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TB CARE II

Community Programmatic Management of Drug Resistant Tuberculosis Planning Tool

University Research Co., LLC

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Abbreviations

c-PMDT	Community (strategy) programmatic management of drug resistant TB
DM	Diabetes Mellitus
DOT	Direct Observed Treatment
DR TB	Drug-resistant Tuberculosis
DST	Drug-Susceptibility Testing
FBO	Faith Based Organizations
GDF	Global Drug Facility
GF	Global Fund to Fight AIDS, TB and Malaria
HAIN GenoType MTBDRplus	A multiplex polymerase chain reaction line-probe assay that detects *M. tuberculosis* complex and genetic mutations associated with isoniazid and/or rifampin resistance in one day. The equipment is a patent of Hain Lifescience.
HHS	Health System Strengthening
HIV	Human Immunodeficiency Virus
HR	Human Resources
LPA	DST Line Probe Assays (i) innoLiPA assay- Innogenetics, Belgium; (ii) Hain Lifescience GenoType® MTBDRplus
M&E	Monitoring and Evaluation
MDR TB	Multidrug-resistant Tuberculosis
MGIT	Mycobacteria Growth Indicator Tube (liquid growth culture)
NGO	Non-Government Organizations
NTP	National TB Program
PMDT	Programmatic Management of Drug Resistant TB
PPE	Personal Protective Equipment
PPM	Public-Private Mix
R&R	Recording and Reporting
RIF	Rifampicin
SLD	Second Line anti-tuberculosis Drugs
SWOT	Strengths-Weaknesses-Opportunities-Threats (analysis)
TA	Technical Assistance
TAC	Technical Assistance Centers (centers of excellence)
WHO	World Health Organization
Xpert MTB/ RIF System	Automated Real-Time Nucleic Acid Amplification Technology for Rapid and Simultaneous Detection of Tuberculosis and Rifampicin Resistance
XRD TB	Extra Drug Resistant TB

Introduction

Many countries hospitalize TB patients to receive TB treatment. This approach is being used for sensitive TB patients and is being continued for MDR TB treatment. The hospital based model of care for MDR TB patients has been adopted by other countries only during the intensive phase of the treatment (6-8 months). The rationale for this extended hospital stay was that specialized treatment providers would be able to monitor the administration of complex drug regimens, treat side effects, and optimize adherence to treatment thus limiting MDR community transmission (1). With actual models of MDR TB inpatient care requiring months-long hospital stays, countries are facing a shortage of hospital beds to satisfy the increasing demand of MDR patients in need of treatment. This results in MDR TB treatment bottlenecks, with patients waiting months for a hospital bed to be available so they can begin treatment. Meanwhile untreated MDR TB patients pose a tremendous risk of disease transmission in the community (2), and the delay in initiating their treatment contributes directly to the TB mortality rate..

However, there is no evidence that hospitalization actually limits community transmission (3) (6). This is due in part to the unfortunate reality that most patients have been infectious for several months before being diagnosed combined with the expected delays of treatment initiation after diagnosis due to hospital bed shortages. Additionally, by hospitalizing TB and MDR patients in the same facility, TB sensitive patients are at high risk of MDR TB nosocomial infection as they may become infected with MDR TB and XDR strains from undiagnosed or untreated patients. Patients hospitalized, often far from home, are deprived from family activities and emotional support. To mitigate isolation, relatives often stay with patients in the hospital or near the facility thus incurring extra expenses and additional family disruption. As a result, patients refuse treatment and treatment default rates increase.

Why is decentralized PMDT needed?

- There are not enough hospital beds available for MDR TB treatment initiation resulting in long waiting list for hospitalization without patients receiving treatment.
- There is a high likelihood of nosocomial transmission of MDR/XDR-TB in health facilities.
- Some MDR TB patients refuse to be hospitalized due to lengthy hospital stays that interfere with patients' responsibilities to attend to family needs and demands.
- Patients' trips to the centralized hospitals for monitoring and medication are lengthy, arduous, unpleasant and costly, contributing to poor treatment adherence
- Clinic-based ambulatory treatment (patients attending a healthcare facility) and when possible home-based ambulatory treatment (provided by a worker in the community) will improve cost-effectiveness

Another important factor that TB programs should consider is the higher costs associated with inpatient treatments. For example, it was estimated that the cost of MDR TB hospitalization accounted for half of the annual National TB Program (NTP) budget in South Africa (1) (4).

Studies in South Africa (5) had found good levels of compliance with treatment in coinfected patients receiving MDR TB/HIV treatment at the community level with only 5% defaults, 93% of visits attended and preliminary outcomes favorable with 77% cured/still on treatment, 82% undetectable viral load. Another study in South Africa (6) found that the time to initiation of treatment was reduced when MDR TB treatment was initiated using a community based model (from 106 days on average when hospitalized to 59 days on average in the community model), as well as the time to sputum conversion from 59 days in community model to 92 days in hospital based model). It is possible an early treatment initiation will lead to a reduction in the conversion time. The study did not provide information on the severity of the disease, such as presence and extension of cavitation that may have impacted the conversion time. Promising outcome results for the community MDR TB treatment has been found also with coinfected MDR TB-HIV patients (7) and pediatric population (8).

According to WHO 2011 Progress Report on MDR-TB and XDR-TB (9), there is an estimated annual incidence of 440,000 cases of MDR TB worldwide; of this only 13,000 patients are actively receiving treatment. There has been a vast improvement in the capacity of countries health systems to diagnose MDR TB patients stemming from better case finding diagnostic protocols in combination with better and faster diagnostic technologies which are increasingly available such as Gene Xpert assay.

Studies in South Africa (5) had found good levels of compliance with treatment in patients receiving treatment at the community level with only 5% defaults, 93% of visits attended and preliminary outcomes favorable with 77% cured/still on treatment, 82% undetectable viral load.

As a result of this improvement, we can expect that the number of patients waiting to initiate MDR TB treatment, and the amount of time they have to wait, will only worsen unless countries move to other models of care that allow for greater flexibility. The World Health Organization (WHO) recommends (10) TB high burden countries move from hospitalization models for MDR TB treatment to ambulatory services provided in the community closer to the patients' residence. This crucial step to bridge the gap between the main health system at the hospital level and health services at the community level needs careful planning and organization to ensure the provision of quality services and the reduction of the risk for infection transmission within the household and the community in general.

Planning Framework

C-PMDT Tool Objectives

The c-MDR TB tool focuses on operationalizing implementation of MDR TB community level interventions, drawing on information gained from the experience of several countries implementing a community model to deliver MDR TB services to patients. One aim of the tool is to assist in the transition from initial planning stages to the development of an operational plan at the district level to implement decentralized MDR TB services. Additionally, the tool can aid in raising awareness for activities required in scaling up MDR treatment services in the community and provide evidence based advocacy for NTP programs, organizations, and donors working on MDR TB control.

Specific objectives:

- To identify which activities should be implemented to provide MDR TB services at the community level
- To identify the targets of the activities
- To determine where to implement these activities
- To propose a time frame for the implementation of the activities
- To identify implementing partners/individuals for the activities
- To propose a budget linked to activities
- To monitor and evaluate the strategic interventions
- To assess the need for Technical Assistance

The community PMDT (c-PMDT) tool presented in this document is not intended to replace other existing tools, but rather to complement them with the addition of a community strategy component. The tool is aligned with existing guidance from international organizations including: the World Health Organization (WHO), the Green Light Committee, and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). Specific resources include: *Guidelines for the Programmatic Management of Drug-resistant TB* (WHO, 2011), *Management of MDR-TB: A Field Guide* (WHO, 2009), *Community-Based Care for Drug-Resistant Tuberculosis: A guide for implementers* (USAID-PIH, 2011), Stop TB Planning Tools for Global Fund Round 10 TB proposal preparation and the WHO MDR planning Toolkit (11).

MDR TB planning team members should include representation from the following institutions/agencies:

- Hospitals, Health centre, clinics, Clinical laboratories (Microscopy, Hain MDRplus, MGIT culture/DST, LJ culture/ DST, XpertMTB/RIF), pharmacies at the district/subdistrict level
- National/district reference laboratories where samples for culture/DST will be processed
- Sample referral system courier services/postal services for sample transportation
- MDR service providers (hospital and community), private providers, informal health providers
- Health providers from HIV, Diabetes, Family planning services
- Community organizations, civil organizations, faith based organizations, NGOs
- Civil groups, patient groups, DOT supporters
- Technical agencies and organizations
- Donors

Audience

The "planning team" should include TB country planners and technical organizations, along with national, district and sub-district managers of TB programs. At the district level team members should include representatives from the main hospitals and clinics that will provide MDR services, national and district drug management officers, MDR diagnostic centers- especially those where XpertMTB/RIF units are placed- and national/district reference laboratories where samples for DST will be processed. Additionally, community organizations, civil groups, and faith based organizations that will provide psychosocial support to the patients should be invited to participate. It is essential that all relevant stakeholders be present during the planning process in order to ensure that specific concerns are addressed, and to facilitate coordination among them. The "planning team" will also decide what technical assistance will be needed from in-country technical bodies or from international technical organizations.

"The building blocks serve three purposes. First, they allow a definition of desirable attributes — what a health system should have the capacity to do in terms of, for example, health financing. Second, they provide one way of defining WHO's priorities. Third, by setting out the entirety of the health systems agenda, they provide a means for identifying gaps in WHO support."

