSF clinic were generally good and supported effective advocacy for policy change: Treatment success ranged from 63-78% over the period 2016-2018, compared to 40-49% in Maharashtra state and 47-54% nationally[49]. The proportion of patients lost to follow up (LTFU) was also considerably lower at the MSF clinic, ranging from 0-8%, compared to 14-19% at state and national level[50]. Outcomes in terms of deaths were less clear and cannot be easily compared as the MSF clinic complicated MDR and XDR TB patients. As a result, comparing MSF clinic death rates with combined MDR/XDR death rates at national level shows that the MSF clinic had a slightly higher death rate at 18-23%, whereas it was 14-20% at state level and 15-

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[46] (MSF, 2016 Project Document Mumbai 2016); KIIs (MSF staff)

47 Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis. WHO 2014. Available at: https://apps.who.int/iris/bitstream/handle/10665/130918/9789241548809_eng.pdf

[48] (USAID/TB CARE II Project 2015)

[49] It is important to note that comparisons do not take into account a variety of contextual factors, such as the types of patients attending the MSF clinic versus those that attend government clinics etc. We have only compared figures from the private MSF clinic, as that is where the use of new regimens was more fully utilised.

[50] (Revised National TB Control Programme, India TB Report 2019 2019); (National Tuberculosis Elimination Programme Annual Report, India TB Report 2020 2020); (National Tuberculosis Elimination Programme Annual Report, India TB Report 2021 2021); (MSF, Project monitoring: Mumbai Q4/Annual Report- 2020 2020)

16% at national level[51]. A comparison against XDR patients only however shows that death rates at state and national level were high at 26-19% and 9-34% respectively[52]. Figure 3 and Figure 4 provide a summary comparison, and full details are shared in Annex 9[53]. Based on these results the treatment outcomes and thus model of care demonstrated at the MSF clinic can be seen as successful and contributing to advocacy for policy change as outlined in the Project ToC (Annex 2).
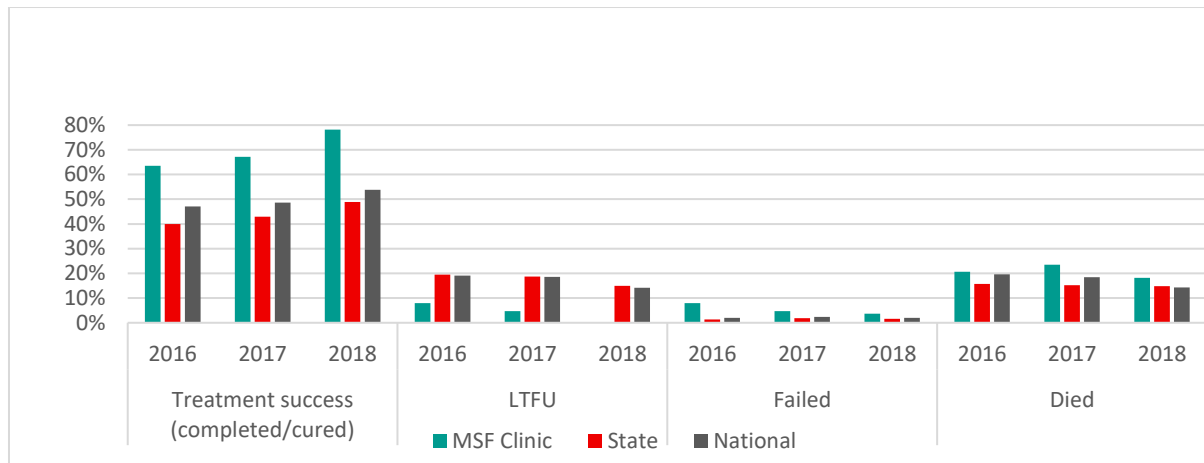
Figure 3: MSF Clinic Outcomes compared with State and National Combined MDR and XDR Patient Outcomes
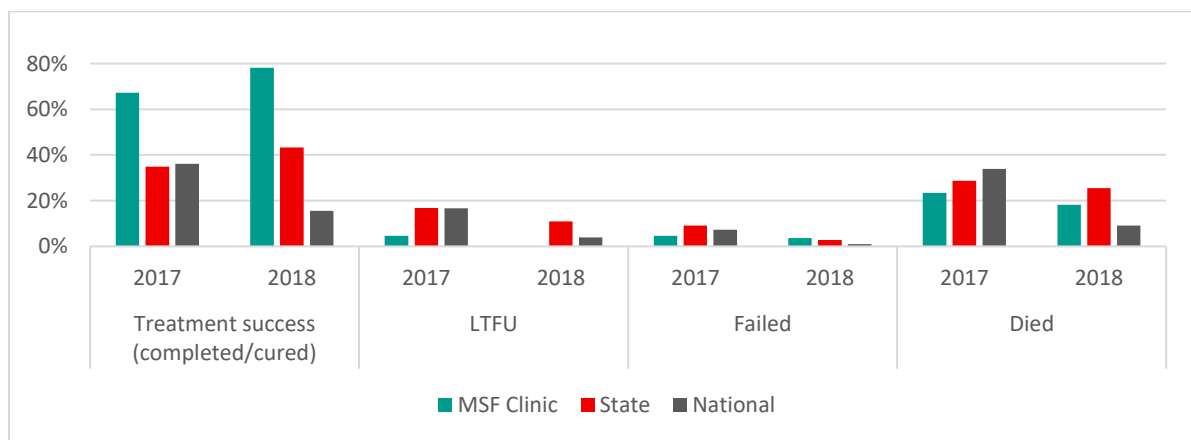
Figure 4: MSF Clinic Outcomes compared with State and National XDR Patient Outcomes

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[51] (Revised National TB Control Programme, India TB Report 2019 2019); (National Tuberculosis Elimination Programme Annual Report, India TB Report 2020 2020); (National Tuberculosis Elimination Programme Annual Report, India TB Report 2021 2021); (MSF, Project monitoring: Mumbai Q4/Annual Report- 2020 2020)

[52] Ibid

[53] Ibid

EQ5: How effective has the Project been in achieving policy-related results?
- **EQ5.1**: To what extent have project's policy related results been achieved?
- **EQ5.2**: How has the MSF Project contributed to these results?

<u>Finding 15</u>: The Project's operational research activities directly influenced five key WHO publications and indirectly influenced four key GoI guidelines around the use of new drugs in children and the use of bedaquiline and delamanid in combination.

Based on analysis of the Mumbai project's operational research activities, WHO DRTB related guidelines and GoI DRTB related guidelines over the period 2016-2021, it appears the Project directly influenced a number of WHO publications, and through these indirectly influenced several key GoI guidelines, as summarised in Figure 5 and Figure 6[54]. This was achieved both through operational research papers based solely on Project data, and also in some cases through the inclusion of Mumbai patient datasets in larger metanalyses which then influenced WHO guidelines[55].

In addition to the above, the WHO "Guidelines for treatment of drug-susceptible tuberculosis and patient care: 2017 update" utilized evidence from "Adverse Events among HIV/MDR-TB Co-Infected Patients Receiving Antiretroviral and Second Line Anti-TB Treatment in Mumbai, India" (2017) but this does not appear to have been incorporated into any GoI guidelines as yet based on review of references and citations.

It is important to note (with the exception outlined in Finding 17) that it is not possible to ascribe any specific or relative level of contribution to these guidelines, as each of the WHO guideline documents referenced a significant number of other studies in their guidelines in addition to the studies completed under the Mumbai project.

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[54] (Government of India/Central TB Division, Guidelines for Programmatic Management of Drug Resistant Tuberculosis in India 2021); (Government of India/Central TB Division 2021); (Government of India/Central TB Division 2016); (Government of India/Central TB Division 2016); (Government of India/Central TB Division 2018); (Government of India/Central TB Division 2017); (Government of India/Central TB Division 2019); (Government of India/Central TB Division 2020); (Government of India/Central TB Division 2020); (Government of India/Central TB Division 2019) (WHO, Compendium of WHO guidelines and associated standards: ensuring optimum delivery of the cascade of care for patients with tuberculosis. Second edition - June 2018 2018); (WHO, Guidance for national tuberculosis programmes on the management of tuberculosis in children. Second edition 2014); (WHO, Guidance for the surveillance of drug resistance in tuberculosis. Sixth edition 2020); (WHO India 2014); (WHO, Recommendation on 36 months isoniazid preventive therapy to adults and adolescents living with HIV in resource-constrained and high TB- and HIV-prevalence settings. 2015 update 2015); (WHO, Report of the Guideline Development Group Meeting on the use of bedaquiline in the treatment of multidrug-resistant tuberculosis. A review of available evidence (2016) 2016) (WHO, The use of bedaquiline in the treatment of multidrug-resistant tuberculosis. Interim policy guidance 2013); (WHO, Target regimen profiles for TB treatment. Candidates: rifampicin-susceptible, rifampicin-resistant and pan-TB treatment regimens 2016); (WHO, The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents. Interim policy guidance 2016); (WHO, The use of delamanid in the treatment of multidrug-resistant tuberculosis. Interim policy guidance 2014); (WHO, WHO consolidated guidelines on tuberculosis. Module 4: Treatment. Drug-resistant tuberculosis treatment 2020); (WHO, WHO treatment guidelines for drug resistant tuberculosis. 2016 update. Annexes 4, 5 and 6 2016)
[55] (Bisson GP 2020); (Lan Z 2020); (Osman M 2019); (Ahmad N 2018)
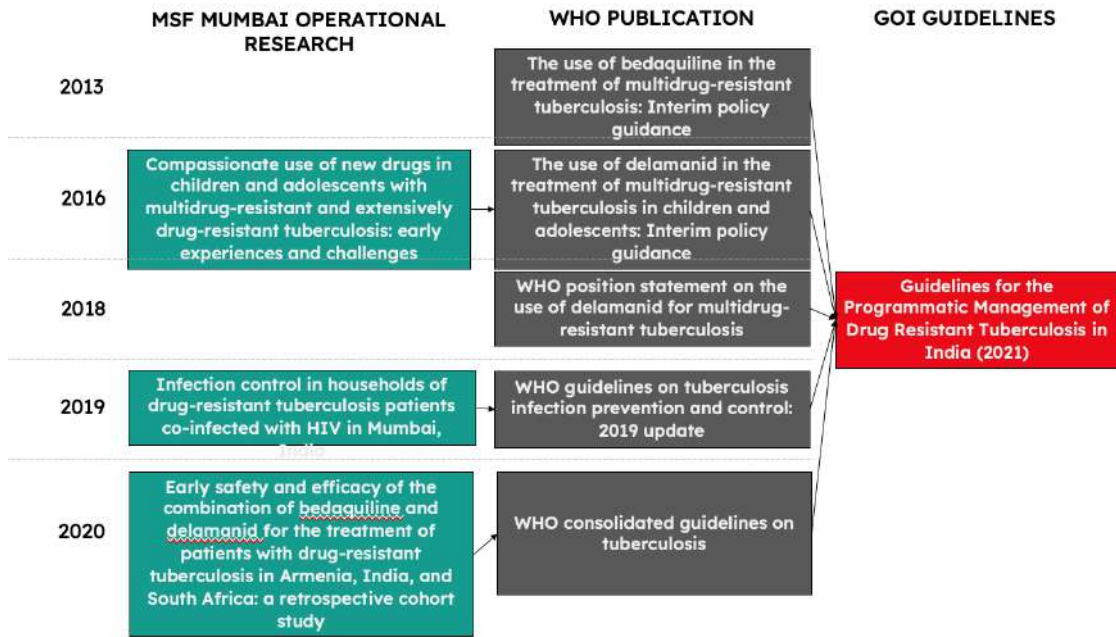
Figure 5: Influence of Project on 2021 GoI guidelines
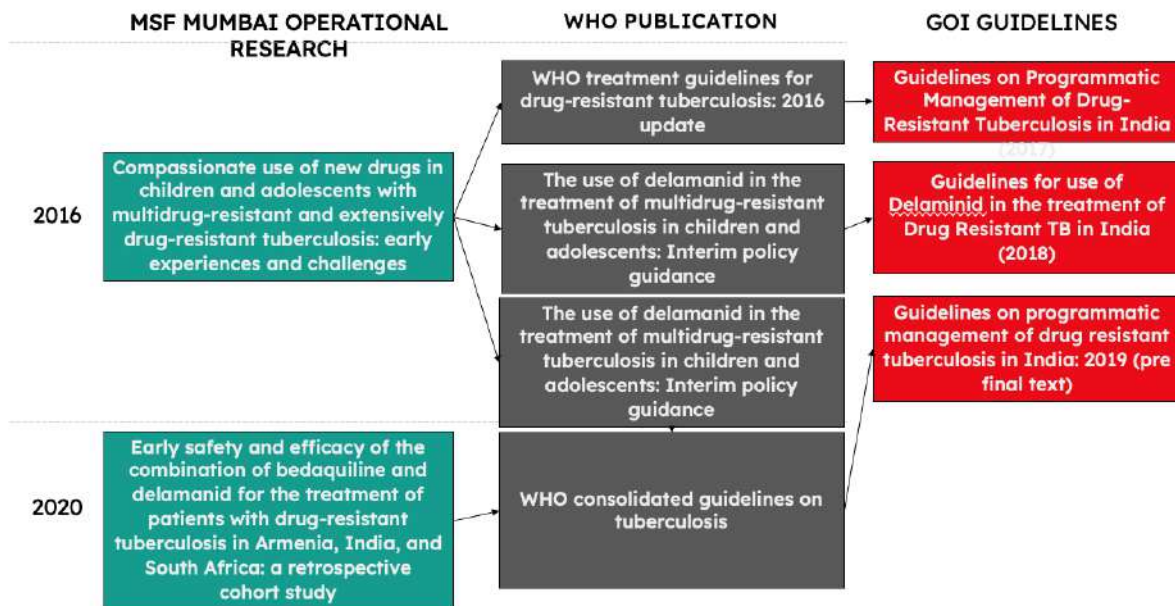
Figure 6: Influence of project on 2017-2019 GoI guidelines

Finding 16: The Project's contribution to the 2020 WHO DRTB treatment guidelines was significant, as patients from the Mumbai project comprised more than half of the cohort used by WHO to inform the use of bedaquiline and delamanid in combination.

