

---

# Theory of Change for MSF DRTB Project in Iraq (Drug Resistance Tuberculosis)

---

## What is the Theory of Change (ToC) and the Action Model and Change Model Schema?

Creating a Theory of Change (ToC) can help organizations grasp the bigger picture of the change they want to see. MSF's DRTB involvement in Iraq could benefit from this analytical approach. A ToC depicts how an intervention's efforts result in desired or observed impacts or results. These include program theory, result mapping, effect route, and investment logic. ToCs help in identifying and answering critical evaluation questions, key indicators, data gaps, prioritize other data collection, and report data effectively. The DRTB project evaluation adopts the following models or schema for ToC development.

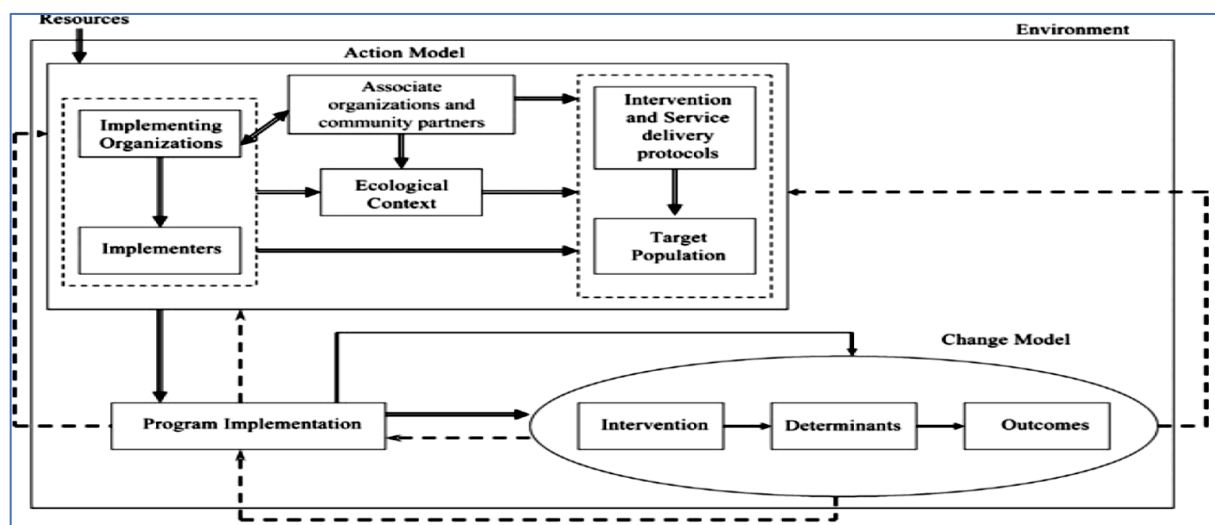


Figure 1. Action Model/Change Model Schema.

Source: Chen, H.T. (2005). Practical program evaluation: Assessing and improving planning, implementation, and effectiveness.

**A ToC validation workshop was held in February 2022 to discuss and validate the ToC drafted by the independent evaluators as part of an evaluation of the DRTB project. This document presents the final version of the ToC schema following the ToC workshop. The main objective of this process is to serve evaluation purposes. As this document was developed as part of the evaluation process, the subsequent steps in data collection might contribute to some changes (mostly minor).**

As part of the TOC development, the evaluators initiated a comprehensive desk review that aims at developing better understanding about the project. The evaluators adopted a retrospective deductive development from formal and informal documentation about the problems the program is addressing, the causes and consequences of the problem, and wider literature and professional experience that is relevant to the project and effective practices.

# 1. Logical/change model

## 1.1. THE INTERVENTION

---

### The project life cycle:

For this project and the development of the ToC of the project, we will look at three stages of the project:

1. **Initial Stage:** it was the initial stage of the project which continued between end of 2017 until end of 2019.
2. **Maturity Stage:** this is the stage during which the project started to harvest results associated with its activities. This phase continued through 2020.
3. **Exit Stage:** this stage during which MSF started to explore a decision to adopt an exit strategy and to close the project. This stage continued through 2021 until end of June 2022.