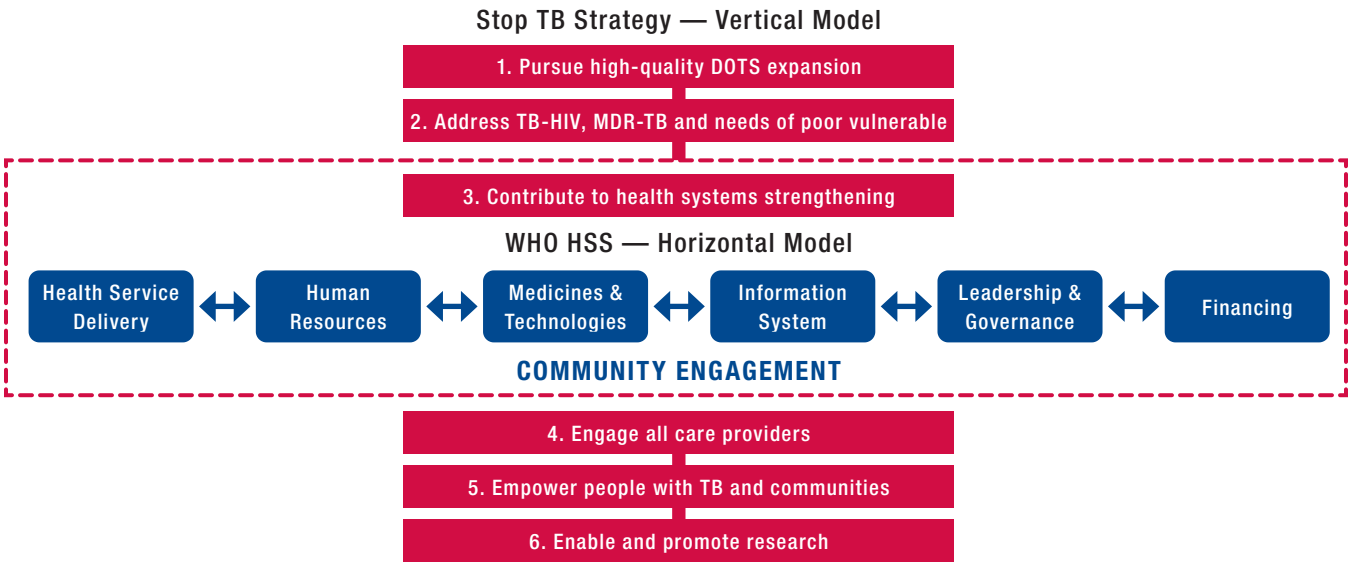
WHO Health Systems Framework for Action

Conceptual Framework

This tool was designed following the framework proposed by WHO for health systems structure and strengthening (12). According to the WHO, a health system is one which "consists of all organizations, people and actions whose primary intent is to promote, restore or maintain health" (12). The framework for action proposed by WHO consists of six building blocks that will interact among them to define the operational structure of the health system.

The introduction of community based MDR management will have a broad impact felt not only in the TB program, but in other health programs across the board. We propose to build the c-PMDT tool using the health system model proposed by WHO that better serves future planning efforts for MDR management considering interactions that the TB activities will have in other projects carries out in the community in spite of a vertical model that focuses solely on TB program goals and objectives.

Figure 1. Interaction of Stop TB Strategy model and the WHO HSS model



The 6 building blocks involved in WHO's health system model are as follows: Service delivery, information systems, medicines and technologies, human resources, leadership and governance, and financing. We will explore with this tool the interrelations of the building blocks with the community structures since the beneficiaries of the TB activities are not only TB patients but the community at large. Community members will play an active role in supporting and promoting TB awareness and control activities and treatment support. In addition, community members such as traditional healers, village doctors, community health workers, and community organizations will also provide health services (preventive and/or curative) to community members. The interaction between community structures and facility services will determine the model of provision of MDR TB services at the community level.

C-PMDT Interaction with Health System

The community MDR TB strategy should be integrated within the countries national TB and MDR plan. Since the community strategy will interact with other locally provided services and programs, it should also be coordinated with them to avoid creating parallel delivery systems and to maximize the efficacy of the community health platform.

The implementation of MDR TB activities at the community level will inevitably influence the structure of the health system in the region/country as represented in each of the health system building blocks.

The community strategy will interact with other locally provided services and programs, it should also be coordinated with them to avoid creating parallel delivery systems and to maximize the efficacy of the community health platform.

Figure 2. WHO health systems building blocks

For example, the daily MDR DOT services provided to an MDR TB patient should be integrated with ARV treatment follow up if patients are MDR TB-HIV co-infected. The same coordinated strategy should be applied to diabetes treatment management if required, and/or with family planning services if the patient is a female of reproductive age during the MDR TB treatment. Also the community activities will impact other health system blocks by forcing the TB leadership block to adjust to a new decentralization of TB services, with new guidelines and a new regulatory environment to allow for the provision of MDR TB ambulatory services. Additionally, the human resources block will need to adapt to the increased demand for staff capable of providing MDR TB services by increasing the amount of trainings they offer, improving training curriculum, or possibly designing new certificated programs for new personnel allowing those who pass the course to perform activities such as treatment initiation by MDR TB nurses or providing injectables. Furthermore, the health information block will need to be strengthened to include records from community workers/DOT supporters and to support the coordination of reporting mechanisms between labs, hospitals, health facilities, and community workers. Finally, the financial block will need to adapt a decentralized management and the medicines block will need to ensure the availability of SLD and quick access to MDR laboratory tests at the district/sub-district level.

Table 1. c-PMDT interventions interactions with the health system building blocks

Building Block	c-PMDT Types of Interventions
Health Service Delivery	• MDR DOT at the community and household (injectable) • Management of side effects • Integration services: MDR-HIV, MDR-DM • Patient support • Psychosocial support
Information System	• Mapping of MDR TB patients • m-health recording and reporting • Manual and electronic medical recording and reporting updated to include the community involvement • Referral coordination
Medicines and Technologies	• Second line drug (SLD) procurement • SLD distribution/redistribution • Drug sensitivity test (DST) testing • Rapid detection of RIF: Gene XpertMTB-RIF; Hain MDRplus and other tools
Leadership & Governance	• Decentralization of care at the district level • Civil society participation: support groups, DOT supporters • Licensure, accreditation, registration • Supervision
Human Resources	• Integrated training • Performance management • Incentives for retention
Financing	• Performance based funding: – Increase supply: DOT supporter incentives (performance), DOT provider incentives (performance) – Increase demand: Patient support (transport, food..), Conditional cash transfers • Health insurance and coverage

C-PMDT Toolkit Structure

We need to consider several elements before implementing the strategy at the community level. We will need to have an understanding of the situation, the resources available and the needs before designing a strategy with activities oriented to improve gaps and provide with the structure to support PMDT efforts at the community and health system level (13). The PMDT operational plan will include a budget for implementation that will be linked to activities and timeframe for implementation. It will include also an M&E framework to measure progress of the c-PMDT operations.The implementation of community activities to support MDR TB treatment will require of detail planning and it is expected that technical assistance will be required to support not only planning efforts but to implement the strategy. Each country should consider what will be their needs for national e international technical assistance.

The c-PMDT toolkit is composed by:

1. Situational analysis table
2. Panning matrix
3. Budgeting tool
4. Operational plan
5. M&E framework
6. Technical assistance needs

1. Situation Analysis

- Health and health system context and model of MDR care
- Analysis of TB burden
- Resources available
- SWOT analysis
- Identification of the gaps

2. Planning Matrix

Identification of strategic interventions under each strategic objective (building block), Annex A.

- Activities clearly specified
- Have target(s) defined in SMART criteria (Specific, Measurable, Achievable, Realistic, Time bonded)
- Match each strategic intervention with at least one strategic objective
- Match each intervention with at least on strategic intervention

3. Budgeting Tool

Estimates of budget needed as well as resource mobilization from government and local and international partners/donors

- Results will be included in the c-PMDT operational plan
- Consistent with the strategic core plan
- Refer to each strategic intervention and each activity identified
- Establish the cost
- Identify the funding contribution of the government and of each partner for every year and for the overall period covered by the plan
- Identify the funding gap for every year and for the overall period covered by the plan — Use WHO budget tool (14)

4. Operational Plan

- Definition of clear operational objectives:
  - Should match with the situation analysis
  - Should be defined in SMART criteria terms
- Clearly identify the activities (and sub-activities) that need to be implemented along with the strategic interventions
- Be consistent with the strategic core plan, the budgeting plan and the monitoring and evaluation plan: the activities and strategic interventions in the operational plan must be the same as those identified in the strategic core plan and the budgeting plan
- The operational plan should be established and detailed for the next 1 or 2 years of the implementation period

5. Monitoring and Evaluation Framework

- Consistent with strategic core plan, the budgeting plan and the operational plan
- Refer to each strategic intervention and activities identified in the core plan
- Should include:
  - Impact indicators (for the overall goals)
  - Outcome indicators (for the strategic objectives)
  - Output indicators (for the strategic intervention)
  - Process indicators (for some key activities)

6. Technical Assistance Plan

Should be based on the operational plan and refer to the implementation of those activities that are expected to require some type of technical assistance.

- **Task:** Brief description of the activity and type of TA that will be required (national, international, training, scope, etc.)
- **Estimated cost:** Estimated cost of the TA, available funds and funding sources and unmeet funding
- **Available funding & source:** Estimated amount available and source of funding such as NTP, GF grants, partner budgets, etc.
- **Timeframe:** Estimate the amount of time for each consultancy, training and support and when it should be provided

1. Conduct a Situational Analysis of MDR TB

Both the situation analysis tool and the planning tool are designed following the building block structure to facilitate links with other national health plans using the same approach. Questions included in the table below are illustrative and should be adapted to each country context.

To fill in the situation analysis table (15), you will need to have access to the following information:

- Data obtained from the most recent MDR program review, monitoring assessment conducted in the country, other situation analyses conducted previously and/or the country annual TB-MDR TB program report. Epidemiological data can be obtained from the country TB program surveillance or from data reported to WHO (Global TB controls annual reports). This information needs to be filled into the "existing resources" column.
- Data obtained from the expected burden of disease and diagnostic and treatment targets established in the country MDR plan. This information needs to be filled into the "planned" resources column.
- The "gaps" column will be calculated by comparing the "existing" and "plan" columns. The gap will either be expressed in terms of numerical values or as a "yes/no" response when the presence or absence of an item is evaluated (e.g. a guideline developed).