As outlined in Figure 5, evidence from one of the Project's operational studies was used in the 2020 WHO consolidated guidelines on tuberculosis, specifically in Module 4 – Drug resistant tuberculosis treatment[56]. The guidelines on DRTB treatment presented seven overall recommendations on treatment regimens for rifampicin-susceptible, isoniazid-resistant TB (Hr-TB) and MDR/RR-TB,

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[56] (WHO, WHO consolidated guidelines on tuberculosis. Module 4: Treatment. Drug-resistant tuberculosis treatment 2020)

including all-oral shorter and longer regimens for MDR/RR-TB, monitoring of patients on treatment, the timing of ART in MDR/RR-TB patients infected with HIV, the use of surgery for patients receiving MDR-TB treatment, and models of patient support and care[57]. The Mumbai Project provided evidence under the section dedicated to longer regimens for multidrug- or rifampicin-resistant tuberculosis. Specifically, a cohort of 46 patients from the Project from a total intervention population of 84 patients informed evidence for the use of delamanid and bedaquiline in combination. It is important to note that this was not the only population or evidence used in the evidence review, and ultimately the overall evidence available was considered insufficient to make any recommendation on the use of bedaquiline and delamanid in combination[58][59] and thus GoI's 2021 Guidelines for the management of DRTB also did not make any recommendation in this area[60]. Despite this, the Project's contribution to this area is still viewed as significant.

Finding 17: The significance of the Project's contribution to other WHO guidelines could not be established, but it did not appear to directly influence any GoI guidelines.

MSF stakeholders felt that the Project's activities had made a significant contribution to several WHO guidelines, which is reflected in Figures 3-4, as well as some city and/or district level practices[61],[62]. With the exception of the significant contribution outlined in Finding 16 above, it was not possible to objectively triangulate the significance of these contributions, as WHO and GoI guidelines referenced a large number of studies and did not detail the relative level of contribution of the various research studies and stakeholders involved in producing and sharing evidence or advocating for policy change. While the significance of the Project's contribution to other WHO guidelines could not established, we have provided an overview of the reach of Project's operational research in Annex 90.

There was evidence of the Project's operational research being shared at national and international forums, however GoI guidelines did not reference any of these studies[63], and so it would appear that the Project failed to directly influence any GoI publications[64].

Finding 18: Stakeholders felt the Project could have done more to actively advocate for priority interventions at both a national and international level, and thus that the Project's contribution was not as significant or catalytic as it could have been.

The approach to advocacy was seen as constrained and many stakeholders felt that more could have been done, especially in engaging with national level stakeholders in India[65]. The key stakeholders are the Central TB Division, the Secretary Health, the parliamentarian representing the Global TB Caucus and the Minister of Health. Despite the pioneering work done by MSF Mumbai, which is recognised in India by the local WHO office, government health officials, NITRD – an autonomous institutions set up

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[57] Ibid

[58] As stated in the WHO guidelines: "The data on concurrent use of bedaquiline and delamanid are also sparse (49, 86), and did not allow for meaningful analysis; hence, there is no formal WHO recommendation on this subject. However, both medicines may be used concurrently among patients who have limited treatment options, provided that appropriate treatment monitoring (including baseline and follow-up ECG and electrolyte monitoring) is in place."

[59] (WHO, WHO consolidated guidelines on tuberculosis. Module 4: Treatment. Drug-resistant tuberculosis treatment 2020)

[60] (Government of India/Central TB Division 2021)

[61] Such as infection control practices at government clinics within Mumbai, which was confirmed by a GoI stakeholder

[62] KIIs – MSF India and International staff

[63] But did directly reference other research papers in addition to the WHO publications which the Mumbai Project did influence

[64] (Government of India/Central TB Division, Guidelines for Programmatic Management of Drug Resistant Tuberculosis in India 2021); (Government of India/Central TB Division 2021); (Government of India/Central TB Division 2016); (Government of India/Central TB Division 2018); (Government of India/Central TB Division 2017); (Government of India/Central TB Division 2019); (Government of India/Central TB Division 2020); (Government of India/Central TB Division 2019)

[65] KIIs – MSF India; MSF international; NGOS/CSOs; GoI and affiliated organisations

by the government, and other academic and non-state actors[66], MSF OCB India was never a part of any of the technical working groups related to TB in India. This was attributed to the government's resistance to partnering with civil society actors and mistrust of foreign NGOs with international staff[67].

- EQ5.3: What factors, internal and external, enabled, or constrained achievement of results

Finding 19: Key external and internal constraints included government resistance to NGOs and the Project's limited advocacy and collaboration with others. Enabling factors included the widely acknowledged expertise and drive of key Mumbai project team members; and the Prime Minister's ongoing focus on eliminating TB in India.

Key informants from various stakeholder groups all agreed that direct advocacy by MSF as a foreign NGO in India is difficult and may create challenges in operating in the country. An example of government mistrust of foreign NGOs is the recent changes in the Foreign Contributions Regulation Act (FCRA) under which all NGOs operating in India have to register to receive foreign funds. The government has restricted payment of all contributions to NGOs in India from foreign sources by requiring NGOs registered under FCRA to open a bank account in the main branch of the State Bank of India in New Delhi. Government agencies are similarly reported to be hesitant in including Foreign NGOs in decision making bodies or technical working groups. However, there are a few local NGOs and networks that are involved in advocacy with the Ministry of Health on TB, including the Global Coalition of TB Advocates based in New Delhi. The limitations around advocacy and collaboration are discussed under other relevant findings.

Enabling factors included the acknowledgement of the expertise and drive within MSF that was able to provide results in a challenging environment. At the same time, there was growing acknowledgement of the growing problem of TB in India and in 2018, the Indian Prime Minister Mr Modi launched the *'TB Free India'* Campaign at Delhi End TB Summit which aims to end TB in India by 2025. While the achievability of the target can be argued, especially in the changed COVID 19 pandemic environment, the political will to take action against and prioritise TB is undoubted. At the global level, there was growing emphasis on the elimination of TB. The End TB Strategy was adopted by the World Health Assembly in 2014 and this was followed by two high level meetings on tuberculosis: the Moscow Health Minister's Conference in 2017 and the UN High Level Meeting on TB in 2018.

- EQ5.4: What could have been done to make the intervention even more effective? (e.g., better, timelier results)

Finding 20: There was a consensus that more could have been done to improve the effectiveness of the Project's advocacy, for example by improving collaboration with other key stakeholders in India and beyond to effect policy change more quickly.

As outlined in findings under Coordination, a significant range of stakeholders felt that the Project could have improved its effectiveness through a more thorough and appropriate approach to advocacy and collaboration with others[68]. Some specific suggestions for how the intervention could have been more effective included[69]:

▪ Identification of all stakeholders and strategizing advocacy activities to target them

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[66] KIIs - NGOS/CSOs; GoI and affiliated organisations; WHO stakeholders
[67] Ibid
[68] KIIs – MSF India and international staff; NGOs/CSOs; GoI and affiliated organisations
[69] Ibid

- Developing a plan of action to advocate with national and state level government stakeholders responsible for influencing policy
- Advocacy on areas that were not covered by MSF in its attempts to influence policy (psycho-social counselling, diagnostics etc)
- Effective information flow within MSF advocacy teams at the local, national and global levels

  - EQ5.5: What were the intended and unintended consequences (positive or negative) of the Project and the approach chosen?

Finding 21: The main unintended consequence of the approach taken was that the Project was unsuccessful in directly influencing key GoI policies and guidelines as a result of the limited approach to advocacy.

There was limited evidence on unintended consequences, however one example of a positive unintended consequence of the large Project team was that during emergencies such as cyclones and COVID-19, MSF was able to tap into these resources to support the response. Beyond that, as outlined in previous findings, a wide range of stakeholders felt that the Project had not achieved the level of results anticipated in the way originally planned due to the limited approach to advocacy and collaboration with others.[70]

EFFICIENCY

EQ6: How efficient is the MSF Mumbai Project?
  - EQ6.1: Could the allocated resources (financial, HR, set-up) have been used more efficiently?

It is important to note that the findings below are based on purely qualitative analysis of key informant interviews and background documents. This is based on the approach approved during the inception phase of the evaluation, as it was felt that a quantitative analysis of efficiency and/or cost-effectiveness was either not appropriate (as the Project was designed catalytic rather than cost-effective, and costs were high due to the pilot nature of the interventions) and/or not feasible with the time and resources available for the evaluation.

Finding 22: A reduction in the number of international staff over the course of the project was seen as positive, but more targeted use of international staff was seen as necessary in order to improve efficiency.

The number of international staff hired directly under the Project decreased significantly from 2016 to 2020, with six at the start of the Project and three at the end of the Project[71,72]. This was reflected across the Mission and was based on a previous review of the use of international staff. Overall, international staff represented a very small proportion of the total staff, but often filled key coordination roles such as that of Project Coordinator and Medical Referent.

The reduction of international staff was seen to have improved efficiency for a number of reasons: There was sufficient locally available expertise; local staff salaries and allowances were lower; local staff had more understanding of the culture and context; and using local staff bypassed government resistance to foreigners which otherwise impacted on MSF's ability to coordinate and collaborate

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[70] Ibid

[71] (MSF, 2017 Medical Report final 2017); (MSF, Mumbai DR-TB/HIV Project Annual Report 2018 2018); (MSF, Project monitoring: Mumbai Q4/Annual Report- 2020 2020)

[72] All international staff were required to leave the country in June 2017 due to political issues, so the number dropped to zero during that time

effectively with the government. This was seen as especially relevant in terms of the Project's ability to work with government via forums such as technical working groups, where participation of foreigners or foreign organisations was seen as "politically incorrect"[73].

However, MSF and external stakeholders did see some benefits of utilizing international staff in order to bring in different perspectives, and to bolster the perception of neutrality and rigor of operational research.

Finding 23: High staff turnover and poor communications contributed to siloed working, a perceived lack of transparency, and limited acceptance of divergent viewpoints.

There was a relatively high staff turnover within the Project, of both national and international staff[74], which resulted in times when staff had to cover multiple roles, which contributed to poor communication between different components of the Project and with the Mission[75]. Conversely, some saw the large number of technical decision makers from different sources (Mumbai/Project level, Delhi/Mission level, SAMU) with insufficient clarity over who was responsible for making and sharing key decisions as contributing to poor communication[76]:

> "Decisions are not taken in a comprehensive manner with all the relevant people…. this creates issues with harmonization and coherence overall"
>
> MSF India Staff

These issues around poor communication contributed to some perceptions of a lack of transparency around how key decisions were made, and a limited acceptance of new or divergent viewpoints, especially around how best to approach the Project's advocacy objectives[77].

Finding 24: Some stakeholders felt that other interventions could have benefited more patients for the same overall investment levels, and still influenced key policies.

As outlined earlier, the Project's Model of Care was complex and included several different components of community-based and clinical care. Some stakeholders queried how decisions were made around which interventions would be focused on from a patient care perspective, in the relative investment levels in the MSF clinic compared to in MEW, and in the focus on treatment compared to prevention or control activities. Some felt that other initiatives could have improved treatment outcomes in more people, while still influencing key policy changes. Examples shared included the possible value in improving community contact tracing in Mumbai considering the level of community transmission, and the focus on combo treatment relative to other possible interventions[78]:

> "The [MSF] clinic was not made to be sustainable…but we could have been more cost-effective and then more resources could have been allocated to MEW, and they could have received better care… I think we missed an opportunity to get a majority of patients on oral regimen earlier than when it happened"
>
> MSF Staff

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[73] KIIs – Mumbai and Delhi external stakeholders
[74] (MSF, India Field Visit (Angela Uyen – Advocacy) 2018 2018); (MSF, 2017 Medical Report final 2017); (MSF, Mumbai DR-TB/HIV Project Annual Report 2018 2018); (MSF, Project monitoring: Mumbai Q4/Annual Report- 2020 2020); KIIs – MSF India and international staff
[75] Ibid
[76] KIIs – Mumbai, Delhi and International MSF staff
[77] KIIs – MSF India and international staff
[78] KIIs – MSF India and international staff

Finding 25: Other examples of how the Project could have been more efficient included the use of local contractors to conduct outreach activities; and procuring drugs more cheaply through use of government-approved drug suppliers.