The distinction between these three phases is important, as the change process might be different in each stage.

## 1.2. THE DETERMINANTS

---

In order to achieve project goals, successful projects must identify leverage mechanisms. These help in looking at which strategies worked and how well they were implemented. The assumptions should be that once the specified leverage processes are activated or the root causes of the problem are addressed, the project goals will be met on time. The intervention factors or determinants are the leverage point. Determining these variables should be based on the designers' formal or informal philosophy(s). The determinants will impact the actions (or inactions) taken to solve the issues. These determinants can also impact stakeholders' (including implementers') perceptions of the problem, solution, and benefits. The project intervention(s) should theoretically address these determinants to obtain intended effects (objectives and outcomes).

For DRTB Project, MSF team worked on the following determinants, leverage mechanisms and route causes:

- A. MSF planned to conduct operational research to support the introduction of World Health Organization (WHO) recommendations on the new full oral regimens. The operational research was important from a scientific perspective and would encourage local authorities to adopt the recommendations faster. The operational research on the recommended regimen will build evidence and it will contribute to a broader knowledge and changes. It is important to note that the operational research needs were created by the MSF and not at the request of national stakeholders.
- B. MSF was providing hands on approach for the technical support to build capacity at National TB Program (NTP), Ministry of Health (MoH) authorities, and MoH health workers. That would also help in addressing the fears associated with the possible adverse reactions when using Bedaquiline (BDQ), as there was misinformation regarding the safety for the use of BDQ.

- C. There was a need to create motivations to change the perceptions of policy makers in the national authorities about the programmatic benefits of introducing the new DRTB treatments.
- D. MSF decided to donate drugs and equipment to the national centre for chest and respiratory diseases in the medical city and the TB sector in Sadr City. While it is a gap filling, it was essential to ensure continuity of services to patients. This was an important gap, despite that MSF should adopted carefully as it may create unintended effects.
- E. MSF did not consider enhancing the capacity to diagnose DRTB cases as an objective by its own, but an opportunity to enhance the enrolment on the new treatment regimen. The support of the Lab rehabilitation as well as technical support in the consulting clinic for chest diseases and in the national reference lab in the medical city were essential to achieve the objectives of the project.
- F. MSF focused on enhancing the role of nursing in providing patient-centred care through provision of education and counselling to patients and their families.

The context during the initial period of the project (2017 and 2018) was characterized by the following needs:

- ✓ Improving and strengthening the technical capacities of health staff involved in the programmatic management of drug resistance TB (PMDT) activities.
- ✓ Improving and strengthening the NTP capacities to detect and diagnose drug-resistant TB cases.
- ✓ Updating and ensuring the availability of national PMDT guidelines in line with the WHO recommendations.
- ✓ Ensuring the availability of treatment for the management of drug-resistant TB patients.
- ✓ Support initiating the treatment with the 2nd line TB medicines in hospital settings for all drug-resistant TB patients.
- ✓ Enhancement of a patient-centred TB care and services that aim to enhance quality of life for DRTB patients.
- ✓ Strengthening the infection control measures in hospital wards, Chest and Respiratory Diseases Clinics (CRDCs) and TB management units (TBMUs).
- ✓ Strengthening decentralized PMDT services at governorate and district levels.
- ✓ Implementing a pharmacovigilance system and strengthening of a routine surveillance system for drug-resistant TB.

### 1.3. THE OBJECTIVES AND OUTCOMES

---

The following objectives and outcomes statement represent the MSF intentions in general terms during the project life cycles. The ToC Workshop confirmed these as the set of objectives and outcomes that shaped the scope of the project.

#### **Project Objectives:**

1. Improving quality of DRTB case detection in MSF supported clinics in Sadr City in Baghdad, Iraq.
2. Improving the DRTB clinical care and management with quality assurance in Sadr City in Baghdad, Iraq.

**Project Outcomes:**

1. TB/DR TB Increase early case detection strengthened.
2. Programmatic and clinical care and management of DRTB strengthen.
3. Capacity built on new WHO guideline, new DRTB drugs and pharmacovigilance carried out.
4. Patient support and education enhanced.