Situational Analysis Table

Table 2. Situational analysis table with assessments under each building block (strategic objective). Adapted from Stop TB Planning Tools (15)

Building Block 1 — MDR Service Delivery			
Areas of Assessment	Existing	Plan	Gap
Diagnostic capacity for MDR-TB, TB-HIV in public/private facilities (Number of laboratories with diagnostic capacity for MDR/XDR and diagnosis of side effects and complications) (Y/N)			
MDR clinical management (model of care for initiation of treatment: hospitalization/ambulatory, beds available, standardized MDR treatment, hospitals/clinics with capacity for MDR treatment initiation and management of side effects/complications) (Y/N)			
Guidelines developed (decentralized management of MDR, decentralized procurement, storage, distribution SLD, sputum collection and transportation, infection control in community settings, contact tracing..) (Y/N)			

Building Block 1 — MDR Service Delivery *continued*			
Areas of Assessment	Existing	Plan	Gap
Programmatic management (side effects protocols, management and referral system; audiometry test available; infection control appropriate, functional sputum collection / transportation system, assessment and management risk of default, incentives, enablers and patient support mechanism in place; psychosocial support) (Y/N)			
Mapping MDR cases, community health services and supporters (MDR DOT) (Y/N)			
Building Block 2 — Information System			
Epidemiology (MDR cases expected, diagnosed , put on treatment, MDR treatment outcomes) (Y/N)			
M&E (manual/electronic R&R system updated to include community MDR activities, DR survey, DR surveillance; Drug information system (R&R) functioning) (Y/N)			
Building Block 3 — Medical Products and Technology			
SLD forecasting, procurement , storage, distribution/redistribution (Y/N)			
Rapid diagnostic tests for MDR and supplies (Y/N)			
Building Block 4 — Leadership and governance (management, corrdination, supervision)			
PMDT district planning committee established(stakeholders and civil society involvement) and coordination mechanisms established (Y/N)			
Legal framework that enables new certificate programs/task shifting			
Curriculum and training program on MDR management for health professionals and community workers (MDR DOT supporters) (Y/N)			
Supervisory mechanism established (Y/N)			
Building Block 5 — Health Workforce			
Assessment of health personnel trained in MDR management and required considering location (Y/N)			
Training programs/ new certificates and accreditation (Y/N)			
Task shifting to health workers and community DOTS supporters (Y/N)			
Building Block 6 — Financing			
Incentives and enablers (Y/N)			
Social welfare – insurance scheme for TB/MDR/XDR (coverage of services diagnostic, follow up, side effects, drugs, patient support, others) (Y/N)			

Model Of Care

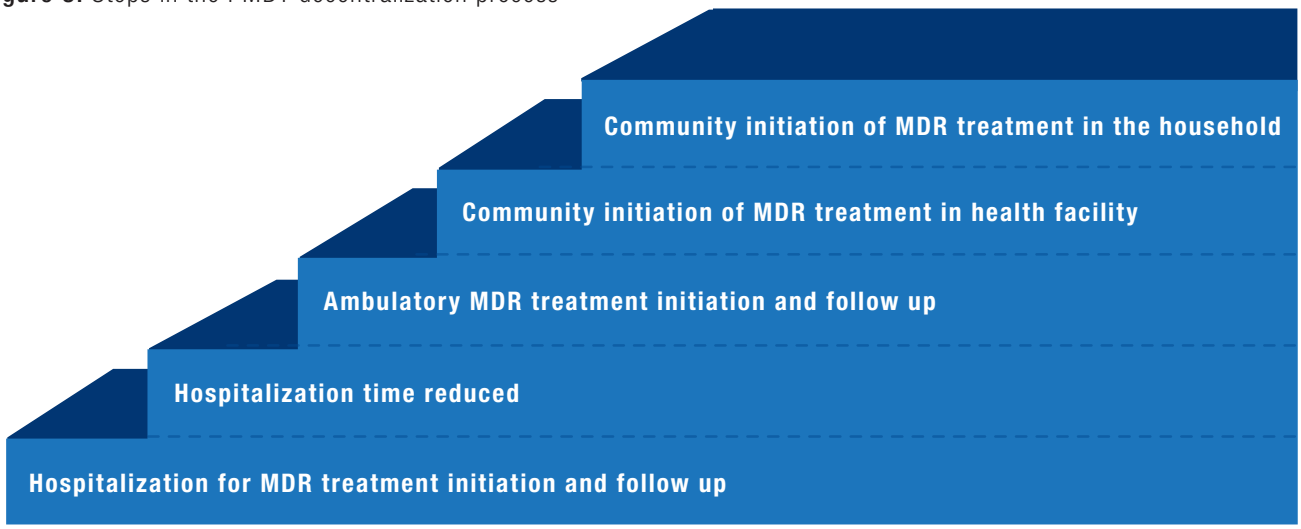
The model of care to provide MDR TB services differs among countries depending on the level of decentralization in their provision of health services. In general, countries are slowly transitioning from inpatient MDR TB initiation to MDR TB initiation through ambulatory services. One important step in the process of decentralizing MDR TB treatment will be the provision of MDR TB ambulatory treatment initiation in health facilities located at the district, sub-district, or community levels.

Treatment for MDR TB patients can also be provided at the patient's household level through a mobile team composed of a nurse and assistant/driver or by MDR TB trained community DOTs supporters.

Community PMDT is defined by two components:

- **Time:** Reduction of hospitalization time
- **Location:** Decentralization of health services at the community level

Figure 3. Steps in the PMDT decentralization process



Model Of Community MDR Care

Combination community health clinic and community DOT supporter:

During the intensive phase of the MDR TB treatment where patients require daily injections for at least 6 months, patients could attend their local clinic if their health status permits it and if the clinic is located within a reasonable distance from their home. To reduce the amount and intensity of treatment side effects, many programs divide treatment into two doses observed under DOTS. The first dose along with the injection (if in intensive phase) can be provided in the morning at the health clinic, and the second dose can be provided by a DOT Supporter in the patient's household in the afternoon.

Combination community mobile health team and community DOT supporter:

During the intensive phase of treatment a mobile health team from the community clinic will be responsible for daily visits to the patient household. During this visit a nurse will provide the injectable, and assess side effects. A second dose may be provided daily by a DOT supporter in the afternoon.

Community health clinic only:

When patient health status allows it and distance and travel conditions to the clinic are reasonable, MDR patients can travel to the clinic to receive treatment. Some of the programs we exhibited chose this model, providing patients with DOT treatment in one non-divided dose.

Community DOT supporter only:

Other programs, most notably in Peru, trained MDR DOT supporters to provide injectables. This training allowed for them to visit patients twice daily (once in the morning and once in the afternoon) in their households to provide treatment.

SWOT

The planning team should assess the Strengths-Weakness-Opportunity-Threats (SWOT) of the PMDT program in order to gain insight about any internal issues related to program performance as well as external opportunities and potential obstacles for implementation. For these reasons the SWOT analysis is sometimes called the Internal-External Analysis.

- In the Strengths quadrant team members should look for the existence of the following resources: partnerships with diagnostic and treatment centers, a legislative framework, technical and managerial expertise, support from NGOs and other organizations, the existence of provincial TB surveillance, medication management, patient and provider education, a reference laboratory, and field consultant support.
- Weaknesses quadrant may include: any regional differences that negatively affect the public health response regarding prevention, testing, and care; a lack of coordination for MDR surveillance, diagnostics in reference labs, and drug management; possible misallocations of MDR patients to provincial/district areas which lack the necessary infrastructure and trained human resources; and any gaps evidenced during the situational assessment.
- Opportunities quadrant may include: opportunities from outside the TB program that can assist the program in achieving its goals. For example: scaling up GeneXpert in private settings and linking up with outside programs such as FP, food security, etc. can increase MDR TB case finding; integrating TB infection control as a part of the global infection control initiative can promote its inclusion in the occupational health process in health facilities and at the community level; engaging new partners (FBO, NGOs, etc.) who can provide patient psychological support in the community; integrating management of MDR with other diseases (HIV, diabetes, etc.) can increase case finding and treatment capabilities; engaging new partners in TB service delivery (e.g. DOT, health promotion, advocacy, etc.) to improve quality of services; and improving linkages with correctional facilities in order to provide services in the community for ex-inmates, etc.
- Threats quadrant may include: challenges evidenced that will negatively impact the PMDT strategy. For example: an increased prevalence of HIV not being managed; immigrants with poor access to the health system; prevalence of chronic disease (diabetes, respiratory disorders, cancer, renal disorder, etc.) which remain un-diagnosed and treated; financial constraints; etc.

