



**Government of Malawi  
Ministry of Health**

**Malawi National Tuberculosis  
Control Programme**

**A GUIDE FOR  
COMMUNITY-BASED  
CARE FOR  
DRUG-RESISTANT  
TUBERCULOSIS**



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This manual was developed in collaboration with the TB CARE II project and is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents of this manual are the sole responsibility of the National TB Control Programme and do not necessarily reflect the views of USAID or the United States Government.

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## Preface

Management of multidrug-resistant TB (MDR-TB) has become a major public health problem and a challenge to effective TB control. Pathogens have almost invariably developed resistance to the drugs used to kill them. The National TB Programme in Malawi has been able to detect incident MDR-TB cases from the routine surveillance of previously treated smear-positive TB cases. These have been confirmed by a supranational laboratory in South Africa.

Use of second-line anti-TB drugs in Malawi only started in September 2007 using a community-based approach, having adapted the WHO 2006 generic *Guidelines for the Programmatic Management of MDR-TB*.

These community-based guidelines have been developed to assist health workers at health facility levels and are intended for use by all health care providers and allied health workers in Malawi. These guidelines will be updated as new evidence emerges. Correct management of MDR-TB cases is critical in order to avoid the development of extremely drug-resistant (XDR) strains of TB.

The Ministry of Health believes in a knowledgeable health workforce and in this regard every effort will be made to disseminate new information to health care providers so that they are abreast with latest information on MDR-TB management.

The user of these guidelines is encouraged to refer to the appropriate chapters for a specific problem and it is hoped that by using these guidelines health workers shall be effectively engaged in community-based management of the fight against multi-drug resistant tuberculosis in Malawi.

**Rt. Hon. Khumbo Kachali**

Vice President and Minister of Health

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## Acknowledgements

The Ministry of Health appreciates the efforts of the collaborative writing group responsible for developing this document. The contributions of the following authors and editing team members are especially acknowledged: N. Mphasa, S. Chirwa, M. Khomba, M. Magugu, B. Tembo, A. Makwakwa, Dr. K. Mbendera, F. Nyakwawa, Dr. J. Mpunga, R. Banda, I. Dambe, H. Banda, Dr. D. Nyangulu, L. Mlauzi, C. Kang'ombe, I. Nyasulu, A. Dimba, J. Kwanjana, M. Kamiza, R. Kandulu, W. Mtoga, M. Chisutu, F. Sindani, M. Kalulu, M. Kaponya, C. Kamba, B. Banda, G. Samuti, Dr. R. Banda, Dr. M. Rich, and Dr. M. Herce.

The Ministry would like to thank the USAID TB CARE II project and World Health Organisation (WHO) for their financial and technical assistance in the development and printing of these guidelines. The Ministry would also like to acknowledge the technical assistance offered by Partners In Health (PIH).

### **Dr. Charles C. V. Mwansambo**

Principal Secretary

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## Source Documents

This Guide has largely been adapted from:

- *Community-based Care for Drug-resistant Tuberculosis: A Guide for Implementers.* USAID 2011

And from the following source documents and guidelines:

- *Guidelines on the programmatic management of drug-resistant tuberculosis: Emergency update 2008.* WHO/HTM/TB/2008.402
- *Guidelines on the programmatic management of drug-resistant tuberculosis: 2011 Update.* WHO/HTM/TB/2011.6
- *Programmatic Management of Multidrug-Resistant Tuberculosis in Malawi.* Government of Malawi 2012
- *Management of MDR-TB: A field guide.* WHO/HTM/TB/2008.402
- *The PIH Guide to the Medical Management of Multidrug-Resistant Tuberculosis: International Edition.* Partners In Health 2003