The ToC workshop confirmed that the project's objectives have changed during the project life cycle in response to changes in the context. However, the two objectives highlighted above remain the core objective areas for the project.

Table 1. Overview about the objectives and outcomes of DRTB project during different stages.

	INITIAL STAGE	MATURITY STAGE	EXIT STAGE
Project Objective(s)	<ol style="list-style-type: none"> <li>1. Introduce new, shorter regimens injectable-free, under pilot conditions, for MDR/XDR patients from the catchment area of Sadr City in Baghdad, Iraq.</li> <li>2. Improve case finding strategies in the area of Sadr city in Baghdad, Iraq.</li> <li>3. Support the progressive introduction of a decentralized patient-centred model of care in Sadr City, Baghdad.</li> </ol>	<ol style="list-style-type: none"> <li>1. Improve quality of TB case detection in MSF supported clinics in Sadr City, Baghdad.</li> <li>2. Strengthen TB/DR TB Increase early case detection in Sadr City, Baghdad.</li> </ol>	<ol style="list-style-type: none"> <li>1. Quality care provided in decentralised CRDC sites in Sadr City to reduce morbidity and mortality due to DRTB.</li> <li>2. Ensure an all oral (short and long individualized) injectable free treatment in all decentralised sites and at National TB Institute (NTI).</li> </ol>
Project outcome(s)	<ol style="list-style-type: none"> <li>1. Improved case finding of RR+ cases.</li> <li>2. National Reference Lab (NRL) supported to provide quality diagnosis of MDRTB (XDR) cases.</li> <li>3. Upgraded treatment for MDR/ XDR patients with new oral drugs (BDQ).</li> <li>4. Acceptable case holding (patient support activities) – treatment adherence.</li> <li>5. Advocacy/ documentation of impact of our strategies and improved networking with other actors/ partners.</li> <li>6. Research on short course BDQ regimen started.</li> </ol>	<ol style="list-style-type: none"> <li>1. Increased number of TB/DR TB cases in Rusafa district.</li> <li>2. Improved case detection through proper quality of sputum collection.</li> <li>3. Improved case detection for DRTB through testing of high-risk groups with GeneXpert is noted.</li> <li>4. Improved programmatic and Clinical care and management of DRTB.</li> </ol>	<ol style="list-style-type: none"> <li>1. Improved access to diagnosis of more complex forms of DRTB (pre-XDR/XDR).</li> <li>2. Increased case detection of drug sensitive TB cases.</li> <li>3. Reduced time to treatment initiation.</li> <li>4. Introduction of new drugs and regimens in Iraq and Support the NTP in access and use.</li> <li>5. Decentralized DRTB care at TBMU level.</li> <li>6. A model that can be reproducible by the NTP in the rest of Baghdad city-as first step - and eventually nationwide.</li> <li>7. Increased knowledge of clinicians involved in TB/DRTB care in Sadr City and National TB program.</li> <li>8. Visibility and policy change.</li> <li>9. Reduced lost to follow up rate.</li> <li>10. Improved quality of patient care and treatment outcome at Decentralised sites and in NTI.</li> </ol>

## LOGICAL MODEL

The logic model conceptually should describe the following key program or project components as sub-set:

- (1) inputs (i.e., resources dedicated to or consumed by the program),
- (2) activities (i.e., what the program does with the inputs to fulfil its mission),
- (3) outputs (i.e., the direct products of program activities), and
- (4) outcomes (i.e., benefits to participants during and after project activities). Often, the outcomes component is further divided into short-term and long-term.

The project documents indicated that the DRTB project has been characterized by changing logical models through its life cycle.

The following figure (Figure 2.) presents a summary explanation of a holistic logical model as conceptualized by the evaluators and validated during the ToC workshop. The data to develop this model was extracted from different project documents and reports. The evaluation team developed this logical model based on different documents provided by MSF. As it is below, the model represents a comprehensive overview of how the project intended to achieve its objectives and outcomes.