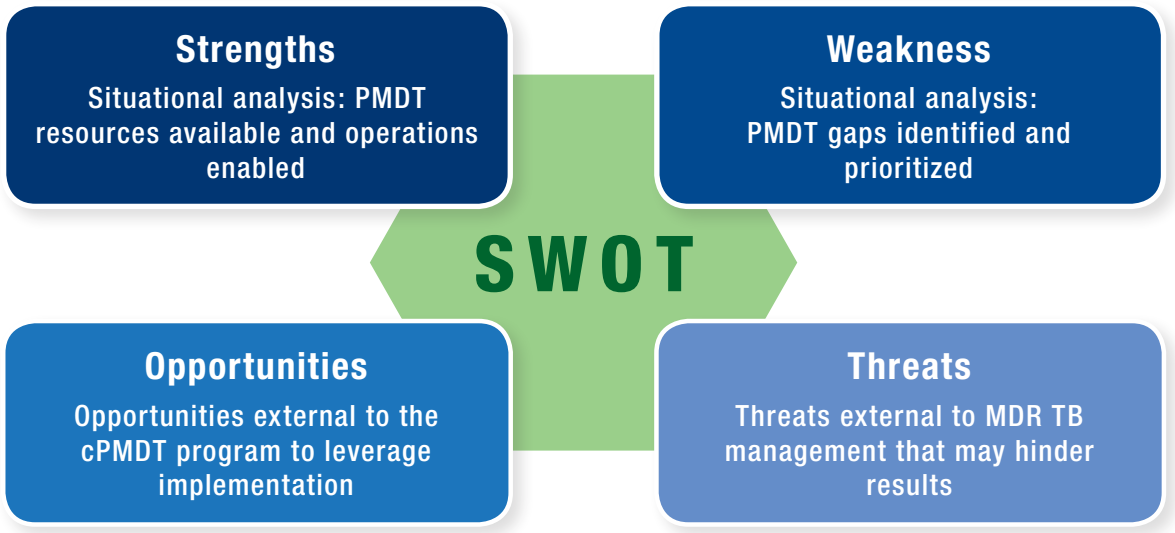
Identification Of The Gaps

After conducting the situational assessment and the SWOT analysis, the next step is to prioritize actions regarding feasibility, cost-effectiveness, and available budget. When prioritizing which actions to plan, the team should follow WHO recommendations provided by the WHO Guideline Development Group (16) regarding diagnosis, treatment, monitoring, and model of care for MDR patients.

Based upon best available evidence and cost-effectiveness modeled studies, WHO in their Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis, 2011 Update (10) propose the following recommendations:

- Rapid molecular testing for isoniazid and rifampicin even in previously untreated patients if resources are available;
- Monthly culture for monitoring through the duration of treatment;
- An intensive phase of 8 months' duration instead of the previous minimum of 6 months;
- The addition of pyrazinamide to a minimum of four second-line anti-TB drugs;
- The use of fluoroquinolones and ethionamide is strongly recommended and later-generation fluoroquinolones are preferred;
- All patients with drug-resistant TB and HIV should be placed on ART as soon as they can tolerate it;
- Systems that primarily employ ambulatory models of care are recommended over others based mainly on hospitalization.

Figure 4. SWOT analysis of district c-PMDT program tool



In the Table 3 below we present an example of gaps identified through the situational assessment and priority interventions suggested to reduce gaps:

Table 3. Example of gaps identified and suggested priority interventions

Gap	Priority Inverventions
Number and % of MDR detected is reduced compared to the MDR expected in the district	Improve MDR case detection strategy by improving access to diagnostic tests and improving MDR diagnostic capacity (training, more inclusive testing protocols…)
Number and % of MDR patients put on treatment out of total number diagnosed is reduced	Increase treatment capacity by decentralizing MDR services and ensuring SLD availability
Long time interval from MDR patient diagnosis to treatment initiation (waiting list)	Decentralization of services and treatment initiation through ambulatory models
% MDR among new TB cases, % MDR among previously TB treated cases — applied to all TB cases in the district higher than expected	• If number of MDR in new cases is high, then there is high community transmission and IC strategies need to be prioritized in the household, community, and facilities • If number MDR in retreatment cases is higher, then improvement of treatment adherence needs to be prioritized
Reduced number of diagnostic labs/locations, number of trained staff, number of hospital beds… per MDR patients and MDR expected (a ratio per MDR patient needs to be proposed)	• Capacity building and infrastructure improvement • Task shifting strategies: new certification programs to initiate and provide MDR treatment in the community

The activities prioritized could also be included under each of the building blocks from the WHO model. Some examples are provided in the Table 4 below.

Table 4. Examples of linking strategic interventions to strategic objectives

Strategic Objectives	Priority Strategic Interventions and Activities
1. Services delivery	**Integrated service delivery packages:** define integrated packages of services, and the roles of primary and other levels of care in delivering the agreed packages, as part of its health policy development support **Service delivery models:** inclusive of public and private providers, community health workers, task shifting, outreach, contracting, accreditation, social marketing, uses of new technologies such as telemedicine, hospital service organization and management, delegation to local health authorities, other forms of decentralization, etc. **Quality of care:** supportive supervision and performance assessment; training and continuing education; procedures for registration, licensing and inspection, etc.
2. Workforce	• Address workforce education, recruitment, retention and performance and define regulatory options to improve quality of practice, such as licensing and accreditation • Redesign training programs to produce health workers (service providers and management and support workers) capable of delivering specified health services.
3. Information	Avoid parallel reporting systems where possible and promote single reporting to development partners
4. Medical products	• Reliable procurement • Promote equitable access, rational use of and adherence to quality product
5. Financing and social protection	Extend financial and social protection of vulnerable population groups
6. Leadership and governance	• Development policies and resource frameworks • Regulatory framework • Development of local resource institutions' capacity to support local health managers; and development of methods to monitor progress

2. Develop A Planning Matrix

In the **Annex A** we include strategic interventions under the strategic objectives from the health systems approach that include a community component. The planning matrix was adapted from the Stop TB Planning tools and updated to incorporate the new framework (15). It also propose activities specific under each strategic intervention to be considered when appropriate or necessary. The matrix includes columns to summarize gaps identified through the situational assessment and propose some indicators to measure implementation of activities. The last column will link implementation of activities with an estimated budget.

The matrix includes columns to summarize gaps identified through the situational assessment and propose some indicators to measure implementation of activities.

Define Strategic Objective and Activities

After conducting the situational analysis, the PMDT planning team will be in a situation to define the strategic objectives appropriate for their country/ region program. Also they will need to propose and decide on activities that the program should implement. To guide this process it will be helpful to follow the information contained in Annex A as well as include other activities that may have not been considered in the proposed matrix. Each program should decide on the model and activities that will better fit their needs and objectives.

Table 5. Outline of c-PMDT strategic objectives and activities included in the planning matrix (Annex A)

Outline of c-PMDT strategic objective and activities	
Strategic Objective 1: High quality of MDR TB service Delivery	
1.1	Distribution of MDR TB services
1.2	MDR TB case finding
1.3	Quality assured laboratories for MDR TB in the district
1.4	Referrals and coordination
1.5	Infection control
1.6	Integration of MDR TB and other comorbidities
1.7	Risk of default
1.8	Patient support
1.9	Incentives and enablers
1.10	Supervision
1.11	Community participation
Strategic Objective 2: Information System	
2.1	Recording and reporting
2.2	Surveillance System
2.3	Data analysis
Strategic Objective 3: Medical products and technologies	
3.1	Drug management
3.2	Xpert
Strategic Objective 4: Leadership and governance	
4.1	Policy guidance
4.2	c-PMDT planning and management
4.3	Guidelines
4.4	Supervision
Strategic Objective 5: High quality of MDR TB service Delivery	
5.1	Staffing
5.2	HR system management
5.3	Training
5.4	Community workforce/networks
Strategic Objective 6: Budget and financial mechaisms	
6.1	Budget
6.2	Financial mechanisms

3. Estimate Budget Needed

Studies (17) had found great variability in the overall cost of MDR treatment per patient. The cost per patient for MDR TB treatment in Estonia ($US 10,880), Peru ($US 2,423), the Philippines ($US 3,613) and Tomsk ($US 14,657) were influenced mainly by the model of care chosen, mostly the duration of the hospitalization time as well as by the drug regimen selected to treat MDR. In Estonia hospitalization was maintained for 6 months which accounted for 43% of MDR TB treatment budget and during approximately 8 months in Tomsk accounting for 52% of the budget. These types of studies are useful to prepare budgets and financial statements.

The overall cost-effectiveness of care for a patient receiving treatment for MDR-TB can be improved with an ambulatory model. The benefits, when compared with hospitalization models, include reduced resource use and at least as many deaths avoided among primary and secondary cases.

The same study (17) calculated a global cost for treatment of outpatient models of care as $US 13,259 per patient treated and the inpatient model was $US 34,599 per patient treated.

Other studies (17) (18) have focused on assessing not only the cost but the cost-effectiveness of treatment strategies used, that is, if the model of treatment chosen offers good value for money regarding efficiency achieved. These studies did not find that patients treated in hospital settings achieved better treatment outcomes that those patients treated in ambulatory settings in low and middle income countries. The overall cost-effectiveness of care for a patient receiving treatment for MDR-TB can be improved with an ambulatory model. The benefits, when compared with hospitalization models, include reduced resource use and at least as many deaths avoided among primary and secondary cases. These findings support the conclusion that, unless there is strong evidence that hospitalization is necessary to achieve high rates of adherence to treatment, patients with MDR-TB should be treated using mainly ambulatory care.

Estimates of the total budget required as well as the amount of resources to be mobilized by government and local/ international partners and donors should:

- Be consistent with the strategic core plan
- Refer to each operational objective, each strategic intervention and each activity identified
- Establish the cost
- Identify the funding contribution of the government and of each partner for every year and for the overall period covered by the plan (19)
- Identify the funding gap for every year and for the overall period covered by the plan. It is recommended to use the WHO budget tool (20)

Budget Matrix

Table 6. Consolidation of PMDT estimated costs and funding available

C-PMDT Budget	Estimated Costs	% Available from Domestic Sources	% Available from International Sources Global Fund (19)
1. Direct patient costs			
1.1 SLD	(SLD estimation Table 7)		
1.2 Ancillary drugs	(Ancillary estimation Table 8)		
1.3 Patient support	(Patient/DOTS estimation Table 9)		
2. Screening costs	(Screening estimation Table 10)		
2.1 Patient follow up			
2.2 Side effects			
2.3 Contact tracing			
3. Program costs			
3.1 Training			
TOTAL			

Second Line Drug Cost Estimation

A simple calculation can be used to estimate the cost of SLD drugs, this formula can be found in the *TB CARE II-Community-Based Care for Drug-Resistant Tuberculosis: A Guide for Implementers* (21). A sample cost for second-line drugs as provided by the WHO–STOP TB SLD Estimation and Request tool (14) was included in Table 7 below for an empirical standard MDR TB regimen treatment. The standard empirical treatment has been demonstrated effective as an initial approach by several studies (3) (8), but others found than individualized regimens had a higher treatment success than standard regimes although the difference was not significant (22). This simple calculation method will be useful to quickly estimate expenses for newly MDR TB diagnosed, mostly having into consideration the increased number of MDR patients diagnosed with rapid diagnostic methods such as Gene Xpert or Hien, and that will receive a standard treatment until DST tests results are received.