Overall, Project activities were quite resource intense. Most of the budget was spent purchasing drugs, and at the MSF clinic the ratio of clinicians and counsellors to clients was high compared to the public health system[79]. In addition to above findings, other examples of potential efficiency gains included through utilizing drug suppliers pre-approved by the government rather than exclusively using WHO-approved suppliers[80]; and through contracting other respected and established organisations[81] to conduct some community outreach activities, such as palliative care and counselling services[82], rather than using MSF-hired staff[83][84].

SUSTAINABILITY

EQ7: Are Project results likely to be sustained?
- EQ7.1: Were appropriate sustainability aspects embedded in the Project design and were risks to sustainability considered?
- EQ7.2: To what extent are the Project results (objectives and impact) likely to continue after the Project?

Finding 26: Project exit strategies were based on high-risk assumptions, such as the government's capacity to take over implementation, and most lacked a defined timeline.

The Project's strategy outlined exit criteria for each individual project area, all of which were dependent on the government's ability to take over implementation of activities[85][86]. There were no defined timelines for this to occur[87], and these strategies were implicitly based on high-risk assumptions, such as the government having the human and financial capacity to provide the same or similar level of care to an increased number of patients.

It was widely felt that these exit strategies were not appropriate if Project sustainability was to be achieved over any reasonable timeframe. Both MSF staff and wider stakeholders felt that if the government did not have the resources to implement the changes to policies and take over interventions, then nothing would be left behind in Mumbai when the Project ended, and that even with updated policies and guidelines in place, implementation roll-out was likely be slow due to the sheer size of the country amongst other factors[88]:

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[79] (MSF, 2017 Medical Report final 2017); (MSF, Mumbai DR-TB/HIV Project Annual Report 2018 2018); (MSF, Project monitoring: Mumbai Q4/Annual Report- 2020 2020);

[80] KIIs – MSF India staff; GoI and affiliated institution stakeholders

[81] Such as nursing homes or other CSOs/NGOs

[82] District government stakeholders felt that local NGOs such as TISS provided better quality counselling services despite having fewer counsellors per patient

[83] Who were more expensive in most cases, and seen as less effective at providing patient counselling

[84] KIIs – MSF India staff; CSO stakeholders

[85] At that time, the MSF clinic, KEM and SEWRI

[86] (MSF, 2016 Project Document Mumbai 2016)

[87] Although the HIV related intervention in KEM was planned to be "short and sweet", and did end by 2019

[88] KIIs – MSF India and international; GoI and affiliated organization stakeholders; CSO/NGO stakeholders; WHO stakeholders

> "Hopefully the trial will provide evidence that all shorter oral regimen is the most efficient way to treat DRTB, otherwise there is no sustainability – the clinic, patient support, all will disappear if or when the Mumbai Project ends"
>
> MSF India Stakeholder

Finding 27: MSF stakeholders' views on the importance of sustainability varied, with several seeing sustainability as an unnecessary goal for catalytic projects, and others concerned about the lack of Project sustainability.

Some MSF stakeholders felt that at an organizational level MSF did not generally try to embed sustainability into Projects. This was partly attributed to the organization's usual focus on short-term emergency response, combined with a sense that for a Project to be truly catalytic, the aim was to demonstrate what worked without worrying about costs, and worry about sustainability later[89]:

> "There is a reluctance to say our model is sustainable, as we are heavily resourced, but we are always working towards simplification…. [we tend to] think later about how the model can be scalable"
>
> MSF India Stakeholder

Other stakeholders were however concerned by the lack of sustainability and the implications of this for the future[90]:

> "If we close tomorrow, what are we leaving behind…Yes, we saved lives, but nothing will change for future patients…there will be nothing left in terms of change in the health care system"
>
> MSF India Stakeholder

Finding 28: Overall the model of care was considered highly unsustainable, with limited likelihood of the government being able to replicate it in the foreseeable future.

Across the board, stakeholders felt that the Project's model of care was neither cost-effective nor affordable and would only continue as long as MSF was continued to implement activities[91]. This included treatment using new/oral drugs and patient support activities. While the treatment guidelines in India have been changed since March 2021 and are now aligned with the WHO updated guidelines on treatment of drug resistant tuberculosis, there is a shortage of drugs; drugs are available only through certain hospital and treatment centres and, more importantly, the continuation of Bedaquiline and Delamanid in combination beyond the recommended 24 weeks, which has shown good results with MSF clients, was not incorporated into either the revised WHO or GoI guidelines, so cannot yet be rolled out more widely[92].

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[89] KIIs – MSF International; MSF India
[90] KIIs – MSF International, MSF India
[91] KIIs – MSF International, MSF India, Government of India and affiliated organisations, WHO, CSO/NGO stakeholders
[92] (Government of India/Central TB Division 2021); (WHO, WHO consolidated guidelines on tuberculosis. Module 4: Treatment. Drug-resistant tuberculosis treatment 2020)

However, while stakeholders felt that quality would likely be compromised to some extent, the interventions would be sustainable in the longer term if taken over by the government (as opposed to nonstate actors who would only continue as long as funding is available)[93]. Several stakeholders felt that the patient support aspect of the model of care was the least likely to be sustained due to a lack of human resources within the government to provide counselling services[94], but some suggested that local NGOs may be able to take over some aspects of this[95,96].

MSF supported complex clients, who otherwise had no hope, with its unique approach and ensured that many of them were cured. However, the lack of support to these patients if MSF left the area was highlighted as a concern[97]. There were differing opinions on who should take over the services provided by MSF if or when they chose to leave the Project area. Some favoured a takeover of at least the diagnostic and treatment services by the public health system while some favoured a handover to local non state actors able to deliver these services with some training and handholding[98]. However several stakeholders noted the risk that any handover would potentially lead to a return to inadequate services and compromise on quality as the project addresses the very gaps that exist in the system[99].

<div style="background:#e8e8e8;padding:8px">

Finding 29: The sustainability of policy results is severely constrained in India considering the government's limited resources but is more promising in other contexts where governments have the resources to implement the guidelines.

</div>

As outlined previously, most stakeholders expressed doubts about the Indian government's ability to implement the revised DRTB guidelines due to the lack of available resources. However, it was highlighted that the Project was designed to have a catalytic impact on policies and guidelines and thus DRTB care beyond India. In this wider context, MSF internal stakeholders felt the prospects for sustainability were considered more promising, especially in contexts where governments have more resources to implement the improved guidelines[100]:

> "If [the] Mumbai Project influenced WHO and they then change guidelines, that is a big achievement….if we have influenced WHO international guidelines [but not Government of India guidelines directly] that is okay. There are plenty of countries that update their guidelines based on WHO, and will use delamanid and bedaquiline combo after that, this is easy to spot."
>
> <p align="right">MSF International stakeholder</p>

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[93] KIIs – MSF India, GoI and affiliated organisations; WHO, NGO/CSO stakeholders
[94] KIIs – MSF India, MSF International, Government of India and affiliated organisations
[95] KIIs – Government of India and affiliated stakeholders
[96] Although it was not clear whether these NGOs would be able to find ongoing or increased funding to do this
[97] KIIs - MSF India, GoI and affiliated organisations; WHO, NGO/CSO stakeholders
[98] KIIs – GoI and affiliated organisations; WHO, CSO/NGO stakeholders
[99] Ibid
[100] KIIs – MSF International, MSF India staff

CONCLUSIONS

Our conclusions below are cross-cutting against the evaluation criteria. We have indicated which of the criteria apply to each criteria using the following coding:

R Relevance **C** Coordination **E** Effectiveness **E** Efficiency **S** Sustainability

CONCLUSION 1	The Project's <u>strategy and interventions</u> were seen as <u>highly relevant and adaptive</u> to the TB context in Mumbai, to MSF's experience and expertise, and <u>to the overall objective to influence DR-TB policy.</u>	**R**

- The overall Project strategy and interventions were relevant to the context and to the overall objective. While it was not explicitly planned, a key strength of the Project was its ability to adapt in line with changes to the context, which supported the ongoing relevance of the interventions.

CONCLUSION 2	The <u>approach to influencing policy</u> was <u>pragmatic rather than strategic.</u> There were <u>missed opportunities</u> to <u>identify and prioritize</u> the specific <u>guidelines</u> being targeted and the <u>stakeholders that could support influencing of those guidelines.</u>	**R** **C**

- The Project was reluctant to actively and directly advocate or lobby Government of India for policy change due to the Government's adversarial relationship with foreign organisations. As a result, the overall approach to influencing policy was pragmatic and instead of identifying a broader range of stakeholders that could support its policy targets, instead worked with only a limited number of key individuals and organisations affiliated with the Government.

CONCLUSION 3	The <u>advocacy approach</u> was <u>dependent</u> on the demonstration of an <u>effective and replicable model of care.</u> The model of care <u>was effective</u>, but its ability to drive policy change was <u>constrained by its complexity</u> and <u>limited replicability</u> and thus <u>lack of sustainability.</u>	**S** **E** **R**

- Prior to the onset of this evaluation, there was no document which clearly defined the Project's model of care. As a result, demonstrating and sharing the model of care with key stakeholder was not possible, and so advocating for scale up and replication was not possible. Furthermore, it was ultimately seen as too complex and resource intensive and thus not sustainable.

CONCLUSION 4	There were <u>missed opportunities to build relationships</u> with other key internal and external stakeholders which <u>would have improved the Project's ability to advocate for policy change</u> and improved sustainability	**S** **E** **C**

- The Project did not sufficiently build on the stakeholder mapping which was conducted or build relationships with the necessary stakeholders' organisations which could have supported it in influencing key policies. This contributed to perceptions of a lack of sustainability and did little to break down barriers with the government.

CONCLUSION 5	The project <u>directly influenced some key WHO DR-TB treatment policies</u> and thus <u>indirectly influenced DR-TB policies in India and beyond</u>, but there were <u>missed opportunities</u> to improve the catalytic effect through <u>improved advocacy and collaboration</u> with others.	C E

- While the Project was successful in influencing some key guidelines in India and beyond, due to the Project's constrained approach to advocacy and collaboration with others, the contribution was not as significant or as catalytic as it could have been.

CONCLUSION 6	The <u>lack of focus on efficiency</u> and <u>sustainability</u> in the Project resulted in <u>unintended consequences</u> and <u>affected overall Project results.</u>	E S E

- The Project's decision not to focus on efficiency and sustainability may have appeared pragmatic due to the intended catalytic nature of the Project, however there were clear tensions between the desire to be pioneering but simultaneously demonstrate an affordable and replicable model. This ultimately affected perceptions of the Project's model of care and thus the Project's ability to use it to advocate for policy change.

RECOMMENDATIONS

As the Mumbai Project continues to operate, we have provided some indicative recommendations as for the Project specifically, some of which we anticipate will be applicable to the wider India Mission and catalytic projects more generally. The recommendations below are mapped against the conclusions and are based on the evaluation team's insights and expertise combined with input from the CG during a working session held in early August 2021.

<u>Conclusion 1</u>: The Project's strategy and interventions were seen as highly relevant and adaptive to the TB context in Mumbai, to MSF's experience and expertise, and to the overall objective to influence DR-TB policy.

⇒ **Recommendation 1: Build on projects adaptability**
One of the key strengths of the Project's approach was its ability to adapt to the context. MSF should build on this by making it an explicit part of future strategies; and ensuring that Project monitoring and evaluation systems and processes are robust enough to capture changes in the context and preliminary project results to support timely adaptation.

<u>Conclusion 2</u>: The approach to influencing policy was pragmatic rather than strategic. There were missed opportunities to identify and prioritize the specific guidelines being targeted and the stakeholders that could support influencing of those guidelines.

⇒ **Recommendation 2: Develop a more strategic approach to advocacy**
To improve the required support from key policy makers and those influence them MSF should utilise a more strategic approach to advocacy. Key steps include mapping all stakeholders in the policy environment, identifying and prioritising areas that require policy change, matching MSF's expertise and experience to focus on specific areas for change and plan the approaches to advocating for change and influencing policy, including the role of MSF actors at various levels (local, national, SAMU, Global) and the effective flow of information.

Suggested resources:
1. *'TB/MDR-TB Advocacy Tool Kit'* published by the Advocacy Partnership[101]
2. *'Advocacy, Communication and Social Mobilisation for TB Control: Collection of country-level good practices'* [102]

Recommendations 3-5 (of 5) →

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[101] Available online at: http://www.stoptb.org/ assets/ documents/ global/ awards/ cfcs/tb_mdr%20advocacy% 20tool%20kit.pdf
[102] Available online at: http://www.stoptb.org/ assets/documents/resources/publications/acsm/ ACSM_final_24 %20Nov.pdf

<u>Conclusion 3</u>: The advocacy approach was dependent on the demonstration of an effective and replicable model of care. The model of care was effective, but its ability to drive policy change was constrained by its complexity and limited replicability and thus lack of sustainability.

⇒ **Recommendation 3: Ensure a balanced Model of Care**

The Project's model of care aims to be simultaneously pioneering, by piloting new/innovative interventions, while also demonstrating a model which is replicable. New and pioneering interventions are by their nature resource intensive and expensive, however, to demonstrate a model which is seen as realistic for the government to adopt in the future, there is a need to ensure that the Project's model of care takes the wider health system context and resources into account. This can be done by reviewing the model of care to ensure that the right balance is achieved in terms of being able to provide an evidence base for new interventions, while also demonstrating to stakeholders that in a non-pilot situation, the model is affordable and thus replicable and sustainable.