MSF OCB Evaluation of Drug Resistant Tuberculosis (DRTB) Intervention in Baghdad ANNEX 3

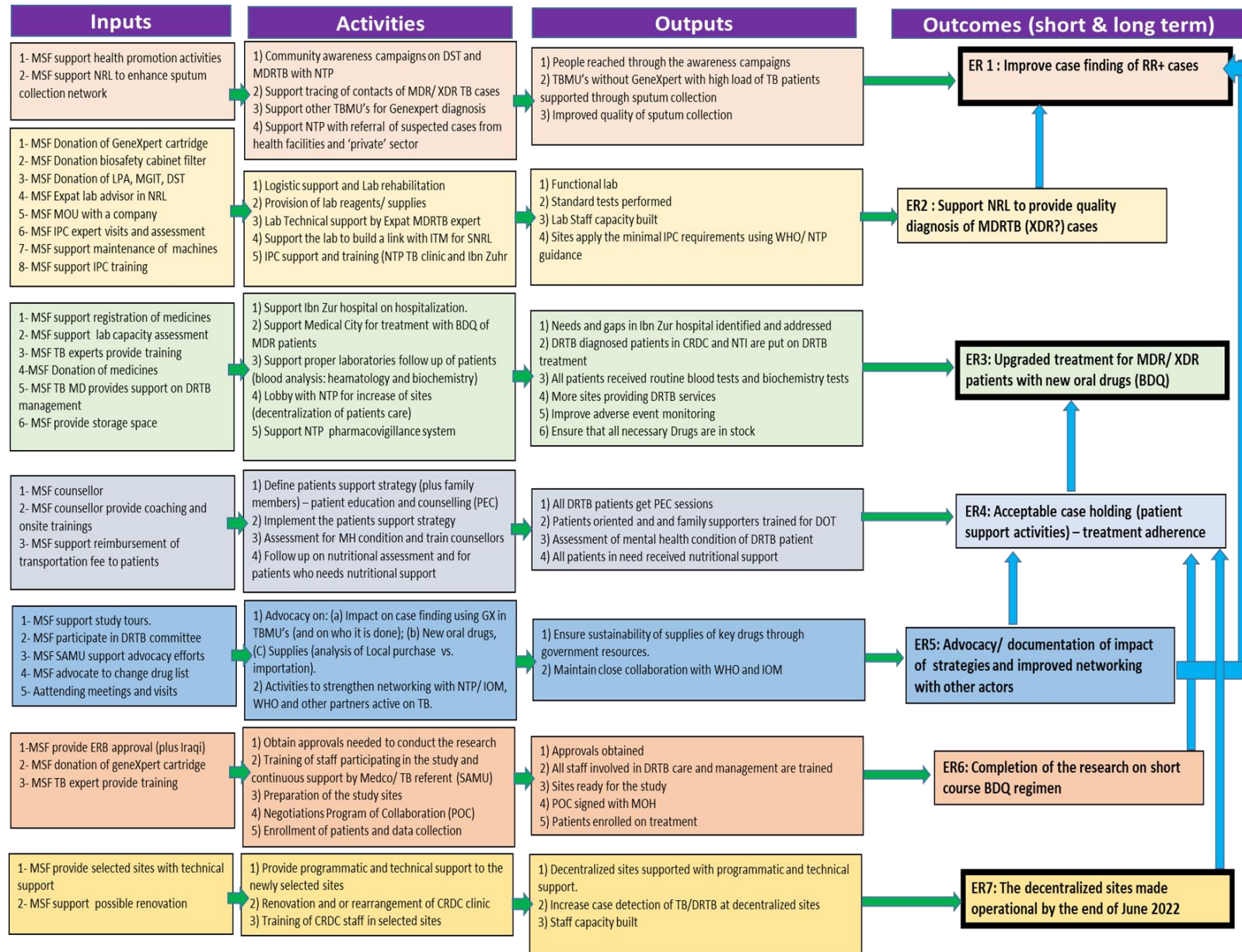


Figure 2. Summary explanation of a holistic logical model



## 2. Action model

The MSF DRTB intervention action model is a systematic approach to reaching a specific population with services to achieve the desired objectives. The programmatic model analysis will help determine whether MSF's strategy worked or missing factors or interventions. The action model analysis verifies that the activities implemented considered the needs of target groups, peer organizations and stakeholders. It helps assess staffing and other resources for project-friendly environments. The action model will assess the project design, including MSF's change strategies and service delivery models.