The costs of SLDs are frequently changing. In Table 7 we are providing an example to illustrate calculation but you will need to obtain the actual price/cost from the GDF

prior to the SLD calculation and ordering/procurement. It is also important to consider that costs for SLD vary from country to country, depending on the importation rules and regulations.

To obtain a more detailed calculation that considers the coefficient of drug use per each drug, the *WHO–STOP TB SLD Estimation and request tool* (14) can be used.

Table 7. Monthly budget calculation for SLD adapted from TB CARE II-Community-Based Care for Drug-Resistant Tuberculosis: A Guide for Implementers

Drug (unit)	Quantity to Order	Assumptions	Cost ($US) per Dose	Budget (quantity to order x cost per dose ($US))
Pyrazinamide *(500 mg tab)*	3xDxP	Mean consumption is 1500 mg/day		
Kanamycin *(1 gr vial)*	1xDxP	Will discard unused portion of vial	$0.53	
Amikacin *(500mg/2ml inj)*	2xDxP	Will discard unused portion of vial	$0.15	
Capreomycin *(1 gr vial)*	1xDxP	Will discard unused portion of vial	$3.21	
Ethionamide *(250 mg tab)*	3xDxP	Mean consumption is 750 mg/day	$0.10	
Prothionamide *(250 mg tab)*	3xDxP	Mean consumption is 750 mg/day	$0.16	
Cycloserine *(250 mg tab)*	3xDxP	Mean consumption is 750 mg/day	$0.51	
PASER *(4 gr sachet)*	2xDxP	Most patients reveive 8 gr/day	$1.97	
Levofloxacin *(250 mg tab)*	Dx(P/2)	Half the patients are <50 kg (750 mg/day)	$0.05	
Levofloxacin *(500 mg tab)*	3xDxP	Half the patients are >50 kg (1000 mg/day)		
Ofoxacine *(200 mg cap)*	4xDxP	Mean consumption is 1 gr/day	$0.03	
TOTAL COST				Amount to be included in the budget matrix

Note:

D: Number of Days that patients reveive treatment in the time period for which you are ordering

P: *Number of patients taking the drug*

Ancillary Drug Cost Estimation

In Table 8 we include a list of ancillary drugs to serve as an example for countries/districts to design their own. Also other drugs and supplies may need to be included as appropriate based on country program experience on the needs of the patients treated with SLD

Table 8. Monthly budget estimation for ancillary drugs and other supplies

Drug	Quantity	Cost per dose	Assumptions "p" (% estimated use)	Budget (quantity to order x cost per dose)
Anti-emetics: metoclopramide, prochlorperazine	pxDxP			
Anti-convulsants: phenytoin				
Anti-psychotics: haloperidol, risperidone				
Antihistamines: chlorpheniramine				
Anti-diarrheals: loperamide				
Neuropathic pain: amitriptyline				
Levothyroxine				
Family planning: depo provera				
Other Supplies				
Needles, syringes, solvents				
Needle disposal containers are needed for each DR-TB Supporter who is providing injections				
Particulate respirators (N-95, FFP2), surgical masks				
Anti-emetics: metoclopramide, prochlorperazine				
ARV (if HIV/AIDS)				
AZT-3TC				
TDF-3TC-EFV				
EFV				
D4T-3TC-NVP				
TOTAL COST				Amount to be included in the budget matrix

Note:

p: *Percentage side effect requiring medication expected*

D: Number of Days that patients reveive treatment in the time period for which you are ordering

P: *Number of patients taking the drug*

Patient/DOTS Provider Support Cost Estimation

Table 9. Monthly estimation of costs to provide patient support and cost for transportion and incentives incurred by the community DOTs supporters

Items	Quantity	Cost
MDR patient transportation costs	PxV	
MDR patient daily motivation (food, others) support cost	PxF	
MDR-DOTS Provider monthly incentive	DPxP	
Onetime costs for MDR-DOT Provider	(mobile phone, storage box, DOT books, umbrella torch)	
Other and miscellaneous costs (monthly mobile phone)	DP	
Hearing aids		
TOTAL COST		Amount to be included in the budget matrix

Note:

V: *Number of visits to the health facility (once a month) or more depending on side effects*

F: Food packages provided monthly per patient.

DP: Number of DOTs providers receiving allowance (could be linked to level of effort)

Patient Follow Up Cost Estimation

Table 10. Monthly estimation of MDR patients follow up costs. In Annex C it is included a table with suggested follow up test and frequency for the tests to be conducted

Lab Follow Up	Assumptions Quantity Tests (Annex C) per Patient	Cost per Patient
MDR patient evaluation & follow up	Smear, culture, DST	
Screening HIV		
MDR-HIV coinfected, (extra: CD4, CTX)		
Follow up MDR after completion treatment		
Screening side effects	Liver Function Test, Thyroid Function Test, Blood Sugar, Kidney Function Test, X-ray, Blood Electrolytes, etc.)	
Audiology		
Hospitalization	(Based on avg stay = e.g. 1.5 months at 15 USD a day)	
Visits to the health facility		
Visits in the household		
MDR contact tracing		
TOTAL		Amount to be included in the budget matrix

4. Develop An Operational Plan For C-PMDT

The operational plan is a document that contains information useful for the implementation of the activities. It is recommended that the operational plan include the following information (13):

Background

For the background section of the operational plan include main findings resulting from the situational analysis and the SWOT analysis conducted by the planning team. It should then detail planned activities which were chosen and built to complement existing strategies in order to leverage and facilitate their implementation.

The background section should also include external factors to the PMDT program that could influence implementation of activities (opportunities and threats). A good understanding of potential external influences to the program will be very valuable when prioritizing activities and including partners involved in the planned activities.

In addition, you may want to include other information in the background section, such as:

- A district map with public and other health facilities; TB and MDR TB diagnostic units and reference hospitals; and MDR TB cases identified and communication structures (roads and other means of transportation)
- Estimation of the number of MDR TB patients in the district and the actual number diagnosed and receiving treatment
- The number of health facilities ready to treat MDR TB cases and those with the capacity to do it (infrastructure and trained personnel)
- The number of laboratories/facilities (public and private) with capability to conduct rapid MDR TB testing (Xpert/ Hien) and planned transportation of sample to reference units to conduct culture and DST.

A good understanding of potential external influences to the program will be very valuable when prioritizing activities and including partners involved in the planned activities.

- Number of facilities with audiometry, radiology, ultrasound, pediatric TB diagnosis units
- The number of health Staff trained to provide MDR TB and HIV treatment
- The number of community health workers (Mobile teams and DOT supporters trained to provide DOT in the household)

Strategic Objectives

The MDR TB planning team will identify those activities that are linked to the strategic objective. In Annex A we included a matrix with activities organized under the strategic objectives following the health system strengthening framework.

Activities presented in the matrix aim to decentralize provision of MDR TB services, moving them closer to the patient's household, in the peripheral-community health facility, or in the patient's household itself.

Table 11. Example of strategic interventions and activities to decentralized c-PMDT activities

Strategic Interventions	Examples of Activities to Decentralize PMDT Services
Planning, regulatory and budgeting	• Development of Operational plan for PMDT services • Regulatory framework enabled to allow the new certified training program's DR TB trainees to practice. • Assessment capacity of health facilities to provide MDR services
Capacity building	• Development of Training curriculums • Address specific, immediate training needs • New Certification programs for nurses to initiate MDR treatment, training of community workers to provide injectables • Conduct on-the-job training to reinforce previous training
Coordination and Supervision	• Monthly visit to each health facility providing DR TB services to review records, assess performance, provide feedback, and provide support • Maintain up-to-date *District DR TB Register* based on *DRTB Treatment Cards* kept at health facilities • Every 6 months, for each health facility, update list of staff responsible for DR TB services and their training needs and for community DR TB Supporters • Conduct periodic district meetings of health facility and community personnel providing DR TB services (e.g. for motivation, sharing monitoring results, problem-solving, brief training). • Address specific programmatic issues: – Referral mechanisms – Risk of MDR default management – Reach out to specific populations: HIV, prisons, vulnerable populations, health care workers – Co-management: DR TB –HIV, DR TB-Diabetes – Management of DR TB pediatric population – Psycho-social evaluation and patient support mechanisms – Infection control in facilities and congregational settings
Drugs and Supplies	• Order yearly supply of forms and registers for the district • Distribute forms and registers to health facilities • Order SLD TB drugs for the district quarterly • Order other TB-related supplies for the district quarterly (needles, syringes, sterile water for injection, sputum containers) • Estimate drugs and supplies needed by each health facility and ensure quarterly distribution. • Ensure good storage procedures at the district storeroom • Coordinate re-distribution of SLD (from patients to the facility and between facilities)
Laboratory Support	• Monthly, visit the main district TB laboratory. • Visit TB microscopy/culture units located in health facilities. • Confirm registrations and laboratory results in *District DR TB Register* by comparing with *Tuberculosis Laboratory Registers.* • Report to the district laboratory supervisor any needs for equipment, supplies, personnel, or training noted during visits to TB microscopy units. • Sputum collection and transport • Monthly Visit Gene Xpert diagnostic units in health facilities or laboratories • Order Xpert cartridges for the district quarterly

Roles and Responsibilities

In the Table 12, below is included possible role and responsibilities that health workers, management, community workers and community organizations could play in the PMDT activities.