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## Abbreviations

<b>AFB</b>	Acid-fast bacilli
<b>AIDS</b>	Acquired immune deficiency syndrome
<b>ART</b>	Antiretroviral therapy
<b>CO</b>	Clinical Officer
<b>c-PMDT</b>	Community-based programmatic management of DR-TB
<b>CPC</b>	Cetylpyridinium chloride
<b>CPT</b>	Cotrimoxazole therapy
<b>DOT</b>	Directly observed treatment
<b>DST</b>	Drug susceptibility testing
<b>DRS</b>	Drug resistance survey
<b>DR-TB</b>	Drug-resistant tuberculosis
<b>DTO</b>	District TB Officer
<b>HIV</b>	Human immunodeficiency virus
<b>HSA</b>	Health Surveillance Assistant
<b>HTC</b>	HIV testing and counselling
<b>IC</b>	Infection control
<b>MDR-TB</b>	Multidrug-resistant tuberculosis
<b>NGO</b>	Nongovernmental organisation
<b>NTP</b>	National Tuberculosis Control Programme
<b>NTRL</b>	National Tuberculosis Reference Laboratory
<b>PAS</b>	P-aminosalicylic acid
<b>PIH</b>	Partners In Health
<b>TB</b>	Tuberculosis
<b>USAID</b>	United States Agency for International Development
<b>WHO</b>	World Health Organisation
<b>XDR-TB</b>	Extensively drug-resistant tuberculosis

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## Table of Contents

PREFACE	3
ACKNOWLEDGEMENTS	4
1. INTRODUCTION	9
2. COMMUNITY-BASED CARE	11
3. COMMUNITY-BASED CARE MODEL	12
3.1. Roles and responsibilities of the Outpatient MDR-TB Team	12
3.2. Responsibilities of the Focal DR-TB Nurse	17
3.3. Duties of the Focal DR-TB Nurse in the outpatient clinic	18
3.4. Linkages and integrated care for MDR-TB patients	19
3.5. Communication channels	20
3.6. Patient appointment and review system	21
3.7. TB infection control in the community	22
3.8. Caring for caregivers	23
4. DR-TB DOT SUPPORTERS	24
4.1. Profile of a DR-TB DOT Supporter	24
4.2. Identification of DR-TB DOT Supporter	26
4.3. Tools for the DR-TB DOT Supporter	26
4.4. Initial training of DR-TB DOT Supporters	27
4.5. Performance-based incentives	28
4.6. Monthly performance evaluation	29
4.7. Monitoring DR-TB DOT Supporters	30
4.8. The DOT Book	30
5. SOCIAL SUPPORT	34
5.1. Home assessment	34
5.2. Food packages and direct patient support	36
5.3. Transportation	37
5.4. Temporary housing	37
5.5. Work	38

6.	<b>ADHERENCE SUPPORT</b>	<b>39</b>
6.1.	Directly Observed Treatment (DOT)	39
6.2.	Recognising side effects and monitoring response to treatment	40
6.3.	Support groups	41
6.4.	Preventing default	41
7.	<b>SUPPLY CHAIN MANAGEMENT</b>	<b>43</b>
7.1.	Centralised control of second-line TB drugs	43
7.2.	Standardised prescription form	44
7.3.	Ordering second-line TB drugs	45
7.4.	Items often forgotten	45
7.5.	Storage conditions in the community	46
8.	<b>COMMON LABORATORY ISSUES</b>	<b>47</b>
8.1.	Transportation of specimens	47
8.2.	Diagnosing and keeping track of MDR-TB suspects	47
8.3.	Monitoring cultures	48
8.4.	Blood tests for side effect screening	49
9.	<b>CONTINUITY OF CARE</b>	<b>50</b>
9.1.	Indications for hospitalisation at start of treatment	50
9.2.	Indications for a patient on community-based care to be hospitalised	51
9.3.	Discharge from the hospital	51
9.4.	Follow-up after completion of treatment	52
9.5.	Additional considerations	52
10.	<b>CONTACT TRACING</b>	<b>53</b>
11.	<b>RECORDING AND REPORTING</b>	<b>54</b>
11.1.	Treatment card for patients receiving second-line TB drugs	54
11.2.	Quarterly report of community-based activities by the Outpatient MDR-TB Team	55
11.3.	Transfer form	57
12.	<b>FREQUENTLY ASKED QUESTIONS</b>	<b>58</b>