### 2.1. IMPLEMENTING ORGANIZATION

---

MFS has the expertise to collaborate with service providers to improve DRTB treatment and management by maximizing the utilization of available novel drug combinations. MSF's knowledge and resources in supporting the DRTB in Iraq were invaluable. Between 2015 and 2019, MSF's TB initiatives were mostly focused on high-prevalence areas, and MSF has substantial expertise in settings where operational research goals and DR-TB care provision overlap. The studies did not reveal whether MSF has previously worked in a low-TB prevalence area like Iraq.

Beside its programmatic and operational support, MSF has an important advocacy mechanism in place. MSF Access Campaign is MSF unit, based on different locations, and it's specialized in advocacy related issues for improving access to diagnostic and treatment tools. Among others, the unit prepare reports on different medical areas. TB has been one of the focus areas in the past years.

The key assumptions for this project were:

1. MFS has the required experience to work with service providers in Sadr City to improve DRTB treatment and management. MSF's knowledge and resources supporting the DRTB in Iraq were valuable and used to obtain the greatest possible results in the local context.
2. Aiming to address specific needs of patients and at-risk populations, as well as advocacy or change goals, are all important components of MSF initiatives.
3. In addition to programmatic and operational support, MSF has a strong advocacy arm that usually supports projects like the DRTB project in Iraq.
4. The approach taken by MSF towards innovation in TB and DRTB care has focused on demonstrating safer, more effective, and more patient-centred models of care, combined with rigorous operational research to support change in national and global policy. MSF continue to find ways to innovate more in the areas of case-finding and prevention activities, by rapidly taking on new evidence, as well as by demonstrating practical models for rapidly scaling up community-based intensified case-finding strategies, coupled with TB prevention interventions and work to improve retention in care.
5. SAMU and MSF Cell levels in MSF will play key role in creating and driving the change process in DRTB project in Iraq.

## 2.2. PROJECT IMPLEMENTERS

---

The implementers are in charge of delivering services to various target groups. Medical doctors, counselors, lab managers, lab technicians, and translators are all part of the DRTB program. Indirect assistance comprises Human Resources, Finance, and other comparable activities. The implementers' qualifications, competences, passion, and enthusiasm can directly affect service quality.

The key assumptions for this project were:

1. There will be a dedicated, well-matched and stable project team to implement the DRTB project. Efficiency could be gained by integrating the ER project team and DRTB project team.
2. The project team are well skilled in different areas (including on change management, handling resistance, applying change management and advocacy skills).
3. There will be good engagement from MSF leadership levels at county office level (Head of Mission and Medical Coordinator) with leadership of the counterpart at MoH.

The project implementers were responsible for delivering services to clients (in this project, both for the TB patients and government counterparts). They need to quickly gain the trust of their counterparts in the initial phase. Besides their technical and medical competencies, they need to have the capacity to handle resistance and apply change management (especially at the initial stage).

## 2.3. PEER ORGANIZATIONS

---

Within its context, this project has benefited from or even required cooperation or collaboration with governmental organizations responsible for TB services at different levels (policy level and service delivery levels). If linkages or partnerships with these functional groups are not properly established, implementation of the project may be hindered.

The key assumptions for this project:

1. NTP will support the project objectives and strategies and will advocate to policy changes at higher levels.
2. Chest and Respiratory Clinics will be fully cooperating with MSF staff.
3. TB Management Unit will be engaged during the implementation of the project.
4. National Reference TB Lab role is central to achieve the project outcomes.
5. MSF will collaborate with other partners (i.e., WHO and IOM) to achieve the desired outcomes.