Table 12. Role and responsibilities of main actors providing MDR services

Area of Service	MDR TB Patient Support	MDR Case Finding	MDR Treatment Initiation	MDR Treatment Follow Up	Side Effects Management
MDR TB specialist			MDR diagnosis and treatment initiation of cases complicated and severe comorbidities	Management of complicated MDR in-patients	Management of severe side effects managed in tertiary hospitals
MDR trained Primary care physicians/nurses in health facility		Contact tracing in health facility	Initiation of non-complicated ambulatory cases	Inpatient and ambulatory follow up. Coordination with community services	Management of side effects in the health facility and comorbidities
Community nurses/ Mobile team	Counseling and education (treatment adherence, infection control)	Active MDR contact tracing in the household and/or the health facility	Some programs created a new certificate for nurses initiation of MDR treatment ambulatory in non-complicated cases	Coordinate services in the community and referrals. Provision of injectables and DOT supervision in health facilities or mobile teams. Manage patients at risk of default	Management of non-serious side effects in the health facility or ambulatory
Laboratory, Xpert;		Laboratory services for DR TB patients, coordination with sputum collection and transportation services	Coordination with facilities for immediate treatment initiation	Follow up treatment tests	Screening tests for side effects
M&E	Maintain database (register) of all DR TB patients in the region/district. Maintain a rooster with trained DOTS supporters	Register for TB non converters and treatment failures.Register for contact of MDR TB. Mapping patients for contact tracing	DR TB register and notification to the national system	DR TB follow up visits scheduling centralized services	Referral system for side effects and complications

Table 12. Role and responsibilities of main actors providing MDR services *continued*

Area of Service	MDR TB Patient Support	MDR Case Finding	MDR Treatment Initiation	MDR Treatment Follow Up	Side Effects Management
Pharmacist			Manage second-line drug stock (inventory, forecasting, and drug supply) for the region/district	Prepare pediatric anti-TB drug doses. Prepare drug packs for each DR TB patient and deliver them to the community team.	Provide medications package for each side effect and comorbidities (ARV, antidiabetics, etc.)
Finance officer	Patient support and DOTS Supporter transportation and food, cash transfers	Incentives management	Incentives management	Incentives management	Support for side effect medication if not covered by the insurance
DOTs Supporters	Counseling and education. Emotional support	Active MDR contact tracing in the household		DOTs supervision in the continuation phase. Some programs trained DOTs supporters to provide injectables. Accompany patient to follow up/medication refill visits in the facility	Identification of severe side effects and referral to health facility
FBO, community organizations	Stigma reduction. Psychosocial support. Improve infection control in congregational settings				
Community/family	Emotional and economic support. Patient support groups. Infection control in the household and congregational settings	Cooperation for contact tracing and testing		DOT supporters and community members involvement in treatment adherence and motivation	Support in side effects management in the household
MDR TB patient	Follow up recommendations, nutrition. Cured ex MDR patients involvement is support groups and advocacy	Recommendation of family and friends with TB symptoms to access health services to be tested	Compliance with treatment as prescribed	Report missing doses. Comply with follow up visits and lab tests	Report side effects. Compliance with treatment

Table 13. Role and responsibilities of health authorities in the c-PMDT strategy

Management/technical	PMDT Planning	Guidelines and Protocols	Supervision	Coordination	Drugs	M&E
Local health authority	• Mapping of MDR cases and facilities providing services, labs • Role and responsibilities of local stakeholders • Training and staffing	Distribution of protocols to the peripheral facilities	• DOTS supporters performance, • m-Health • Incentives system • Supervision and payment • Infection control implementation in community settings and facilities	• Coordination mechanism for referrals between the community and health facilities • Coordination of sputum collection and transportation coordination stakeholders at the local level • Coordination with private services and providers	PRestocking and redistribution of treatment packages to patients	• Recording and reporting from community treated patients, • Defaulters tracing and contact tracing
Regional/provincial health authority	• Organize and plan the c-PMDT strategy in the region, • Integrate DR TB with other services, e.g., HIV and maternal services. • Development of the operational PMDT plan	Adapt national protocols to the regional environment.	• TB and DR TB diagnosis and treatment units • Infection control in the facilities and congregational settings	• Coordinate diagnosis and treatment units in the region. • Coordinate with the central level, other institutions, e.g., NGOs and patient support system • Coordinate services in correctional	• MProcurement from central SLD facility • Distribution and redistribution of SLD based upon timely demand • Storage and inventory	Consolidate, analyze a nd Reporting and notification to central level
National health authority	Establish norms and procedures for the control of DR TB • MDR Plans development, • Placement of lab units (Xpert) • Legal framework for occupational health	Development of PMDT guidelines and protocols	• Assess needs • Supervision performance against establishes program targets • Quality assurance of drugs available	• Coordinate operational research on community care • Advocate for community care • Coordination with National reference lab and supranational lab • Coordination with international partner and donors for TA and funds	SLD forecast and procurement	• Monitor, and evaluate the program • Quality lab and services monitoring
International organization	TA for planning PMDT	TA for protocol development and tools	TA to enable supervisory systems	Coordination among international programs operating in the country and with the local MDR program	Global Fund procurement	WHO reporting

Activities

Activities should be defined based on the prioritization of gaps identified in the situational and SWOT analyses. The goals and objectives for the c-PMDT operational plan should be consistent with the strategic MDR TB and TB core and budgeting plans.

Who: The activities that are selected need to be linked to a stakeholder (partner, service, organization) responsible for its implementation. Roles and responsibilities for each stakeholders/partner need to be defined based upon their availability. Since the community PMDT strategy will impact each of the health system building blocks, different stakeholders will be responsible for different activities and will work together to ultimately achieve success.

Where: In addition to selecting activities, the planning team will decide on the location in which these activities will be carried out. For example, the team will decide on the location of a new unit of Gene Xpert assay after considering optimal modes of transportation (distance, roads), the number of health facilities that can be served, and the volume of patients (outpatient loads) that can be reached.

When: A chronogram for the implementation of activities should be prepared in consideration of responsible partners, timing, and geographic area.

Resources and Unmet Needs

We should include information regarding to:

- Planned costs that will be needed to implement plan activities
- Available resources
- Unmet needs and ways to fill these gaps

Table 14. Activity schedule for partners implementing c-PMDT strategy

WHAT: Activities	WHO: Responsible party /partner	WHERE: District, location	WHEN: Year 1				WHEN: Year 2			
			Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1.Strategic intervention: Supervision	Partner A	Location A								
1.1 Activity	Partner B	Location B								
1.2 Activity	Partner A									
1.3 Activity										
2. Strategic intervention: Training										
2.1 Activity										
2.2 Activity										

Table 15. Resources and needs schedule

WHAT: Activities	Resources				Unmet Needs	
	Available		Needed			
	Human	Financial	Human	Financial	Human	Financial
1.Strategic intervention: Supervision						
1.1 Activity						
1.2 Activity						
1.3 Activity						
2. Strategic intervention: Training						
2.1 Activity						
2.2 Activity						

5. Develop a Monitoring and Evaluation Plan

The c-PMDT M& E plan should be an integral part of the PMDT M&E activities, and should not duplicate indicators which are already in PMDT plan. Any new indicator included for the C-PMDT strategy should be consistent with the goals and strategic objectives specified in the strategic TB and MDR TB country plan. The strategic objectives are usually long term objectives that respond to a broader vision of the strategy and align with key strengths and weaknesses of the strategy. Strategic interventions and activities refer to shorter and more defined benchmarks that support the achievement of the program strategic objectives.

Indicators selected for monitoring the activities should be SMART: Specific, Measurable, Available, Relevant and Time-bound.

M&E Logical Framework

Table 16. M&E logical framework

What c-PMDT program intends to do	*Measurement of program's effect and resources used*		*Expected results*
Goal	**Impact indicators**	**Illustrative indicators**	**Targets**
Responds to the program's vision and mission	Will provide information for the overall long term effects of the c- MDR TB program		
Strategic Objective	**Outcome indicators**	**Illustrative indicators**	**Targets**
The change expected to occur (increase the number of MDR patients detected or put on MDR treatment) that contribute to the achievement of the goal	Will provide information on strategic short term and medium term effects of the c-MDR TB program	• %Laboratory-confirmed MDR-TB patients successfully treated (cured plus completed treatment) • %Detect MDR among TB cases (key outcome indicator) • % cured, completed, died, failed, defaulted, transferred according to patients treatment history	100% of laboratory confirmed MDR-TB patients will start treatment (23) >75% of patients with confirmed MDR-TB are successfully treated (23)
Strategic Intervention	**Output Indicators**	**Illustrative indicators**	**Targets**
Deliverables of the project	Indicators that ensure results from the completion of activities	• New and re-treatment TB patients receiving diagnostic DST for MDR-TB (number and percentage) • Number and percentage of sputum smear positive TB patients confirmed as MDR among all new and retreatment patients. • Laboratory-confirmed MDR-TB patients enrolled on SLD treatment (number and percentage) • Percentage of MDR-TB cases initiated on a second-line anti-TB treatment who have a negative culture at the end of 6 months of treatment • Percentage of MDR-TB cases registered and started on MDR-TB treatment who were identified as XDR TB	> 50% of MDR-TB estimated cases will be detected and notified (23)
Activities	**Process Indicators**	**Illustrative indicators**	**Targets**
Work tasks to be performed	Indicators that ensure the short term operationalization of the activities	Included in the c-PMDT planning matrix- Annex A-	

6. Technical Assistance Plan

Should be based on the operational plan and refer to the implementation of any activities expected to require some type of technical assistance. For activities highlighted as requiring technical assistance, it is advisable to include the following:

- **Task:** Brief description of the activity and type of TA that will be required (national, international, training, scope, etc.)
- **Estimated cost:** estimated cost of the TA, available funds and funding sources and unmet funding
- **Available funding & source:** NTP, GF grants, partner budgets, etc. for this activity?
- **Timeframe:** crucial to secure funding and best consultants

To obtain detailed information on how to develop a country TA plan you can visit the WHO TB TEAM web site that provides a means for tracking planned technical assistance missions and for countries to request support where needed.