<u>Conclusion 4</u>: There were missed opportunities to build relationships with other key internal and external stakeholders which would have improved the Project's ability to advocate for policy change and improved sustainability.

<u>Conclusion 5</u>: The project directly influenced some key WHO DR-TB treatment policies and thus indirectly influenced DR-TB policies in India and beyond, but there were missed opportunities to improve the catalytic effect through improved advocacy and collaboration with others.

⇒ **Recommendation 4: Develop more strategic partnerships**

MSF in India had a good partnership with the NITRD which is an autonomous institute under the Ministry of Health and Family Welfare in India. Information sharing and coordinating with the NITRD was able to influence policy at the national level. Even though this is not directly attributed to MSF, it is acknowledged by senior government functionaries. MSF can forge similar partnerships with governmental institutions or institutions set up under the aegis of the government. This is especially important in a large country like India where international NGOs are considered insignificant compared to the size and resources of the government programme and non-state actors are sometimes kept at a distance due to a perceived 'problem' factor where NGOs, especially INGOs are seen as troublemakers as they can draw attention to local problems in international forums.

<u>Conclusion 6</u>: The lack of focus on efficiency and sustainability in the Project resulted in unintended consequences which affected overall Project results.

⇒ **Recommendation 5: Ensure Efficiency and Sustainability are considered in project design**

The Project should ensure that sustainability and efficiency are embedded in the overall strategy and design. For efficiency, ensuring transparency over HR and strategic and operational decisions which have an impact on project efficiency would be a positive first step. In the longer term, building the capacity to outline the relative cost-benefits of different interventions would be valuable. For sustainability, this would mean having a timebound exit strategy, with risks/assumptions and mitigations clearly outlined. Key steps in an exit strategy could include:

- Invite MoH to participate in MSF Round Tables and multi-year review of operations (MYRO)
- Include local NGOs (capable of taking over activities) in the MYRO
- Discuss exit modalities with all stakeholders in a round table
- Develop an operational plan to transfer ownership of interventions
- Explore the use of automation or digital technologies for some of the activities, e.g., adherence support[103], diagnosis, stigma and information sharing, training etc.
- Explore forging links with urban ASHA workers, scoping their role in urban TB control and visualizing a framework in which they could be used as community motivators for DR-TB[104].

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[103] DOST, a digital adherence app is already being developed by MSF and it provides adherence support etc.
[104] In high burden areas, a cross section of the urban ASHAs could also be trained to step into the shoes of lay counsellors to the patients.

ANNEXES

ANNEX 1: TERMS OF REFERENCE

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TERMS OF REFERENCE

Doctors without Borders/Médecins Sans Frontières (MSF) is an international medical humanitarian organization determined to bring quality medical care to people in crises around the world, when and where they need regardless of religion, ethnical background, or political view. Our fundamental principles are neutrality, impartiality, independence, medical ethics, bearing witness and accountability.

The Stockholm Evaluation Unit (SEU), based in Sweden, is one of three MSF units tasked to manage and guide evaluations of MSF's operational projects. For more information see: evaluation.msf.org.

Subject/Mission:	The Catalytic Role of Mumbai Project with Regards to Policy Changes
Starting date:	February 2020
Duration:	Final deliverable by latest mid-June (date TBC), 2021
Requirements:	Interested applicants should submit: 1) A proposal describing how to carry out this evaluation (including budget in a separate file), 2) CV(s), and 3) a written sample from previous work
Deadline to apply:	March 14th, 2021, 23:59 CET
Send application to:	evaluations@stockholm.msf.org
Special considerations:	Due to the ongoing Covid-19 pandemic the evaluation might need to be conducted remotely, even if data collection in India is the preferred option. The evaluation will involve stakeholders in different locations and evaluators are expected to adapt to different schedules.

PROJECT BACKGROUND[1]

India accounts for about a quarter of the global tuberculosis (TB) burden. In 2018, the estimated TB incidence was 2,690,000. India is the country with the highest-burden of TB and Drug-Resistant (DR) TB, accounting for 27% of the world's 10.4 million new TB cases and 29% of the 1.8 million TB deaths globally. The National Strategic Plan for Elimination of TB 2017-2025 recognises that India has highest burden of Multidrug-resistant-TB (MDR-TB) in the world. India is also the country with the second-highest number (after South Africa) of estimated Human Immunodeficiency Virus (HIV) associated TB cases.

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[1] The information below is taken from Mumbai Project document ARO2020, for 2020-2022.

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Although the national TB program has been planning and rolling out diagnostics, paediatric formulations, and new drugs for DRTB since 2016, the new generation of paediatric formulations and TB drugs, Bedaquiline and Delamanid, remain mostly out of reach for many. In March 2018, The Prime Minister of India committed to eliminate TB by 2025. The national programme revised its National Strategic Plan to ensure universal access to quality diagnosis and treatment of DRTB.

A large number of MDR-TB patients not responding to traditional prescribed regimes have to be treated with an all-oral regimen containing Bedaquiline and/or Delamanid. According to the India TB Report 2020, a total of 66,255 patients with MDR/Rifampicin-resistant TB (RR-TB) were notified in the private and public sector in 2019. Of these, 59,945 MDR/RR-TB patients were notified in the public sector and 56,569 (85%) of the MDR/RR-TB patients were started on treatment. Only 1,738 MDR/RR-TB patients among this group were put on all-oral regimen. Furthermore, in 2019 a mere 2,323 XDR-TB patients were diagnosed of which 1,918 persons were put on treatment. Resource allocation and pace of implementation are far from adequate to achieve their ambitions of eliminating TB by 2025.

THE CITY OF MUMBAI

Mumbai is a hotspot for TB and DRTB transmission with a context that has all favourable conditions for TB to flourish from medical co-morbidities and socio-demographic standpoints. The city has a mean population density of 49,000 per sqm[2], over half of whom live in the slum-like dwellings[3] that have all favourable conditions for TB to flourish - overcrowding, inadequate safe water and sanitation, poor housing, and insecurity of tenure[4]. Mumbai has 12% of the population of Maharashtra state, but accounts for 22% of notified cases of TB[5], and M East ward where MSF project is located, is home to about 5-6% of Mumbai's population but accounts for about 20-25% of the city's DRTB burden.

An estimated 45,000 new TB and about 4,500-5,000 DRTB infections occur in Mumbai annually. Over the last six years TB and DRTB has caused 7,768 deaths per year (8.1% of all causes of death in the city). DRTB treatment outcomes are comparable to national cohort outcomes, i.e. 34.5% treatment success, 28.4% mortality, 29.6% lost to follow up, and 7.5% treatment failure or were changed to XDR-TB treatment (Parmar et al[6]).

MSF-OCB's Mumbai Project

MSF's Operational Centre Brussels (OCB) has been present in Mumbai since 1999.

In 2016, MSF-OCB initiated DRTB activities in M East Ward (MEW) in collaboration with MCGM (Public Health Department of Municipal Cooperation of Greater Mumbai) and the national TB programme.. By becoming a government partner and working within its facilities, MSF hopes to promote improved access, practices and protocols. To date, the Mumbai project runs different activities in several locations. The overall objective is to demonstrate a model of care that reduces mortality, the morbidity

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[2] Municipal Corporation of Greater Mumbai. Oxford University Press; New Delhi: 2010. Mumbai Human Development Report 2009.
[3] Census of India. New Delhi: Office of the Registrar General and Census Commissioner, India, 2001. www.censusindia.gov.in/
[4] United Nations Human Settlements Programme (UN-Habitat) Earthscan Publications Ltd; London and Sterling VA: 2003. *The Challenge of Slums: Global Report on Human Settlements*, 2003.
[5] N. Mistry et al. Drug-resistant tuberculosis in Mumbai, India: An agenda for operations research. Oper Res Health Care. 2012 June; 1(2-3): 45–53.
[6] Parmar MM, Sachdeva KS, Dewan PK, Rade K, Nair SA, Pant R, et al. (2018) Unacceptable treatment outcomes and associated factors among India's initial cohorts of multidrug-resistant tuberculosis (MDR-TB) patients under the revised national TB control programme (2007–2011): Evidence leading to policy enhancement. PLoS ONE 13(4): e0193903. https://doi.org/10.1371/journal.pone.0193903

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of DR-TB and HIV, increases timely access to diagnostics and the most effective drug regimens for patients who have limited treatment options due to an extensive drug-resistance profile and increase the quality of life for patients at MSF supported locations[7].

The Mumbai project is, according to the MSF OCB terminology, a catalytic intervention: the rationale for MSF-OCB to intervene is less the humanitarian imperative than the willingness to demonstrate and achieve change.

Summary of Activities

- 'MSF's private clinic (Govandi) provides comprehensive and patient-centred care and treatment for pre-XDR and XDR-TB and HIV patients who have otherwise very limited treatment options and need additional drugs and paediatric formulations not available in the government system. In particular the clinic provides patients, salvage regimens containing both the new drugs-bedaquiline and delamanid - for patients who have limited treatment options due to an extensive drug-resistance profile or intolerance to other second-line TB medications.
- In the Pandit Madan Mohan Malaviya Hospital, known as MMM hospital (Shatabdi, MEW, Structure from the Ministry of Health, MoH): supporting activities to provide comprehensive care and more effective treatment regimens for some DRTB patients, adopting the same patient-centred approach as in MSF clinic, with some adaptations to comply with MOH guidelines.
- Across M East Ward: providing community-based patient follow-up, as well as counselling in health facilities and through outreach team, with referrals to 'Shatabdi DRTB OPD
- At SEWRI TB hospital, providing counselling services to DRTB patients and referrals of patients in need of more effective regimen containing a combination of the newer drugs to the MSF private clinic.
- Operational Research and advocacy are embedded in operations.

The advocacy general objective is "to demonstrate a (replicable) model of care and produce evidence for influencing policy change and/or improved services for DRTB, HIV & HepC Care in Mumbai, India"[8]. Knowing that from 2020 onwards, focus is on DRTB, as is this evaluation.

The Four Sub-Objectives[9]

- Advocate for the accelerated roll-out of timely and accurate diagnostics: GeneXpert & drug-sensitivity testing I & II
- Advocate for accelerated roll-out and increased availability of Bedaquiline and Delamanid at national level.
- Promote MSF's patient-centred model of counselling and treatment as a model of best practice.
- Highlight the need of tackling DR-TB among paediatric cases in Mumbai.

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[7] Mumbai Project document ARO2020, for 2020-2022.
[8] Mumbai Advocacy Comms Strategy MSF OCB 042020.
[9] Mumbai Advocacy Comms Strategy MSF OCB 042020.

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PURPOSE AND INTENDED USE

This evaluation aims to document how catalytic (leading to change) the DRTB intervention in Mumbai is and determine its relative value or significance in terms of achieving policy changes. The timeframe to be considered is 2016-2020, even though there is a need to look at the project before 2016 to understand its evolution.

The objective of the evaluation is two-fold:
1) to systematically describe the DRTB project approach (the strategy, the model, and activities) and catalytic dimension and the expected outcomes.
2) to evaluate results achieved in terms of policy changes (outcome) and identify potential lessons learnt.

The evaluation findings will be used by the operational management (Project, Mission, Cell) and technical referents within the support departments. The evaluation will help inform future decisions and potential adaptations of the project regarding its catalytic role towards policy changes and contribute to organizational learning. The evaluation asks for clear evidence of what worked and under what circumstances and will identify which elements should be continued and replicated. The evaluation should also highlight which aspects should be better considered in the future, by the Mumbai project or other catalytic or DRTB projects in similar settings.

Evaluation aims to also be presented at other major events such as the MSF Scientific Days, MSF TB symposium and to external stakeholders (all on dates still to be confirmed).

EVALUATION QUESTIONS

1. **Evaluation question: How relevant are the objectives of the project with regards to being catalytic?**
- What are the objectives, expected results, activities, and indicators?
- In what way could the project be more relevant?

2. **Evaluation question: How appropriate is the catalytic dimension of the Mumbai project?**
- What is the theory of change?
- Which policies apply, and to what extent is the project in line with them? (MSF and local, national, and international standards)
- Is the strategy, including advocacy strategy, appropriate to achieve the catalytic dimension?
- Does the strategy take into consideration changes in the environment in a timely manner?

3. **Evaluation question: How effective is the catalytic dimension of the Mumbai project?**
What are the results achieved so far, and to what extent do they correspond to the objectives?
- What were the reasons (enablers and barriers, challenges encountered, expected or unexpected) for achievement or non-achievement of objectives set?
- What could have been done to make the intervention even more effective? (e.g. better, timelier results)
- What were the intended and unintended consequences of the approach chosen?

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4. **Evaluation question: How efficient is the Mumbai project?**
- Which resources have been allocated to achieve the results above? (eg financial, Human resources, set-up)
- Could resources have been used more efficiently?

5. **Evaluation question: How connected is the Mumbai project?**
- How does the project work and coordinate with other actors, including the civil society, TB treatment providers and Ministry of Health?
- Is the project embedded in the local health system, overall national strategy and building on existing capacity?
- How are patients and communities involved in the project?
- How sustainable is the collaboration with other actors? How are risks mitigated?