# INTRODUCTION

The term drug-resistant tuberculosis (DR-TB) means that one or more of the anti-TB drugs used in treatment is no longer effective in killing the bacteria that causes tuberculosis (TB). By definition, there are four different categories of drug resistance, namely:

- **Monoresistance:** resistance to one anti-TB drug.
- **Polyresistance:** resistance to more than one anti-TB drug, other than both isoniazid and rifampicin.
- **Multidrug resistance (MDR):** resistance to at least isoniazid and rifampicin, the two most potent anti-tuberculosis agents.
- **Extensive drug resistance (XDR):** resistance to any fluoroquinolone, and at least one of three injectable second-line drugs (capreomycin, kanamycin, or amikacin), in addition to multidrug resistance.

The emergence of resistance to anti-TB drugs has become a significant public health problem in a number of countries and an obstacle to effective TB control globally. While exact numbers of MDR-TB cases in Malawi are not known, there are hundreds of cases each year that require MDR-TB treatment. In the drug resistance survey that was conducted in Malawi in 2010, results indicated that prevalence of MDR-TB was 0.4% among new smear-positive cases and 4% among previously treated patients. In 2007, the Malawi National Tuberculosis Programme (NTP) started a programme to treat MDR-TB.

Community-based care means that the patient receives the treatment in the community. The directly observed treatment (DOT) can take place in the home. Community-based care is a form of outpatient care and the follow up of treatment, whether or not the DOT is home-based, and is overseen by a well-trained outpatient team. The World Health Organisation (WHO) recommends an ambulatory or outpatient care model for MDR-TB, of which a community-based approach with home-based DOT is a recommended model.

There are a number of benefits to managing MDR-TB using a community-based care approach, including:

- 1.** Overall costs of treatment are lower;
- 2.** Fewer nosocomial infections occur;
- 3.** Decreased hardship on patients due to being away from home and family; and
- 4.** Daily support from family members is possible.

In this Guide, the programme that uses a community-based approach and a strong outpatient team based at a clinic to care for patients with DR-TB is referred to as the “community-based programmatic management of DR-TB” (c-PMDT). The health worker providing DOT and daily treatment support is referred to as the “DR-TB DOT Supporter”.

Placing patients on adequate MDR-TB therapy as early as possible in their disease reduces transmission of MDR-TB. Early treatment improves outcomes since a cure is more easily achieved when a patient has less lung damage. Even though transmission decreases with treatment, it is still important to have infection control measures for home-based care, which are described in this Guide (see Section 3.7).

While most patients can be treated in the community, there will be complicated patients and cases that should be managed in hospital. This guide also helps you to determine which patients should receive hospital care and when you should refer outpatients for evaluation and treatment of complications.

In summary, this booklet provides practical, step-by-step guidance on how to organise, implement, and monitor community-based care for MDR-TB, which includes regular follow up in an outpatient clinic trained in the management of DR-TB. Its principal audience is the outpatient team of health care workers that will follow and care for patients with MDR-TB. It is equally useful for programme planning and supervision at the NTP level. This Guide does not replace other guidelines and documents that contain important medical information, such as Malawi NTP’s *Guidelines for the Programmatic Management of Drug-resistant TB* (June 2012 Revision).

# COMMUNITY-BASED CARE

Community-based care allows patients to receive DR-TB treatment in their own communities. This addresses one of the most serious barriers to adherence, the inconvenience of directly observed treatment (DOT). Receiving treatment at home is more convenient for patients than travelling to a clinic each day.

The patient is fully supervised by trained community supporters. Community-based care is NOT self-administered. Each dose must be administered under DOT. Community-based care reduces costs in the health system and can be more cost-effective than hospital care, but in many ways it is more challenging to implement.

A system of community-based care needs to be developed to support patients when they are ready to return home, even in those settings where initial treatment is delivered in hospital.

This approach places the community patients at the centre of the response to MDR-TB, which in turn can be a powerful force in changing attitudes and social norms regarding TB patients.