TB TEAM, is a global coalition of partners and countries. It facilitates identification of TB technical assistance needs at country level and coordination of partners who provide technical assistance to countries. Support is provided to countries on all aspects of planning for and implementing the Stop TB Strategy and on accessing and implementing Global Fund grants (11). For help in identifying the relevant TBTEAM focal point, you may visit the website or contact the TBTEAM secretariat at central level: tbteam@who.int.

Technical assistance and monitoring activities will increasingly be decentralized to the regional and country levels. To further this aim, countries will be encouraged to develop their own national (or sub-national) technical assistance centers (TACs) also called **MDR TB Centers of Excellence (COE)** to guide and support nationwide scale-up of c-PMDT (24).

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ANNEX A. C-PMDT Planning Matrix

Strategic Objective 1: High quality of TB service Delivery

Building Block: HEALTH SYSTEM DELIVERY			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
1.1 Distribution of DR TB services	1.1.1	Assessment developed in public sector at every level (central, province, district), community, private sector, urban-rural areas, special group (prison, refugees, ethnic minorities, slum, working place etc.)		Yes			
	1.1.2	Mapping of: • DRTB diagnosis services/providers (X-ray, MO, LPA, culture DST, Xpert) • Mapping of DRTB treatment services/providers (initiation, satellite, hospitalization, out-patient) • Mapping of DRTB supporters at the community		Yes			
	1.1.3	Assessment of health facilities readiness at the district and community level with capability to: • Initiate MDR treatment • to follow up (satellite) MDR treatment					
1.2 Quality assured laboratories for DR TB in the district	3.2.1	Laboratories showing adequate performance in external quality assurance (EQA)e for: • smear microscopy, • culture • drug susceptibility testing				Laboratories with adequate EQA performance in the district (#,%)	
	3.2.2	Laboratory turnaround time (TAT)(time to report to the facilities results of the DST)					
	3.2.3	Gene-Xpert		≥ 90%		% of confirmed Xpert RIF positive have a DST result for Fluoroquinolones and a second line injectable drug	
1.3 DR TB case finding	1.3.1	DR TB active case finding: • Among people living with AIDS • Among DR TB contacts		Yes			
	1.3.2	DR TB diagnostic protocols					
	1.3.3	DST is performed on specimens obtained at start of re-treatment for all previously treated cases (whether their current treatment has failed, or they are returning after relapse or default).		100% of previously treated cases are tested for drug resistance		% of previously treated cases tested for drug resistance	
	1.3.4	DST is obtained at the start of the treatment for all new patients		20% of new TB cases are tested for drug resistance		% of new TB cases tested for drug resistance	
	1.3..5	Xpert MTB/RIF: If resistance is detected to Rifampicin, then susceptibility testing is performed for Isoniazid and other first-line drugs, as well as fluoroquinolones and second -line injectable agents most often used in the country		≥ 90% of confirmed Xpert RIF positive have a DST result for Fluoroquinolones and a second line injectable drug		% of confirmed Xpert-RIF positive have a DST result for Fluoroquinolones and a second line injectable drug	

Strategic Objective 1: High quality of TB service delivery *continued*

Building Block: HEALTH SYSTEM DELIVERY			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
1.4 Referrals and coordination	1.4.1	Protocols for coordinated referrals from hospital to the community (clinic/household) and from household/clinic to the hospital		Yes			
	1.4.2	Discharge from the hospital coordinated with community coordinator (nurse) (location, transportation , medication package)		Yes			
	1.4.3	Communication equipment, maintenance and supplies at every level (internet, mobile phone, telephone)		Yes			
	1.4.4	Hotline (24H) for DR TB patients and DR DOT supporters		Yes			
	1.4.5	Sputum transportation system in place for diagnosis of contacts and follow up		Yes			
	1.4.6	Follow up after completion of treatment with sputum culture every month for six months, and thereafter every three months for one year					
1.5 Infection Control	1.5.1	Protocols for community DR DOTS supporters for infection control and prevention and regular TB screening and HCT.				Ratio: Notification rate (all forms) in health care staff (including DOT supporter) over the TB notification rate in general population adjusted for age & sex.	
	1.5.2	Protective preventive equipment provided to facility staff and DR TB Supporters		Yes			
	1.5.3	Policy for protection of staff and DR DOT supporters that become infected with DR TB (occupational health regulation enabled)					
	1.54	Education for IC at the household and congregated settings		Yes			
1.6 Integration of DR TB and other comorbidities(HIV, Diabetes, etc.)	1.6.1	MDR-TB patients know their HIV status.		100% of TB patients know their HIV status		% Registered TB and DR TB patients with documented HIV-positive	
	1.6.2	DR-TB and Anti-retroviral Treatment (ART) treatment initiation out-patient				% HIV-positive TB and DR patients who start on or continue ARV in the community	
	1.6.3	Cotrimoxazole Preventive Therapy (CPT) initiation				% HIV-positive TB patients who receive at least one dose of CPT during TB treatment	
	1.6.4	Coordination of laboratory tests and facility visits for DR TB with other diseases					

Strategic Objective 1: High quality of TB service delivery *continued*

Building Block: HEALTH SYSTEM DELIVERY			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
1.7 Risk of default	1.7.1	DR TB Risk of default assessment: considering side effects, socio-economic situation, DR TB supporter relationship, addictions and other specific situations		Yes			
	1.7.2	ART risk of default assessment integrated: Noncompliance with DR TB, ARV, other treatments		Yes			
	1.7.3	Default tracing system (TB, MDR-TB, ART, CPT, IPT)		Yes			
	1.7.4	DR-TB Supporter trained (curriculum and assessment tools)in regularly identifying potential side effects		Yes			
	1.7.5	HCW (community nurse) monitor and manage side effects following pre-established protocols and coordinates patient transfer to the hospital if severe side effects		Yes			
	1.7.6	Algorithms, ancillary drugs, and other therapies are available to the clinic, community nurse, and DRTB supporter to manage side effects to MDR-TB treatment		Yes			
1.8 Patient support	1.8.1	System enabled to provide DR TB patients with food packages, transport vouchers				% DR TB Patients receiving incentives or enablers among all registered DR TB patients	
	1.8.2	Rented housing near the hospital or clinic for those patients that live in remote areas				% DR TB qualify for rented housing support	
	1.8,3	Educational/vocational support and income generating activities (sewing circles, gardening, raising chickens or pigs, operating phones, etc.) activities for DR TB patients until they can return to work		Yes			
	1.8.4	Psychosocial support and counseling at the community/household for DR TB patients		Yes			
	1.8.5	Support groups: Facilitate the creation of support groups for MDR-TB that meet regularly. Should be guided by a counselor trained in facilitating support groups. Some may require a facilitator with psychiatric training to deal with serious psychosocial issues		Yes			
	1.8.6	ACSM/Communication. Organize awareness-raising activities for targeted vulnerable populations informing them about availability of incentives/enablers and eligibility criteria		Yes			
1.9 Incentives and enablers	1.9.1	System of incentives for : • DR DOT supporters • DR TB providers (doctors/nurses) • DR patients		Yes		% DR TB patients, DOT supporters, DOT providers receiving incentives among all registered DRTB patients / supporters/ providers	

Strategic Objective 1: High quality of TB service delivery *continued*

Building Block: HEALTH SYSTEM DELIVERY			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
1.10 Supervision	1.10.1	Treatment support and supervision including use of m-health strategies					
	1.10.2	Procurement, redistribution of SLD					
	1.10.3	Reimbursements and performance based incentives					
1.11 Community involvement	1.11.1	Involvement of community leaders to address community-wide issues such as stigma towards DR-TB patients					
	1.11.2	Involvement of religious leaders to provide with TB and MDR messages and reduce stigma and discrimination among TB and MDR patients					
	1.11.3	Involvement of volunteer workers from other programs to deliver DOTs at the community level					
	1.11.4	Involvement of private doctors to identify and referred MDR patients for diagnosis					

Strategic Objective 2: Improvement of Health Information System for PMDT

Building Block (BB-2): INFORMATION SYSTEM			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
2.1 Recording and reporting	2.1.1	Registration of trained DR-TB supporters.				# DOT supporters trained per village/functional area	
	2.1.2	Referral coordinated and recorded. Hospital discharge summary with treatment recommendations				#, % referrals coordinated according to protocols	
	2.1.3	A hospital discharge summary (form) should be provided to the community nurse with clinical and treatment recommendations				#,% DR TB patients with hospital discharge summary	
	2.1.4	Centralized appointment calendar for DR TB visits		Yes			
	2.1.5	Tracking data for side effects and complications		Yes			
2.2 Surveillance System	2.2.1	Electronic Reporting System. Standardized recording and reporting for MDR-TB case registration and treatment outcome fully implemented at district level with ongoing functional surveillance system implemented (contacts, HIV, others)		>90%		% Reporting units at all levels of data flow submitting timely reports according to national guidelines (number and percentage). Average TB recording and reporting quality rate on case registration or treatment outcome for a sample of audited in the district	
	2.2.2	Drug-resistant survey data updated in the district					
2.3 Data analysis	2.3.1	Data analyzed in a timely manner for management purposes: Review of data management system: consultative meeting with NTP staff and experts in M&E • Training of health staff at Sub-national level (e.g. district) to use the system • Development of recording and reporting forms • Purchase, adaptation or development of software/web system for data management • Recruit staff for data management and analysis, data entry at regional level • Technical assistance		Yes		#,% MDR suspects that have lab results in a specified time #,% integration DR TB and HIV registers	