6. **Evaluation question: What has been the Mumbai project's impact on policies at the local, national and international level?**
- Which policy changes has the project contributed to?
- Did the project contribute to any other changes (positive or negative)?
- How sustainable are those changes?

EXPECTED DELIVERABLES

1. **Inception Report**
As per SEU standards, after conducting initial document review and preliminary interviews. It will include a detailed evaluation proposal, including methodology.

2. **Draft Evaluation Report**
As per SEU standards. It will answer the evaluation questions and include conclusions, lessons learned, recommendations, and appropriate scenarios.

3. **Working Session**
With the attendance of commissioner and consultation group members. As part of the report writing process, the evaluator will present the findings, collect attendances' feedbacks and will facilitate discussion on lessons learned and recommendations.

4. **Final Evaluation Report**
After addressing feedbacks received during the working session and written inputs.
A short version of the evaluation report should also be produced, to be shared with external stakeholders for example.

5. **Presentation at internal roundtable discussion and at MSF-OCB (remotely)**
Present findings, conclusions, and recommendations at an internal discussion to define the future of the project, mid-June 2021 (date TBC) and, at a different session, to headquarters' staff in a 1-hour webinar.

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TOOLS AND METHODOLOGY PROPOSED

In addition to the initial evaluation proposal submitted as part of the application (see profile requirements chapter), the evaluators should prepare a detailed evaluation protocol during the inception phase. It will include a detailed explanation of proposed methods and its justification based on validated theory/ies. It will be reviewed and validated as a part of the inception phase in coordination with the SEU.

RECOMMENDED DOCUMENTATION

- MSF-OCB documentation at various levels (project, mission, Cell, technical departments)
- Operational research, published studies, and other evaluative exercises.
- External literature and documentation

PRACTICAL IMPLEMENTATION OF THE EVALUATION

Number of evaluators	To be suggested in proposal
Timing of the evaluation	March-June 2021

PROFILE REQUIREMENTS FOR EVALUATOR(S)

Requirements:
- Demonstrable skills and knowledge of evaluation, specifically synthesising mixed data
- Public Health expertise, knowledge of medical operations in humanitarian/development settings
- Expertise of advocacy and policy work as well as multi-sector/-agency collaboration
- Expertise in DRTB programming and activities
- Fluent English
- Experience in India or of the Indian context

Assets:
- Previous experience working with MSF

APPLICATION PROCESS

The application should consist of a technical proposal, a proposed budget, CV/s (all if a team is proposed), and corresponding work samples. As a minimum, the proposal should include a reflection on ethical standards for evaluations, any sensitivity of the topic at hand and a detailed methodology and approach which clearly demonstrate the proposed data collection and link to the evaluation questions. Please note that the SEU is particularly interested in receiving proposals with creative and innovative ways to achieve the stated evaluation purpose.

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Proposals should include a separate financial quotation for the complete services, stated in Euros (EUR). The budget should present consultancy fee according to the number of expected working days over the entire period, both in totality and daily. Travel costs, if any, do not need to be included as the SEU will arrange and cover these. Do note that MSF does not pay any per diem.

Applications will be evaluated on the basis of whether the submitted proposal captures an understanding of the main deliverables as per this ToR, a methodology relevant to achieving the results foreseen, and the overall capacity of the evaluator(s) to carry out the work (i.e. inclusion of proposed evaluators' CVs, reference to previous work, certification).

Interested teams or individuals should apply to evaluations@stockholm.msf.org referencing MUMPO no later than March 14th, 2021. We would appreciate the necessary documents being submitted as separate attachments (a proposal, budget, CV, work sample and such). Please include your contact details in your CV.

ANNEX 2: MSF MUMBAI PROJECT THEORY OF CHANGE
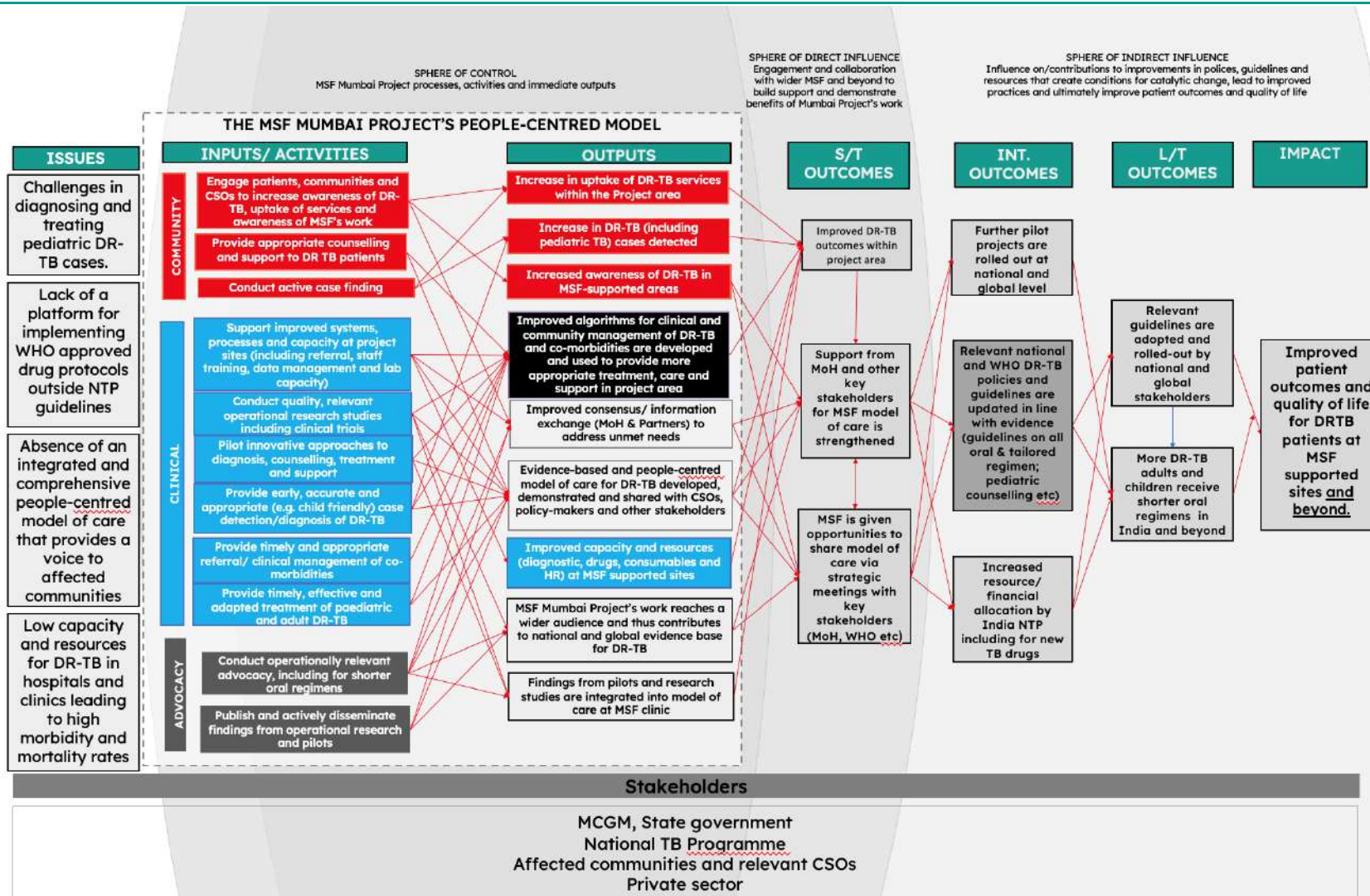
ANNEX 3: EVALUATION MATRIX

CRITERIA	EVALUATION QUESTIONS	SUB-QUESTIONS	JUDGEMENT CRITERIA	DATA SOURCES/ DATA COLLECTION METHODS	ANALYTICAL APPROACHES
Relevance	1. How relevant and appropriate is the Project's strategy (including advocacy strategy) in terms of achieving the central policy-related outcome? (ToR EQ 2)	1.1. How relevant are the objectives of the Project as outlined in the Project strategy to achieving the central policy-related outcome? (ToR EQ 1.2) 1.2. Does the Strategy consider established knowledge around to affecting policy change and catalytic change in general? (ToR EQ 2.3) 1.3. Does the strategy and approach support adaptive management in line with contextual changes in the (policy) environment? (ToR EQ 2.4)	• Evidence of strategy alignment with ToC • Evidence of strategy alignment with established knowledge/literature on achieving policy/catalytic change • Regular, quality planning and consultation with key stakeholders is in place	• KIIs • Document review	• Benchmarking/ comparative analysis of strategy with good practice/established knowledge/literature • Mapping of changes in strategy and model against changes in (policy) environment • Contribution analysis-inspired approach

CRITERIA	EVALUATION QUESTIONS	SUB-QUESTIONS	JUDGEMENT CRITERIA	DATA SOURCES/ DATA COLLECTION METHODS	ANALYTICAL APPROACHES
	2. How relevant and appropriate are the activities and outputs of the project with regards to leading to key policy-related outcomes and the overall project goal or impact, namely catalytic changes in policy which lead to improved DRTB outcomes beyond the project area? (ToR EQ 1, EQ2)	2.1. Is the project aligned with and influencing the most appropriate and relevant policies (MSF, local, national, international)? (ToR EQ 2.2) 2.2. Are the project activities relevant in terms of influencing the desired policy changes at MSF, local, regional and national level? (ToR EQ 1.2) 2.3. Are activities: a) necessary, and b) sufficient to contribute to project outcomes and objectives and the intended catalytic change? (ToR EQ 1.2) 2.4. What assumptions underpin the intervention logic, and have they been upheld? (ToR EQ 1.2)	• Alignment with Project's ToC	• KIIs • Document review	• Qualitative analysis and triangulation between data sources and across stakeholder groups

CRITERIA	EVALUATION QUESTIONS	SUB-QUESTIONS	JUDGEMENT CRITERIA	DATA SOURCES/ DATA COLLECTION METHODS	ANALYTICAL APPROACHES
Coordination	3. To what extent does the MSF Project work complement and coordinate their work with other key stakeholders (ToR EQ 5)	3.1. How effective is the Project's coordination with other actors, including civil society, TB treatment providers and Ministry of Health? (ToR EQ 5.1, EQ 5.2) 3.2. How sustainable is the collaboration with other actors? (ToR EQ 5.3)	• MSF activities are well aligned and coordinated with activities of key stakeholders • MSF has established strong, ongoing and collaborative relationships with key stakeholders	• KIIs • Document review	• Qualitative analysis and triangulation between data sources and across stakeholder groups
Effectiveness	4. Has the DRTB model of care effectively supported the central policy outcome the project? (ToR EQ 3)	4.1. Does the model of care align with established good practice and latest evidence? (ToR EQ 3.1, EQ 3.3) 4.2. Have the results, in terms of DR-TB treatment outcomes, supported effective advocacy for policy change? (ToR EQ 3.1	• Evidence of model alignment with established good practice • Evidence of results in terms of treatment outputs and patient outcomes within the project area	• KIIs • Document review • Review of project M&E data	• Benchmarking/ comparative analysis of the model of care with good practice/established knowledge/literature • Contribution analysis-inspired approach

CRITERIA	EVALUATION QUESTIONS	SUB-QUESTIONS	JUDGEMENT CRITERIA	DATA SOURCES/ DATA COLLECTION METHODS	ANALYTICAL APPROACHES
	5. How effective has the Project been in achieving policy-related results? (ToR EQ 3, EQ6)	5.1. To what extent have project's policy related results been achieved? (ToR EQ 3.1) 5.2. How has the MSF Project contributed to these results? (ToR EQ 6.1) 5.3. What factors, internal and external, enabled or constrained achievement of results (ToR EQ 3.2) 5.4. What could have been done to make the intervention even more effective? (e.g., better, timelier results) (ToR EQ 3.3) 5.5. What were the intended and unintended consequences (positive or negative) of the Project and the approach chosen? (ToR EQ 3.4)	• Evidence of results in terms of relevant policies being revised as a result of MSF advocacy • Gaps in anticipated results identified • Evidence of success/constraining factors • Evidence of unintended results/consequences identified	• KIIs • Document review • Review of project M&E data	• Contribution analysis-inspired approach • Quantitative analysis of policies/guidelines influenced by the Project
Efficiency	6. How efficient is the MSF Mumbai Project? (ToR EQ 4)	6.1. Could the allocated resources (financial, HR, set-up) have been used more efficiently? (ToR EQ 4.1, EQ4.2)	• N/A – no specific criteria will be used for judgement. Instead, broad learning points will be pulled from our data collection and analysis	• KIIs • Document review • Review of M&E data and financial/HR data	• Qualitative analysis and triangulation between data sources and across stakeholder groups

CRITERIA	EVALUATION QUESTIONS	SUB-QUESTIONS	JUDGEMENT CRITERIA	DATA SOURCES/ DATA COLLECTION METHODS	ANALYTICAL APPROACHES
Sustainability	7. Are Project results likely to be sustained? (ToR EQ 5.4, EQ 6.3)	7.1. Were appropriate sustainability aspects embedded in the Project design and were risks to sustainability considered? (ToR EQ 6.3) 7.2. To what extent are the Project results (objectives and impact) likely to continue after the Project? (ToR EQ 6.3) 7.3. See EQ3.2 (ToR EQ 5.4)	• Evidence of exit strategies/transition plans • Evidence of key stakeholders having increased capacity to continue to advocate for effective DRTB treatment of support • Non-MSF sources of funding are available to sustain effective DRTB treatment model within the project area in the medium to long-term	• KIIs • Document review • Review of M&E data	• Qualitative analysis and triangulation between data sources and across stakeholder groups

ANNEX 4: LIST OF DOCUMENTS REVIEWED

USAID/TB CARE II Project. 2015. "Comprehensive Guidelines for TB and DR-TB Palliative Care and Support, 2015."