## 2.4. TARGET GROUPS

---

The project has two targeted groups: (i) the community, including TB patients and their support systems, and (ii) the policymakers and service providers. The key assumptions for this project:

**First: the community**

Suspected cases of DRTB	Needs: Identify them through appropriate means, offering them the screening and testing services, and provide them with appropriate health education. How the needs will be addressed: MSF established plans for community engagement, contact tracing and supporting sputum transportation system.
Patients	Needs: Receive quality diagnosis, providing them with information and counselling about their condition, access to quality and safe treatment options, support them through the treatment period, address their psychological, financial, and other social needs, monitor their treatment response and support them to complete the treatment successfully. Extend the support to their families to achieve quality care. How the needs will be addressed: In brief, most of the MSF service delivery were around these areas.

**Second: policymakers and service providers**

MOH senior leadership - beyond NTP management	Needs: (1) services are delivered to population in need, (2) confidence about safety and quality. How the needs will be addressed: (1) respecting national ownership to decide on whether the new regimen will be implemented or not. (2) Donating medicines, equipment and materials to fill the gaps, and (3) Networking/ Advocacy, building trust and MSF visibility as a priority especially in a context like Iraq.
NTP management	Needs: (1) NTP strategy and plans are achieving targets, (2) services are provided according to guidance. How the needs will be addressed: (1) capacity building, (2) involving NTP/MOH the stakeholders to identify priorities of intervention.
DRTB physicians	Needs: (1) addressing the deep rooted fear and misconception related to BDQ, (2) gaps in knowledge, (3) desire to feel protected against negative consequences of prescribing new drugs with potential toxicity. How the needs will be addressed: (1) familiarizing them with BDQ, remove fears and misconception and enhance knowledge, (2) supporting the clinical decision making through consultations with project MDs, especially in making the transition to the new regimen, (3) capacity building.

## 2.5. ECOLOGICAL CONTEXT

Contextual variables shaped the environment that directly affected and interacted with the DRTB project. Projects with change elements (like DRTB) require contextual analysis, which means a supportive environment is included in the project's needs assessment. Contextual considerations can make or break a project.

MSF team should be aware and responsive to the following factors:

- Cultural aspects:** There were little anthropologic/cultural studies regarding TB in Iraq available. There is a need for socio-cultural assessment was done to face the socio-cultural challenges, and this needed to be done before defining the protocol or other TB activities.
- High stigma towards DRTB:** The level of stigma towards TB and against TB patients is high in Iraq. There is a general lack of understanding of the disease and it's difficult to achieve trust. It is no education unit for drug resistant cases. In addition, there was a high level of stigma/fear towards MDRTB from the physicians. They are afraid of dealing with DRTB patients. But at the same time there is a huge misperception of the risk of contracting TB at the health facility.

3. **Community level considerations:** Considerations should be made in the design of the operational research protocol regarding the community behaviour towards TB, including perceptions, stigma, etc. This is necessary in case of planning a case finding strategy, but also to plan the follow up strategies (treatment companion and DOT strategy).
4. **Underlying causes for resistance among peer organizations:** The project team should be aware that the potential causes for resistance to change and related factors.
5. **Accepting change is difficult:** This a catalytic project that aims at policy changes, which need time to accomplish.
6. **The role of families:** Given the central role the families play in the society, and despite the high level of stigma towards TB infection, it was important to recognize the important role the families can play to support patients with TB. In fact, family members are trained to support the patients and to play a role in implementation of DOT strategy at home.

Micro-level contextual support includes social, psychological, and material support to keep stakeholders engaged in MSF's DRTB intervention (including all actors). Community norms, customs, and political and economic activities are all part of the macro-level framework. The project's designer should think about how these micro-level elements might affect the targeted objectives. Within the context of the DRTB project, these contextual aspects differ. It comprises factors relating to the interaction between MSF teams and implementation partners, as well as the social dynamic of Iraqi society. It takes a lot of effort to ensure the project team's capabilities, develop effective coordination with partner companies, and acquire contextual support. Finding the necessary resources to assist such an attempt can be difficult, especially given the DRTB project's nature. Context assessment and understanding the counterpart's culture is mandatory in defining objectives for the project planning stage, especially technical support projects, especially with the approach of the operational research.