This type of management uses a well-organised outpatient team trained in management and treatment of MDR-TB to follow patients in the community.

# COMMUNITY-BASED CARE MODEL

The community-based outpatient model of care does not just include treatment support in the form of medicines. All three types of support—clinical care, socioeconomic support, and psycho-emotional support—should be included in community-based care. This section looks at all the components of community-based care.

## 3.1. Roles and responsibilities of the Outpatient MDR-TB Team

The Malawi National TB Programme (NTP) has adopted a strategy of community-based and outpatient ambulatory care of patients with MDR-TB, incorporated into the overall TB management strategy. Each level of management—central, health facility, and community—has specified workers with assigned roles.

The programme will begin with four outpatient **DR-TB Referral Clinics** (one in each Zone). The four outpatient DR-TB Referral Clinics will supervise the care of all outpatient MDR-TB patients. Eventually a similar MDR-TB team could be in each district, each of which would be supervised by the DR-TB Referral Clinic.

The **Outpatient MDR-TB Team** consists of:

- One Clinician Team Leader
- One Clinician
- One Focal DR-TB Nurse
- One Cashier
- One Zonal/District TB Officer (or Assistant District TB Officer)
- One Laboratory Technician
- One Pharmacy Technician

In DR-TB Referral Clinics where there is a high patient load, a permanent TB nurse position focussed full-time on MDR-TB care will be put in place. High patient load is considered as more than 10 patients at a time. Some DR-TB Referral Clinics may also need a full-time DR-TB Nurse. Where patient load is low, it is the regular TB team that should carve out time for MDR-TB patients and care for them under the protocols described in this book. For example, the Focal TB Nurse in a district with low patient load would take on the duties of the Focal DR-TB Nurse.

Roles of each member of the Outpatient MDR-TB Team members are described in this chapter. The Outpatient MDR-TB Team supervises the DR-TB Supporter, the health worker providing the directly observed treatment.

There are many other personnel that supervise and/or support the referral Outpatient MDR-TB Teams at all levels: national, facility (zonal or district), and community. The tables below describe the roles and responsibilities at each level.

As stated above, the Outpatient MDR-TB Team will be located in referral hospitals at the zonal level and later there will be one at each district hospital.

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## **Roles and responsibilities in the three levels of care**

### **AT THE NATIONAL LEVEL:**

<b>ROLE</b>	<b>SPECIFIC RESPONSIBILITIES</b>
<b>NTP Manager</b>	<ul style="list-style-type: none"> <li>Establishes norms and procedures for the diagnosis, treatment and prevention of MDR-TB.</li> </ul>
<b>NTP Focal Person for MDR-TB</b>	<ul style="list-style-type: none"> <li>Drug management and logistics;</li> <li>Plans, assesses needs, monitors, and evaluates the programme;</li> <li>Keeps a central registry of all patients diagnosed with MDR-TB and all patients on treatment;</li> <li>Oversees the plan for all training, and participates in training.</li> </ul>
<b>NTP Monitoring and Evaluation (M&amp;E) Officer</b>	<ul style="list-style-type: none"> <li>Evaluates how c-PMDT is functioning.</li> </ul>
<b>Central Reference Laboratory Manager</b>	<ul style="list-style-type: none"> <li>Manages all diagnostic and monitoring tests.</li> </ul>