Ahmad N, Ahuja SD, Akkerman OW, Alffenaar JC, Anderson LF, Baghaei P, Bang D, Barry PM, Bastos ML, Behera D, Benedetti A, Bisson GP, Boeree MJ, Bonnet M, Brode SK, Brust JCM, Cai Y, Caumes E, Cegielski JP, Centis R, Chan PC, Chan ED, Chang KC, Charles M,. 2018. "Treatment correlates of successful outcomes in pulmonary multidrug-resistant tuberculosis: an individual patient data meta-analysis."

Bisson GP, Bastos M, Campbell JR, Bang D, Brust JC, Isaakidis P, Lange C, Menzies D, Migliori GB, Pape JW, Palmero D, Baghaei P, Tabarsi P, Viiklepp P, Vilbrun S, Walsh J, Marks SM. 2020. "Mortality in adults with multidrug-resistant tuberculosis and HIV by antiretroviral therapy and tuberculosis drug use: an individual patient data meta-analysis."

Government of India/Central TB Division. 2021. "Guidelines for Programmatic Management of Tuberculosis Preventive Treatment in India."

Government of India/Central TB Division. 2016. "Guidelines for use of Bedaquiline in RNTCP through conditional access under Programmatic Management of Drug Resistant Tuberculosis in India."

Government of India/Central TB Division. 2018. "Guidelines for use of Delaminid in the treatment of Drug Resistant TB in India 2018."

Government of India/Central TB Division. 2019. "Guidelines on programmatic management of drug resistant tuberculosis in India 2019."

Government of India/Central TB Division. 2017. "Guidelines on Programmatic Management of Drug-Resistant Tuberculosis in India 2017."

Government of India/Central TB Division. 2020. "Operational Guidelines for TB Services at Ayushman Bharat Health and Wellness Centres."

Government of India/Central TB Division. 2019. "RNTCP Updated Pediatric TB Guidelines 2019."

2021. *Government of India/Central TB Division, Guidelines for Programmatic Management of Drug Resistant Tuberculosis in India.* Government of India/Central TB Division.

2016. *Government of India/Central TB Division, Guidelines on Prevention and Management of TB in PLHIV at ART Centres.* Government of India/Central TB Division.

Lan Z, Ahmad N, Baghaei P, Barkane L, Benedetti A, Brode SK, Brust JCM, Campbell JR, Chang VWL, Falzon D, Guglielmetti L, Isaakidis P, Kempker RR, Kipiani M, Kuksa L, Lange C, Laniado-Laborín R, Nahid P, Rodrigues D, Singla R, Udwadia ZF, Menzies D. 2020. "Drug-associated adverse events in the treatment of multidrug-resistant tuberculosis: an individual patient data meta-analysis."

MSF. 2016. *2016 Project Document Mumbai.* MSF.

MSF. 2016. *2016 Report Summary Operations Update.* MSF.

MSF. 2017. *2017 Medical Report final.* MSF.

MSF. 2020. *2020 Interim Programmatic Outcomes Of Decentralised Drtb Treatment Site In M/East Ward.* MSF.

MSF. 2019. *Advocacy and Communications Logframe 2019.* MSF.

MSF. 2017. *Advocacy and Communications strategy 2017.* MSF.

MSF. 2019. *Advocacy and Communications strategy 2019.* MSF.

MSF. 2020. *Advocacy and Communications strategy 2020.* MSF.

MSF. Unknown. *Collaborative plans for MSF OCB Mumbai project with MDACS, RNTCP, BMC.* MSF.

MSF. 2017. *Concept note: Model of care for Drug resistant TB decentralization in MEW, proposal for MSF Mumbai project (2017).* MSF.

MSF. Unknown. *Concept Paper: Tuberculosis Direction In India 2014-2019.* MSF.

MSF. 2015. *Country Policy Paper – India 2015.* MSF.

MSF. 2019. *Debriefing (Wairumu Gitau – general inc. advocacy) – 2019.* MSF.

MSF. 2015. *Impementation Plan Of MEW (2015).* MSF.

MSF. 2018. *India Field Visit (Angela Uyen – Advocacy) 2018.* MSF.

MSF. 2019. *India Field Visit (Erika Mohr-Holland – M&E) 2019.* MSF.

MSF. 2017. *India Field Visit (Marc Biot – general) 2017.* MSF.

MSF. 2014. *India Programme visit (CO / Dep CO Cell 5 MSF OCB) 2014.* MSF.

MSF. 2020. "Interim Programmatic Outcomes Of Decentralised Drtb Treatment Site In M/East Ward 2016-2020."

MSF. 2014. *Justification of choice of M/East ward for DR-TB intervention (2014).* MSF.

MSF. 2014. *M East Ward ASSESSMENT REPORT MSF, MUMBAI (2014).* MSF.

MSF. Unknown. "M. East Ward DRTB Control Proposal."

MSF. 2020. "MCGM MSF Collaboration Q3 20 Report."

MSF. 2019. *MCGM MSF Collaboration Q1 19 report.* MSF.

MSF. 2020. *MCGM MSF Collaboration Q1 20 Report.* MSF.

MSF. 2019. *MCGM MSF Collaboration Q2 19 report.* MSF.

MSF. 2020. "MCGM MSF Collaboration Q2 20 report."

MSF. 2019. *MCGM MSF Collaboration Q3 19 report.* MSF.

MSF. 2019. *MCGM MSF Collaboration Q4 19 report.* MSF.

MSF. 2016. *Mumbai DR-TB/HIV Project Annual Report 2016.* MSF.

MSF. 2018. *Mumbai DR-TB/HIV Project Annual Report 2018.* MSF.

MSF. 2017. *Mumbai DR-TB/HIV Project Quarterly Report – Q3 2017.* MSF.

MSF. 2019. *Mumbai DRTB-HIV Project Quarter 4 2019 report Achievements and challenges.* MSF.

MSF. 2020. *Mumbai DRTB-HIV Project Quarter 4 2020 report Achievements and challenges.* MSF.

MSF. 2016. *Mumbai Logframe 2016.* MSF.

MSF. 2017. *Mumbai Logframe 2017.* MSF.

MSF. 2018. *Mumbai Logframe 2018.* MSF.

MSF. 2019. *Mumbai Logframe 2019.* MSF.

MSF. 2020. *Mumbai Logframe 2020.* MSF.

MSF. 2020. "Mumbai project Diagnostics debriefing (Zee Ndlovu) 2020."

MSF. 2020. *Mumbai Project Document 2020.* MSF.

MSF. 2015. *Mumbai Strategic COPRO FINAL (2015).* MSF.

MSF. 2015. *Mumbai Strategic COPRO presentation FINAL (2015).* MSF.

MSF. 2021. *Operational Research Repository DRTB 2011-2021.* MSF.

MSF. Unknown. *Patient Support and Counseling Strategy in MEW.* MSF.

MSF. 2019. *Project monitoring: Mumbai 2019.* MSF.

MSF. 2020. *Project monitoring: Mumbai Q4/Annual Report- 2020.* MSF.

MSF. 2016. *Stakeholders analysis Mumbai 2016.* MSF.

MSF. 2020. *Step Up for TB Report 2020.* MSF.

MSF. 2017. *Technical Report (Kathleen England – Diagnostics support for MEW) 2017.* MSF.

MSF. 2017. *Visit Report Mumbai –Patient & Community Support Advisor – Mariana Garcia 2017.* MSF.

MSF-SEU. 2020. "SEU Ethical Guidelines for Evaluation."

2020. *National Tuberculosis Elimination Programme Annual Report, India TB Report 2020.* Ministry of Health and Family Welfare.

2021. *National Tuberculosis Elimination Programme Annual Report, India TB Report 2021.* Ministry of Health and Family Welfare, India.

Osman M, Harausz EP, Garcia-Prats AJ, Schaaf HS, Moore BK, Hicks RM, Achar J, Amanullah F, Barry P, Becerra M, Chiotan DI, Drobac PC, Flood J, Furin J, Gegia M, Isaakidis P, Mariandyshev A, Ozere I, Shah NS, Skrahina A, Yablokova E, Seddon JA, Hesseling A. 2019. "Treatment Outcomes in Global Systematic Review and Patient Meta-Analysis of Children with Extensively Drug-Resistant Tuberculosis. ."

2019. *Revised National TB Control Programme, India TB Report 2019.* Ministry of Health and Family Welfare, India.

WHO. 2018. "Compendium of WHO guidelines and associated standards: ensuring optimum delivery of the cascade of care for patients with tuberculosis. Second edition - June 2018."

WHO. 2017. "Global Tuberculosis Report 2017."

WHO. 2018. "Global Tuberculosis Report 2018."

WHO. 2019. "Global Tuberculosis Report 2019."

WHO. 2020. "Global Tuberculosis Report 2020."

WHO. 2014. "Guidance for national tuberculosis programmes on the management of tuberculosis in children. Second edition."

WHO. 2020. "Guidance for the surveillance of drug resistance in tuberculosis. Sixth edition."

WHO. 2015. "Guidelines for surveillance of drug resistance in tuberculosis. 5th Edition."

WHO. 2011. "Guidelines for the programmatic management of drug-resistant tuberculosis. 2011 update."

WHO. 2017. "Guidelines for treatment of drug-susceptible tuberculosis and patient care. 2017 update. Annex 5 – Reports of the Systematic Reviews."

WHO India. 2014. "Standard for TB Care in India 2014."

WHO. 2015. "Recommendation on 36 months isoniazid preventive therapy to adults and adolescents living with HIV in resource-constrained and high TB- and HIV-prevalence settings. 2015 update."

WHO. 2016. "Report of the Guideline Development Group Meeting on the use of bedaquiline in the treatment of multidrug-resistant tuberculosis. A review of available evidence (2016)."

WHO. 2016. "Target regimen profiles for TB treatment. Candidates: rifampicin-susceptible, rifampicin-resistant and pan-TB treatment regimens."

WHO. 2013. "The use of bedaquiline in the treatment of multidrug-resistant tuberculosis. Interim policy guidance."

WHO. 2016. "The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents. Interim policy guidance."

WHO. 2014. "The use of delamanid in the treatment of multidrug-resistant tuberculosis. Interim policy guidance."

WHO. 2019. "WHO consolidated guidelines on drug-resistant tuberculosis treatment."

WHO. 2020. "WHO consolidated guidelines on tuberculosis. Module 4: Treatment. Drug-resistant tuberculosis treatment."

WHO. 2019. "WHO guidelines on tuberculosis infection prevention and control. 2019 update."

WHO. 2018. "WHO position statement on the use of delamanid for multidrug-resistant tuberculosis. Expedited review of the phase III clinical trial data of delamanid added to an optimised background MDR-TB regimen."

WHO. 2016. "WHO treatment guidelines for drug resistant tuberculosis. 2016 update."

WHO. 2016. "WHO treatment guidelines for drug resistant tuberculosis. 2016 update. Annexes 4, 5 and 6."

WHO. 2018. "WHO treatment guidelines for isoniazid isoniazid-resistant tuberculosis. Supplement to the WHO treatment guidelines for drug-resistant tuberculosis."