Strategic Objective 3: Improve the availability of medical products and technology

BUILDING BLOCK: MEDICINES AND TECHNOLOGIES			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
3.1 Drug management	3.1.1	**Drug Forecast.** Including buffer stock for 1st and 2nd lines drugs updated. Procurement and supply management plan				Units (districts or BMUs) reporting no stock out of SLD anti-TB drugs on the last day of the quarter (number and percentage)	
	3.1.2	**Drug Procurement.** • SLD • Cotrimoxazole Preventive Therapy (CPT) • Anti-retroviral Treatment • Ancillary drugs for side effects management					
	3.1.3	**Drug Storage.** Sufficient capacity for district drugs storage					
	3.1.4	**Drug Distribution and Redistribution.** • Drug distribution to treatment sites and peripheral level • information system functioning that enables SLD redistribution among districts • Stock management practices (transportation, space, shelving, climate control, electronic/ manual stock control system • Pharmacy staff will pack the prescribed regimen, a 30 day supply in approved and sealable bags • All extra drugs not used are being returned back to the central pharmacy by the community team					
	3.1.5	**Drug Transportation of SLD in optimum conditions (cold chain).** • Establish appropriate delivery schedules and modes of transportation					
3.2 Quality assured laboratories for DR TB in the district	3.2.1	Laboratories showing adequate performance in external quality assurance (EQA)e for: • smear microscopy, • culture • drug susceptibility testing				Laboratories with adequate EQA performance in the district (#,%)	
	3.2.2	Laboratory turnaround time (TAT)(time to report to the facilities results of the DST)					
	3.2.3	Gene-Xpert		≥ 90%		% of confirmed Xpert RIF positive have a DST result for Fluoroquinolones and a second line injectable drug	
3.3 Community resources	3.3.1	Material resources (infrastructure, information and essential commodities, including medical and other products and technologies);					

Strategic Objective 4: Strengthen leadership and governance for PMDT

BUILDING BLOCK (BB4) : LEADERSHIP AND GOVERNANCE			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
4.1 Policy guidance	4.1.1	NTP has a written policy for where MDR patients will be referred for treatment : at the community or facility level and personnel responsible for providing the treatment		Yes			
	4.1.2	Establish and extend inclusion of all TB and DR TB services in the social welfare coverage support		Yes			
	4.1.3	Regulatory framework to enable new certification programs					
4.2 CPMDT planning and management	4.2.1	PMDT district planning committee established		Yes			
	4.2.2	Regional/District TB coordinator to supervise TB and MDR-TB diagnosis and treatment and coordinates efforts between the community, local governments and international agencies		Yes			
	4.2.3	c PMDT implementation budget for district available				# (%) of funds budgeted by the government for C-PMDT out of the total TB health budget	
	4.2.4	Stakeholder's involvement including civil society organizations, NGO and FBO and private business. Increased awareness, knowledge about DR TB and involvement among community organizations and opinion leaders		Yes			
	4.2.5	Partner with a PMDT center of excellence for Technical guidance, training, programmatic support, DR diagnostic and referral of complicated cases		Yes			
4.3 Guidelines	4.3.1	DR TB suspect case definition, protocols for DR testing developed.					
	4.3.2	Empirical Treatment regimen available to specific group of patients while waiting for DST results					
	4.3.3	Guidelines for decentralized PMDT: • Guidelines to conduct MDR contact tracing at the community level, including children • Guidelines for management of side effects at the community level and referral protocols • Guidelines for default assessment and management in the community. Involvement of community organizations and leaders • Sputum collection and transportation guidelines • Guidelines for TB Infection Control (facility and congregational settings) • Decentralized SLD procurement , storage and distribution guidelines		Yes		• Health facilities with contact investigation activities (#,%) • Samples recorded and tracked (#,%) • Health facilities with infection control activities (#,%)	

Strategic Objective 4: Strengthen leadership and governance for PMDT continued

BUILDING BLOCK (BB4) : LEADERSHIP AND GOVERNANCE			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
4.4 Supervision	4.4.1	Supervisory mechanism established: • Supervision from Intermediate level (laboratory, care, community, private sector, specific) • Supervision from peripheral level (care, community, private sector, specific) • Transportation • Incentives/enablers • Use of standards checklist for supervision for the different areas of work (DOTS, labs, MDR treatment, DR DOTs supporters, etc.)		Yes		• Supportive supervision visits conducted • Supervisory visits performed with documented feedback reports/out of planned visits during a specified period (#, %)	
	4.4.2	DOT supporter incentives and health personnel linked to performance		Yes		DOT supporters receiving incentives based on performance (#,%)	
4.5 Community workforce/ networks	7.2.1	Identify civil society stakeholders (NGOs, CSOs, FBOs, etc.) who are already involved in TB- (or health-) related activities at community level,					
	7.2.2	adequate coordination of activities related to TB control among different stakeholders					

Strategic Objective 5: Human Resources Development

BUILDING BLOCK (BB 5): HUMAN RESOURCES DEVELOPMENT			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
5.1 Staffing	5.1.1	HR assessment requirement/vacancies for clinical staff, DOT supporters, lab technicians, pharmacists, managers…				# (%) of health facilities with at least one health worker trained on DR TB out of all staff # (%) of posts filled according to HRD plan	
	5.1.2	Updating and listing of functions and tasks by level and by professional category, covering all components of the Stop TB strategy					
	5.1.3	Registration (pool) of trained DR TB supporters updated regularly					
5.2 HR system management	5.2.1	Development/revision of job descriptions for staff involved in DR TB control					
	5.2.2	Incentive-retention package for rural postings					
	5.2.3	Capacity development technical and supervisory					
	5.2.4	Compensation: occupational health issues					
	5.2.5	New certification programs to improve MDR skills (nurses initiating MDR treatment, DOTS supporter providing injections…)		Yes			
5.3 Training	5.3.1	MDR training of staff (training and continued education), TB-HIV, ACSM, monitoring and evaluation (by level, by technical area and by staff category as per job descriptions)				• % of training material developed as scheduled • % of all health care units Trained	
	5.3.2	Training plan for DR TB supporter. Additional training on Injections.				• % of new staff recruited as scheduled	
	5.3.3	Training on laboratory and diagnosis management				• % of training courses organized as scheduled	
	5.3.4	Training on program management–supervision				• % of all laboratories Trained • % of supervisory visits for HRD accomplished	
	5.3.5	Training on monitoring and evaluation					
	5.3.6	Training on HRD management					
	5.3.7	Technical assistance plan developed: • Country-based staff long term and short term national TA • International missions long term and short term external TA					

Strategic Objective 6: Budget and financial mechanisms

BUILDING BLOCK (BB 6): FINANCING			Gap Assessment			Performance	Budget
Strategic Interventions	Activities		Actual	Target	Gap	Indicators	
6.1 Budget	6.1.1	Establish and extend inclusion of all TB services in the social welfare coverage support, DR TB diagnostic services free of charge. (FLD, SLD free of charge, diagnostic, follow up and side effects lab free of charge, Ancillary medication for side effects and complications free of care)					
	6.1.2	Establish and extend inclusion of all TB services in the private social welfare coverage support					
	6.1.3	Patient support: Food support, transportation, housing support, etc.					
	6.1.4	Incentives and enablers (patient, DOT supporter, providers..)					
	6.1.5	Budget programmatic activities for decentralization of MDR services at the community					
6.2 Financing	6.2.1	Secure financing mechanism at the district level				% of MDR-TB budget funded by domestic sources	
6.3 Community resources	6.3.1	Material resources (infrastructure, information and essential commodities)					

ANNEX B. Prices in USD for Second-Line Drugs

Prices in USD for second-line anti-TB drugs through the WHO Green Light Committee mechanism

Drugs	Type	Dosage / form	Pack size (no. units/pack)	Cost per pack (USD)	Cost per unit (USD)	Manufacturer
Amikacin	Injectable	500mg/2ml inj	100	$ 15.09	$ 0.15	Bayer
Capreomycin	Injectable	1 gr vial	1	$ 3.21	$ 3.21	Eli Lilly
Cycloserin	Oral tablet	250 mg tab	100	$ 50.96	$ 0.51	Macleods
Ethionamide	Oral tablet	250 mg tab	100	$ 10.21	$ 0.10	Macleods
Kanamycin	Injectable	1 gr vial	50	$ 26.36	$ 0.53	Panpharma
Levofloxacin	Oral tablet	250 mg tab	100	$ 5.20	$ 0.05	Macleods
Moxifloxacin	Oral tablet	400 mg	5	$ 29.65	$ 5.93	Bayer
Ofloxacine	Oral tablet	200 mg cap	100	$ 3.49	$ 0.03	Macleods
PASER	Sachet	4 gr sachets	30	$ 59.09	$ 1.97	Jacobus
Prothionamide	Oral tablet	250 mg tab	100	$ 16.20	$ 0.16	Fatol

ANNEX C. Estimation of Screening Costs

Rationale estimation of MDR monitoring costs

Assumptions were made for 8 months of injectable and 24 months total treatment duration. It was assumed that patients didn't suffer from complications during the treatment.

		Treatment follow up			Screen side effects					Screen HIV
Month	Clinical visit	Smear	Culture	DST	Liver function	Renal function	Full blood count	TSH	Audiometry	HIV
Baseline	Every 2 weeks	x	x	x	x	x	x	x	x	x
1		x		x	x	x	x		x	
2		x			x	x		x	x	
3		x	x		x	x			x	
4	Monthly	x				x			x	
5		x				x			x	
6		x	x	(x)		x	x	x	x	
7		x				x			x	
8		x				x			x	
9		x	x							
10		x								
11		x								
12		x	x					x		
12-24 months		Monthly	Every three moths	when bac-teriological required				if clinically required		
Number	28	24	8	5	3	8	2	3	8	1
Cost per test										
Total										