## AT THE FACILITY (ZONAL OR DISTRICT) LEVEL:

ROLE	SPECIFIC RESPONSIBILITIES
<b>Zonal TB Officer or District TB Officer (DTO)</b>	<ul style="list-style-type: none"><li>• Coordinates with the national level and other institutions, e.g., NGOs and patient support systems;</li><li>• Acts as the overall coordinator of all community-based and outpatient MDR-TB activities;</li><li>• Integrates MDR-TB with other services, e.g., TB, HIV, and maternal services;</li><li>• Supports the organisation and coordination of the Outpatient MDR-TB Team(s) and regularly provides supervision;</li><li>• Supports monitoring and evaluation;</li><li>• Manages all diagnostic and monitoring tests at the zonal or district level.</li></ul>
<b>Central Reference Laboratory Manager</b>	<ul style="list-style-type: none"><li>• Responsible for the diagnosis and monitoring tests for patients from districts.</li></ul>
<b>MDR-TB Clinician</b>	<ul style="list-style-type: none"><li>• Acts as Team Leader (if there is more than one clinician on the team, one is designated as such);</li><li>• Identifies MDR-TB suspects;</li><li>• Conducts pre-treatment assessment and initiates treatment;</li><li>• Reviews hospitalised MDR-TB patients;</li><li>• Ensures quality of treatment, prescription, and initiation and clinical follow-up during community-based treatment;</li><li>• Manages patients with severe disease or complications from treatment;</li><li>• Monitors patients for problems during treatment, e.g., side effects, adherence problems, etc.;</li><li>• Supervises the Focal DR-TB Nurse.</li></ul>
<b>Focal DR-TB Nurse</b>	<ul style="list-style-type: none"><li>• Shares responsibilities with the MDR-TB Clinical Officer in management of patients with MDR-TB;</li><li>• Supervises the DR-TB DOT Supporter;</li><li>• Coordinates clinical support services;</li><li>• Supervises administration of patient treatment;</li></ul>

ROLE	SPECIFIC RESPONSIBILITIES
<b>Focal DR-TB Nurse</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• Coordinates with the hospital on patient admission and discharge;</li> <li>• Ensures all monitoring tests are submitted;</li> <li>• Assists in clinic and keeps track of follow-up appointments;</li> <li>• Performs home visits in cases of medical complications or adherence problems;</li> <li>• Assesses and improves TB infection control in the home;</li> <li>• Identifies and addresses socioeconomic problems;</li> <li>• Coordinates with clinical, data, and pharmacy staff;</li> <li>• Maintains database (register) of all MDR-TB patients in the zone/district;</li> <li>• Stores outpatient records of all MDR-TB patients;</li> <li>• Produces timely reports according to NTP guidelines.</li> </ul>
<b>Cashier</b>	<ul style="list-style-type: none"> <li>• Keeps accounting books for DR-TB DOT expenses;</li> <li>• Issues transportation funds for staff, DOT supporters, or patients and dispenses any patient incentives;</li> <li>• Keeps records of all supplies and stocks of materials related to the treatment of MDR-TB at the outpatient clinic.</li> </ul>
<b>Laboratory Technician</b>	<ul style="list-style-type: none"> <li>• Provides laboratory services for MDR-TB patients including diagnosis of new patients, monitoring of patients on therapy and laboratory screening tests for side effects.</li> </ul>
<b>Pharmacy Technician</b>	<ul style="list-style-type: none"> <li>• Manages second-line drug stock (inventory, forecasting, and drug supply) for the district;</li> <li>• Prepares paediatric anti-TB drug doses;</li> <li>• Prepares drug packs for each MDR-TB patient and delivers them to the MDR-TB team for distribution to the DR-TB DOT Supporter.</li> </ul>

## IN THE COMMUNITY:

ROLE	SPECIFIC RESPONSIBILITIES
<p><b>DR-TB DOT Supporter</b></p> <p>Supports no more than four patients at any one time but more commonly may have only one or two patients.</p>	<ul style="list-style-type: none"><li>• Supervises all doses of second-line TB drugs in the community (DOT of all doses);</li><li>• Identifies possible side effects or complications and reports them promptly to the MDR-TB Clinician (or the DTO);</li><li>• Accompanies the patient to all medical consultations;</li><li>• Assists the patient in producing sputum samples on a monthly basis;</li><li>• Receives monthly drug kit and verifies that its contents are correct;</li><li>• Refers household contacts for TB and HIV screening and diagnosis;</li><li>• Provides education and emotional support to the patient and family.</li></ul>
<p><b>Patient</b></p>	<ul style="list-style-type: none"><li>• Takes all doses under the supervision of the DR-TB DOT Supporter;</li><li>• Attends monthly consultations at the outpatient MDR-TB clinic;</li><li>• Provides sputum and blood on a monthly basis for testing;</li><li>• Reports any difficulties or problems in care;</li><li>• Follows all home-based infection control measures.</li></ul>
<p><b>Family Members</b></p>	<ul style="list-style-type: none"><li>• Supports the patient during treatment;</li><li>• Accepts education on MDR-TB and reports symptoms of TB in household or close contacts;</li><li>• Implements proper home based infection control measures.</li></ul>