ANNEX 5: LIST OF KEY INFORMANTS

TYPE OF INFORMANT	SCOPE	NAME OF INTERVIEWEE	CURRENT POSITION	DPT
Academic/ Research Orgs	India	Nerges Mistry (Dr.)	Director, Foundation for Medical Research	
		Shibu Vijayan	Director- PATH Intl.	
		Shweta Bajaj	Tata Institute for Social Sciences	
NGOs/CSOs	India	Ravikant Singh (Dr.)	Director, Doctors for You	
		Sanjay Sarin (Dr.)	Country Director, FIND diagnostics	
Government of India	Mumbai	Ajit (Dr.)	former District TB officer (till end of 2020)	MCGM-MoH
	Mumbai	Dr Alpa Dalal	Chair of Unit at SEWRI TB hospital	MOH Sewri
	Mumbai	Pranita Tipre (Dr.)	City TB Officer	MCGM-MoH
	India	Rupak Singla (Dr.)	NITRD, HOD Chest Department and one of the Member of Technical Expert committee	
	Mumbai	Seema (Dr.)	District TB officer, M West ward	
	Mumbai	Shubangi (Dr.)	senior medical officer, Shatabdi TB OPD	MOH
	Mumbai	Shushant Mane (Dr.)	JJ hospital, paediatric department, associate professor	
	Mumbai	Sutar (Dr.)	District TB officer	MCGM-MoH
	Mumbai	Daksha Shah (Dr.)	deputy executive health officer / former city TB officer	MCGM-MoH
MSF Clinical	Mumbai	Aparna S. Iyer (Dr.)	Mumbai project Medical referent	Medical
	Beyond India	Daniela Garone	CO	Ops
	Beyond India	Gabriela Ferlazzo	(TB advisor, SAMU)	SAMU
	Mumbai	Lorraine Rebello	MAM, M East Ward, MSF Mumbai	Medical
	India	Mabel Morales	Medical Coordinator from Nov 2020	Medical
	India	Mrinalini Das	deputy MedCo / M&E	
	Mumbai	Naresh Gill (Dr)	HIV Focal Point KEM Hospital	
	Mumbai	Pramila Singh	MAM, Clinic/ SEWRI, MSF Mumbai	Medical
	Mumbai	Sarthak Rastogi	Chest Specialist	
	Mumbai	Vijay Chavan (Dr.)	chest physician, Shatabdi TB OPD	
MSF Managers	Mumbai	Caroline Holmgren	(Mumbai Project Coordinator)	Ops

	India	Hemant Sharma	Deputy Head of Mission	
	Mumbai	Manju Krishnan	Deputy PC Mumbai	
	Beyond India	Marc Biot	Ops director	
	India	Pierre Poivre	(Head of Mission until Feb 2021)	
	Mumbai	Shilpa Ravi	Former M&E manager, MSF Mumbai	Medical
MSF Outreach/ Support/ Advocacy/ Research	Beyond India	Angela Ngyen	(OCB Advocacy and Analysis Unit)	AAU
	Mumbai	Chinmay Laxmeshwar	Former epi manager	
	Beyond India	Kleio Lakovidi		SAMU
	Beyond India	Petros Isaakidis	operational research, SAMU	SAMU
	Mumbai	Pooja Agrawal	patient support manager	
	Mumbai	Siddhesh Gunandekar	Advocacy, Communication Manager	Advocacy
WHO	Mumbai/India	Dipesh Reddy (Dr.)	Former MSF, WHO consultant Mumbai	
	Mumbai	Imran Syed (Dr.)	Former WHO consultant for RNTCP	
	Beyond India	Vineet Bhatia (Dr.)	WHO SEARO Regional lead for TB	

ANNEX 6: GAPS IN THE CAUSAL LOGIC OF THE MUMBAI PROJECT'S INITIAL STRATEGY
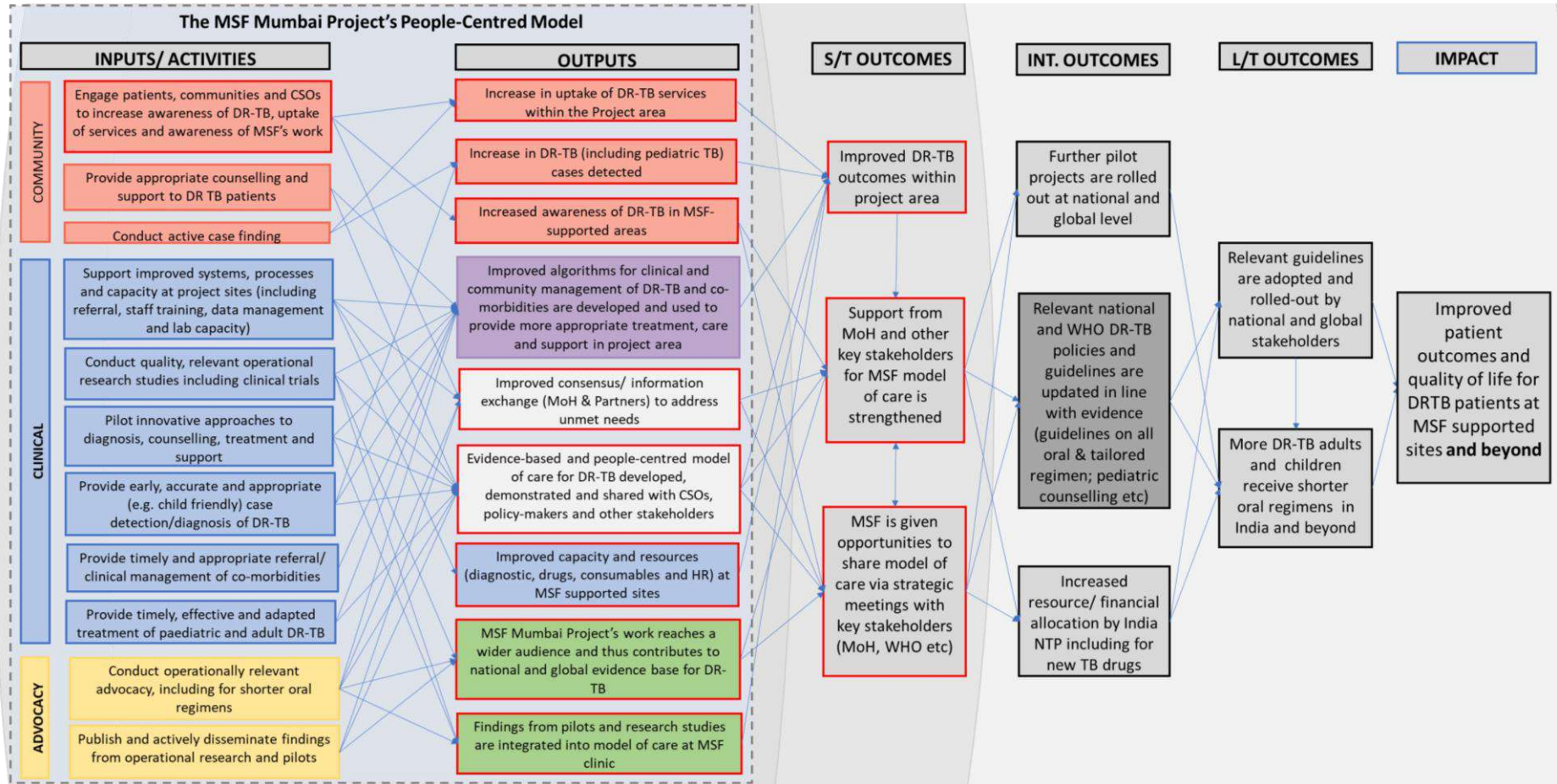
Based on the ToC developed during the Inception phase of the evaluation, we have outlined in red above those outputs and outcomes which were considered key steps in the causal logic for the Project's activities to contribute to the central intermediate policy-related outcome, but which were not explicitly outlined via a ToC or otherwise in the initial Project strategy. It can be seen from looking at the mapping of the causal pathways from activity to output and then outcome level, there was a need to more explicitly outline how the different Project interventions (community, clinical and advocacy) interacted with each other and contributed to change.

ANNEX 7: STRENGTH OF EVIDENCE OF FINDINGS

Below we summarise the strength of evidence of each of our findings against the metric below. It is important to note that some evaluation criteria, such as Efficiency, are almost entirely reliant on internal project documents and interviews with MSF staff, and so based on the metric below, have lower strength of evidence, but we would consider them well triangulated given the context.

RANK	JUSTIFICATION
1	The finding is supported by multiple types of data sources of generally strong quality (good triangulation).
2	The finding is supported by multiple data sources of lesser quality, or the finding is supported by fewer data sources of higher quality (moderately good triangulation).
3	The finding is supported by few data sources of lesser quality (limited triangulation).
4	The finding is supported by very limited evidence (single source) or by incomplete or unreliable evidence.

		FINDING	COMMENTS
Relevance	1.	Project objectives were broadly relevant to influencing DR-TB policies, but there were gaps in outlining how these objectives would be achieved.	Based on wide range of documents, but MSF documents and literature review only
	2.	The Project strategy addressed two out of three key factors which support policy change: evidence of the DR-TB problem; and of possible policy solutions to the problem. It did not however sufficiently address the broader political context.	Based on wide range of documents, but MSF documents and literature review only
	3.	The Project continuously adapted in line with the needs of patients on the ground and the changing policy context, but changes were organic rather than based on a planned adaptive approach.	Based on wide range of documents, but MSF documents and literature review only
	4.	Relevant and appropriate policy gaps were identified in line with MSF's capacity and expertise, but there were missed opportunities to prioritize advocacy activities and potentially advocate for other areas where MSF could have influenced policy change	Based on wide range of documents MSF documents and literature review plus KIIs with multiple stakeholder groups
	5.	Activities were seen as highly relevant and necessary for improving treatment outcomes and demonstrating an effective model of care which could influence wider policy changes	Based on literature review and KIIs with multiple stakeholder groups
	6.	Some key gaps were identified in terms of advocacy activities, which were seen as overly focused on production and sharing of operational research.	Based on KIIs with multiple stakeholder groups
	7.	Project assumptions mostly held, with the exception of those related to advocacy, where assumptions were only partially upheld due to a lack of effective engagement with the key stakeholders starting at the activity level.	Based on review of project documents and KIIs with multiple stakeholder groups

Coordination	8.	MSF built successful relationships with institutions linked to the central government, such as NITRD and WHO, and was effective in influencing the Central TB Division through these partnerships.	Based on KIIs with several stakeholder groups
	9.	The Project built an effective partnership with the local government in Mumbai through the City TB Officer, which supported interventions and thus improved care and treatment outcomes for DR-TB patients in Mumbai, but this was not replicated at national level.	Based on KIIs with several stakeholder groups
	10.	Partnerships with CSOs were limited, with little sharing of practices especially in counselling and psychosocial support, which could have ensured continuity of support for patients in the longer term.	Based on KIIs with several stakeholder groups
	11.	There were several missed opportunities to collaborate with advocacy-focused NGOs, with the MSF Access Campaign, or with other influential stakeholders such as the Global Fund.	Based on KIIs with several stakeholder groups
Effectiveness	12.	The model of care effectively supported changes to relevant DR-TB guidelines by demonstrating best practice in improving treatment outcomes for 'complex' DR-TB clients and aligned with good practices at that time.	Based on project documents, literature review and KIIs with MSF staff
	13.	Areas for improvement included improved provision of palliative care and long-term support to address socio-economic and psychological factors.	Based on KIIs with small number of stakeholder groups
	14.	Treatment outcomes were mostly positive, and thus did support advocacy for policy change.	Based on review of project documents and literature
	15.	The Project's operational research activities directly influenced five key WHO publications and indirectly influenced four key GoI guidelines around the use of new drugs in children and the use of bedaquiline and delamanid in combination	Based on review of project documents, literature and KIIs with several stakeholder groups
	16.	The Project's contribution to the 2020 WHO DRTB treatment guidelines was significant, as patients from the Mumbai project comprised more than half of the cohort used by WHO to inform the use of bedaquiline and delamanid in combination	Based on review of project documents, literature and KIIs with several stakeholder groups
	17.	The significance of the Project's contribution to other WHO guidelines could not be established, but it did not appear to directly influence any GoI guidelines	Based on document and literature review and KIIs with small number of stakeholder groups
	18.	Stakeholders felt the Project could have done more to actively advocate for priority interventions at both a national and international level, and thus that the Project's contribution was not as significant or catalytic as it could have been.	Based on KIIs with broad range of stakeholder groups
	19.	Key external and internal constraints included government resistance to NGOs and the Project's limited advocacy and collaboration with others. Enabling factors included the widely acknowledged expertise and drive of key Mumbai project team members; and the Prime Minister's ongoing focus on eliminating TB in India.	Based on document review and KIIs with broad range of stakeholder groups

	20.	There was a consensus that more could have been done to improve the effectiveness of the Project's advocacy, for example by improving collaboration with other key stakeholders in India and beyond to effect policy change more quickly.	Based on KIIs with broad range of stakeholder groups
	21.	The main unintended consequence of the approach taken was that the Project was unsuccessful in directly influencing key GoI policies and guidelines as a result of the limited approach to advocacy	Based on KIIs with broad range of stakeholder groups
Efficiency	22.	A reduction in the number of international staff over the course of the project was seen as positive, but more targeted use of international staff was seen as necessary in order to improve efficiency	Based on review of project documents and KIIs with various MSF informant groups
	23.	High staff turnover and poor communications contributed to siloed working, a perceived lack of transparency, and limited acceptance of divergent viewpoints.	Based on KIIs with various MSF informant groups
	24.	Some stakeholders felt that other interventions could have benefited more patients for the same overall investment levels, and still influenced key policies.	Based on KIIs with various MSF informant groups
	25.	Other examples of how the Project could have been more efficient included the use of local contractors to conduct outreach activities; and procuring drugs more cheaply through use of government-approved suppliers.	Based on KIIs with various MSF informant groups and two other stakeholder groups
Sustainability	26.	Project exit strategies were based on high-risk assumptions, such as the government's capacity to take over implementation, and most lacked a defined timeline.	Based on review of project documents and KIIs with multiple MSF informant groups
	27.	MSF stakeholders' views on the importance of sustainability varied, with several seeing sustainability as an unnecessary goal for catalytic projects, and others concerned about the lack of Project sustainability	Based on KIIs with various MSF informant groups
	28.	Overall the model of care was considered highly unsustainable, with limited likelihood of the government being able to replicate it in the foreseeable future.	Based on KIIs across multiple stakeholder groups
	29.	The sustainability of policy results is severely constrained in India considering the government's limited resources but is more promising in other contexts where governments have the resources to implement the guidelines.	Based on KIIs across multiple stakeholder groups

ANNEX 8: QUALITATIVE ANALYSIS OF ASSUMPTIONS

The following table is based on qualitative review of project documents and KII notes. Those areas assumptions were only partially upheld indicate where MSF should review and adapt the project design to improve the likelihood of project outcomes being achieved. The yellow across the "advocacy" section reflects poorer progress in this area and provides insights into why the Project's advocacy activities did not support the overall objectives as intended.