## 2.6. INTERVENTION AND SERVICE DELIVERY PROTOCOLS

---

The change model reflects general activities which are translated into a set of concrete, organized and implementable activities and tasks and day-to-day work plans. The translation of strategy into activities requires an intervention protocol or work plan plus service delivery protocol or guidance. Intervention protocol and guidelines are the curriculum or prospectus stating the exact nature, content, and activities of DRTB intervention—in other words, the details of its orienting perspective and its operating procedures. Service delivery protocol (to support NTP/ MoH entities), in contrast, refers to the steps need to be taken to deliver the intervention in the field. To a great extent, these are linked with the technical approach of 'how' the work has been done technically speaking and translating the programmatic objectives into action plans. These combined aspects could be considered what would constitute the '**change strategy**'. In principle, the success of any service delivery projects will depend on the degree to which the service delivery protocols were well established. The components of the change strategy, which are operational in nature, will determine to a great extent the success of the change model. In other terms, the links between the change model and the action model of the project are this component of service delivery protocols.

The following are key project pillars for the service delivery under the project:

### **Laboratory:**

The change strategy focused on the different components based on the following assumptions:

1. MSF has no intention of actively participating in NRL. Nonetheless, MSF acknowledged the NRL's critical role in DRTB diagnosis and care.
2. MSF team, including a visiting MSF TB laboratory adviser, would focus on building a system to ensure uninterrupted supply of reagents, smooth flow of samples, access to molecular and phenotypic DST techniques.

#### **Support DRTB case detection:**

The change strategy focus on the different components based on the following assumptions:

1. MSF would focus on introduction of GeneXpert as first test for TB/DRTB diagnosis in Sadr city. The close collaboration through MSF lab experts, in addition to contributions made by MSF MDs and MedCo to advocate to such change will contribute to achieving this result.
2. MSF would continue to donate GeneXpert cartridges to Sadr city TBMU to ensure that the supplies are available to support service delivery.
3. DRTB contact tracing and screening was not well implemented in NTP. MSF would support screening of household contacts of DRTB cases by interviewing the patients with a symptomatic screening list.
4. MSF would support initiating contracts with a private company to ensure that a sample transportation system in place to support the NTP.
5. High-risk screening cases would be initiated as per NTP guidelines. The Lab advisor will develop an algorithm based on at-risk cases to align with NTP guidelines, which should be in line with the approach to screen all presumptive cases of TB by Xpert.

#### **Clinical management:**

The change strategy focus on the different components based on the following assumptions:

1. NTP need clinical and operational support on the redesign of DRTB treatment regimens.
2. Physicians in Sadr city and Chest and Respiratory Clinic need to be supported through mentorship and training.
3. NTP is willing and ready to work on progressive decentralization of DRTB patients' treatment and follow-up (i.e., moving from the centralized approach for service delivery, only in Sadr city TBMU, to support other health facilities incrementally to offer the services).
4. The implementation of the oral regimen would be possible if MSF implemented the above strategies.

#### **Patient support and improvement of adherence:**

The change strategy focus on the different components based on the following assumptions:

1. MSF would adopt its experience on patient support and educational counselling from other countries (i.e., guidance, tools, and approach) and it will be culturally acceptable.
2. Staff in CRC and TBMU need training and mentorship on MSF guidance.
3. Supporting transport reimbursement to all patients enrolled to oral regimen would enhance patients' retention and treatment adherence.

#### **Operational research:**

The change strategy focus on the different components based on the following assumptions:

1. As many countries opted to adopt the WHO recommended regimen under operational research conditions as per the WHO 2016 recommendations, Iraq MoH would be willing to adopt the same approach.
2. MSF would adopt different strategies (including advocacy) to engage NTP and stakeholders (including through WHO experts) to support the implementation of the research.
3. As this component of the project was crucial, the project strategies would need to be adopted according to progress achieved in implementing the research.

**Capacity building:**

The change strategy focus on the different components based on the following assumptions:

- Training and capacity building activities would contribute directly and indirectly to desired changes.