	ACTIVITIES TO OUTPUTS	OUTPUTS TO SHORT-TERM OUTCOMES	SHORT-TERM TO INTERMEDIATE OUTCOMES	INTERMEDIATE TO LONG-TERM OUTCOMES
Cross-cutting	Municipal Corporation of Greater Mumbai continue to provide necessary permissions for MSF to operate a private clinic in Mumbai and partner with local hospitals	Ministry of health/NTP and other medical actors (NITRD) are open and amenable to forging alliances with MSF	GoI has sufficient overall budget, esp. health resources to increase NTP budget	Adults and children with DR-TB accept new (oral) treatment regimens
	Ministry of Health provides permission to import new drugs that are not a part of the standard treatment protocol for DR-TB in India			
	GoI does not apply repressive measures to curtail the activities of international NGOs			
	Bureaucratic red tape does not slow down MSF project operations		There are sufficient resources for rollout of further pilots	
	Continuity of institutional funding is maintained			
	Currency fluctuations do not lead to reduced purchasing power of the project			
Community	Patients, CSOs continue to support MSF's activities and agree on priority issues	Patient counselling and support activities result are successful/ result in improved adherence to treatment regimens/reduced loss-to-follow-up		
	Awareness raising activities leads to improved knowledge and understanding of DR-TB		Evidence from MSF project is applicable to DR-TB beyond Indian context	
	Engagement and awareness raising activities result in increased demand for services			
	Patient counselling/support activities result are accepted/supported by key stakeholders			
	Levels of TB in the community mean that active case finding result in more cases detected			
Clinical	MSF is able to retain local staff, especially doctors, in the project for continuity	Hospital and TB managers are open to suggestions and recommendations of patient groups/CSOs		
	MSF clinic is not overburdened with too many DR-TB clients		Timeframes/strategy cycles etc. for review of TB policies are aligned with the project timeframe	There are sufficient resources for adoption and rollout of revised guidelines/poli
	Partner hospital staff are not overburdened and are available to support MSF activities	New processes contribute to improved capacity, efficiency and effectiveness at Project sites		
	MSF supported sites are able and willing to incorporate new systems/processes			
	People with DR-TB understand need for individualized treatment and trust MSF doctors	Treatment regimens lead to improved patient outcomes		

	RNTCP will allow clinics to deviate from national guideline and pilot novel activities			cies in India and beyond.
	Research protocols are approved with sufficient speed by appropriate bodies	National TB programme is open to utilizing new technologies for diagnosis of DR-TB	There is sufficient political support for TB which translates into increased budget allocation	
	Submitted manuscripts will be reviewed and published in a timely manner by journals			
	There are sufficient resources and support to integrate OR findings into model of care	Research and findings are viewed as robust and applicable to wider context by key stakeholders		
	Staff beneficiaries of trainings absorb skills and competencies and utilise them			
	Supply of consumables for rapid diagnostics is maintained			
Advocacy	Advocacy efforts target the right/appropriate people/organisations	Improved consensus on unmet needs translates into improved support for MSF's model of care	MSF's work receives traction and support with/from the key actors that influence TB policy in India	
	Key stakeholders are willing to engage in/with advocacy efforts	A strong partnership is maintained with MoH/ NTP to present results from OR activities		
	Advocacy methods are appropriate for the local context and support improved consensus	MSF is able to raise its profile to influence change		

☐ Conditions for the assumption are met

⬛ Conditions for the assumption are partially met

🟥 Conditions for the assumption are not met

⬛ Evidence not clear

ANNEX 9: INDIA MDR AND XDR TB PATIENT TREATMENT OUTCOMES[101]

A9-1.Disaggregated MDR and XDR Patient outcomes (MSF Clinic, State and National)

	2016[102]			2017					2018						
	MDR[103]				MDR		XDR			MDR				XDR	
	MSF Clinic	Conventional regimen[104]		MSF clinic	Conventional regimen[105]				MSF Clinic	Shorter regimen[106]		Conventional regimen[107]		Any regimen[108]	
		State	National		State	National	State	National		State	National	State	National	State	National
Initiated	63	6763	30183	64	8346	36043	504	1436	55	1295	16311	7613	31939	947	2644
Treatment success (completed/ cured)	40	2689	14195	43	3625	17699	176	519	43	682	9728	3772	16478	410	1201
LTFU	5	1318	5761	3	1566	6697	85	239	0	158	2157	1211	4748	103	294
Failed	5	89	595	3	124	776	46	105	2	22	395	105	524	26	78
Died	13	1061	5934	15	1197	6422	145	486	10	127	1793	1094	4823	242	657

A9-2. Combined MDR/XDR Patient Treatment Outcomes (%age, MSF Clinic, State and National)[109]

	Treatment success (completed/cured)			LTFU			Failed			Died		
	2016	2017	2018	2016	2017	2018	2016	2017	2018	2016	2017	2018
MSF Clinic	63%	67%	78%	8%	5%	0%	8%	5%	4%	21%	23%	18%
State	40%	43%	49%	19%	19%	15%	1%	2%	2%	16%	15%	15%
National	47%	49%	54%	19%	19%	14%	2%	2%	2%	20%	18%	14%

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[101] (Revised National TB Control Programme, India TB Report 2019 2019); (National Tuberculosis Elimination Programme Annual Report, India TB Report 2020 2020); (National Tuberculosis Elimination Programme Annual Report, India TB Report 2021 2021); (MSF, Project monitoring: Mumbai Q4/Annual Report- 2020 2020)

[102] For state and national outcomes, figures are based on MDR/Rifampicin Resistant TB patients initiated on Cat IV conventional treatment

[103] XDR data not available

[104] Figures cover patients initiated on treatment from 3rd Quarter 2015 to end of 2nd Quarter 2016

[105] For state and national outcomes, figures are based on treatment outcome of patients initiated in treatment from 3rd quarter of 2016 to end of second quarter of 2017

[106] For state and national outcomes, figures are based on treatment outcome of MDR patients initiated on shorter regimen during 2018

[107] MDR TB patients initiated on conventional regimen as well as MDR TB with additional resistance initated on any regimen

[108] XDR TB Patients initated on any regimen during 2018

[109] Based on numbers of MDR and XDR patient outcomes added together from previous table

ANNEX 10: FULL LIST OF MSF MUMBAI OPERATIONAL RESEARCH WITH CITATIONS

YEAR	MSF MUMBAI PROJECT OPERATIONAL RESEARCH	TOTAL CITATIONS	WHO PUBLICATION CITATIONS	GOI CITATIONS OF WHO PUBLICATIONS
2012	Adverse Events among HIV/MDR-TB Co-Infected Patients Receiving Antiretroviral and Second Line Anti-TB Treatment in Mumbai, India	114	Guidelines for treatment of drug-susceptible tuberculosis and patient care 2017 update Annex 5	
2013	Ocular inflammatory disease and ocular tuberculosis in a cohort of patients co-infected with HIV and multidrug-resistant tuberculosis in Mumbai, India: a cross-sectional study	27		
2013	Poor Outcomes in a Cohort of HIV-Infected Adolescents Undergoing Treatment for Multidrug-Resistant Tuberculosis in Mumbai, India	61	WHO treatment guidelines for drug-resistant Tuberculosis 2016. leading to: WHO consolidated guidelines on drug-resistant tuberculosis treatment (2019)	Guidelines on programmatic management of drug resistant tuberculosis in India: 2019 (pre final text)
2013	High Rate of Hypothyroidism in Multidrug-Resistant Tuberculosis Patients Co-Infected with HIV in Mumbai, India	36		
2013	'I cry every day': experiences of patients co-infected with HIV and multidrug-resistant tuberculosis	86		
2014	Infection control in households of drug-resistant tuberculosis patients co-infected with HIV in Mumbai, India	4	WHO guidelines on tuberculosis infection prevention and control: 2019 update	Guidelines for the Programmatic Management of Drug Resistant Tuberculosis in India (2021)
2014	Patch-testing for the management of hypersensitivity reactions to second-line anti-tuberculosis drugs: a case report	10		
2014	HIV, multidrug-resistant tuberculosis and depressive symptoms: when three diseases collide	37		
2014	Alarming levels of drug-resistant tuberculosis in HIV-infected patients in metropolitan Mumbai, India	67		
2014	"I'm fed up": Experiences of prior tuberculosis treatment in patients with drug-resistant tuberculosis and HIV	24		
2015	Resistance Patterns Among Multidrug-resistant Tuberculosis Patients in Greater Metropolitan Mumbai: Trends Over Time	82		

YEAR	MSF MUMBAI PROJECT OPERATIONAL RESEARCH	TOTAL CITATIONS	WHO PUBLICATION CITATIONS	GOI CITATIONS OF WHO PUBLICATIONS
	Linezolid for multidrug-resistant tuberculosis in HIV-infected and uninfected patients (Letter to Editor)	28	Target regimen profiles for TB treatment: candidates: rifampicin-susceptible, rifampicin resistant and pan-TB treatment regimens	N/A
	Treatment outcomes for HIV and MDR-TB co-infected adults and children: systematic review and meta-analysis	111		
	Outcomes in Adolescents Undergoing Treatment for Drug-Resistant Tuberculosis in Mumbai (Letter to Editor)	3		
	Direct Observation (DO) for Drug-Resistant Tuberculosis: Do We Really DO?	30		
2016	Treating all MDR-TB patients, not just bacteriologically confirmed cases	0		
	Compassionate use of new drugs in children and adolescents with multidrug-resistant and extensively drug-resistant tuberculosis: early experiences and challenges	77	The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents: interim policy guidance WHO 2016. _Leading to:_ WHO consolidated guidelines on drug-resistant tuberculosis treatment (2019)	Guidelines for use of Delamanid in the treatment of Drug Resistant TB in India (2018) Guidelines on programmatic management of drug resistant tuberculosis in India: 2019 (pre final text) Guidelines for the Programmatic Management of Drug Resistant Tuberculosis in India (2021)
	Linezolid-Associated Optic Neuropathy in Drug-Resistant Tuberculosis Patients in Mumbai, India	25		
	Surgical interventions for pulmonary tuberculosis in Mumbai, India: surgical outcomes and programmatic challenges	1		
2018	Early safety and efficacy of the combination of bedaquiline and delamanid for the treatment of patients with drug-resistant tuberculosis in Armenia, India, and South Africa: a retrospective cohort study	91	WHO operational handbook on tuberculosis: module 4: treatment: drug-resistant tuberculosis treatment	Guidelines for the Programmatic Management of Drug Resistant Tuberculosis in India
	Is Chemoprophylaxis for Child Contacts of Drug-Resistant TB Patients Beneficial? A Systematic Review	7		
	Beyond 'cure' and 'treatment success': quality of life of patients with multidrug-resistant tuberculosis	19		
2019	Bedaquiline and Delamanid in combination for treatment of drug-resistant tuberculosis (Letter to Editor)	10		

YEAR	MSF MUMBAI PROJECT OPERATIONAL RESEARCH	TOTAL CITATIONS	WHO PUBLICATION CITATIONS	GOI CITATIONS OF WHO PUBLICATIONS
2020	Ambulatory management of pre- and extensively drug resistant tuberculosis patients with imipenem delivered through port-a-cath: A mixed methods study on treatment outcomes and challenges	5		
	Adapting TB services during the COVID-19 pandemic in Mumbai, India (Letter to Editor)	16		
	One step forward: Successful End-of-Treatment outcomes of Patients with DRTB who received concomitant Bedaquiline and Delamanid in Mumbai, India	0		
	New TB drugs for the treatment of children and adolescents with rifampicin-resistant TB in Mumbai, India	2		
2021	Treatment outcomes of children and adolescents receiving drug-resistant TB treatment in a routine TB programme, Mumbai, India	1		
	Challenging drug-resistant TB treatment journey for children, adolescents and their caregivers: A qualitative study	0		
Meta Analyses Which Included Mumbai Project Data Sets				
2017	Drug-associated adverse events in the treatment of multidrug-resistant tuberculosis: an individual patient data meta-analysis	45	WHO operational handbook on tuberculosis: module 4: treatment: drug-resistant tuberculosis treatment	Guidelines for the Programmatic Management of Drug Resistant Tuberculosis in India
2018	Treatment correlates of successful outcomes in pulmonary multidrug-resistant tuberculosis: an individual patient data meta-analysis.	268	WHO consolidated guidelines on drug-resistant tuberculosis treatment (2019)	Guidelines for use of Delamanid in the treatment of Drug Resistant TB in India (2018) Guidelines on programmatic management of drug resistant tuberculosis in India: 2019 (pre final text) Guidelines for the Programmatic Management of Drug Resistant Tuberculosis in India (2021)
2019	Treatment Outcomes in Global Systematic Review and Patient Meta-Analysis of Children with Extensively Drug-Resistant Tuberculosis.	8		
2020	Mortality in adults with multidrug-resistant tuberculosis and HIV by antiretroviral therapy and tuberculosis drug use: an individual patient data meta-analysis.	15		

Stockholm Evaluation Unit
http://evaluation.msf.org/
Médecins Sans Frontières

Independently written by
Ruth Sherratt and Sameer Sah
HEAD International
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