## Training the Outpatient MDR-TB Team

The NTP, in coordination with the Zonal Health Offices, will arrange DR-TB trainings for the members of the Zonal and District MDR-TB teams to do community-based and outpatient ambulatory care. The trainings will be conducted using both this Guide and the clinical guide, *Guidelines for the Programmatic Management of Drug-resistant TB* (June 2012 Revision).

The training for clinicians and the Focal DR-TB Nurse is a multi-day training.

Separate and focussed training will be done also for the Laboratory and Pharmacy MDR-TB Team members.

Persons not directly on the Outpatient MDR-TB Teams, but needing to know about MDR-TB treatment (e.g., DHOs, DMOs, and other members of the District Health Management team) will receive a one-day orientation.

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### 3.2. Responsibilities of the Focal DR-TB Nurse

The Focal DR-TB Nurse is responsible for coordinating care for MDR-TB patients in the community. The Focal DR-TB Nurse works as part of the Outpatient MDR-TB Team (see Section 3.1). Focal DR-TB Nurses will receive special training in MDR-TB so they can assist in clinical activities, perform appropriate referrals of medical emergencies, and supervise DR-TB DOT Supporters. The Focal DR-TB Nurse has the following roles and responsibilities:

- Performs home visits in case of medical complications or adherence problems:
  - Assesses the patient's home and family at the beginning of treatment,
  - Visits the patient in case of medical problems, including drug side effects,
  - Screens family members for HIV and TB,
  - Educates the family and community about DR-TB, and
  - Tracks defaulters.
- Identifies, reports, and addresses socioeconomic problems:
  - Provides counselling and psycho-emotional support,
  - Coordinates MDR-TB support groups,
  - Helps patients obtain social support.
- Supervises DR-TB DOT Supporters:
  - Assists in identifying an acceptable DR-TB DOT Supporter for each patient,
  - Participates in training of the DR-TB DOT Supporters (see Section 4.4),

- Communicates with the DR-TB DOT Supporters on laboratory specimens and results,
  - Monitors the DR-TB DOT Supporters monthly,
  - Conducts visits to patients' homes to assess quality of DOT, and
  - Organises refresher trainings for all DR-TB DOT Supporters.
- Coordinates with MDR-TB Clinical Officers, DTOs, Laboratory and Pharmacy Technicians:
    - Assists in arranging for hospital admissions in cases of medical emergencies;
    - Coordinates transition from hospital- to community-based care;
    - Coordinates the next outpatient clinic visits;
    - Manages outpatient clinic schedules including laboratory tests; and
    - Works with pharmacy team to deliver medicines to patients.

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### **3.3. Duties of the Focal DR-TB Nurse in the outpatient clinic**

Many of the activities of the Focal DR-TB Nurse are at the facility level; however, the Focal DR-TB Nurse must also participate in community activities. The duties of the Focal DR-TB Nurse will include the following:

- Organises follow-up for MDR-TB patients:
  - Uses the appointment system (see Section 3.6), collecting the files of the patients who are expected to be seen that day by the Outpatient MDR-TB Team before the clinic opens;
  - Measures patients' weights and vital signs;
  - Sends patients to submit blood and sputum samples;
  - Inspects treatment cards and transferring tick records to the copy of the treatment card in the clinic files;
  - Discusses community/adherence issues with the MDR-TB Clinician; and
  - Updates the register for MDR-TB treatment.
- Arranges evaluation of new patients, such as those who are referred to the clinic as MDR-TB suspects:
  - Reviews the referral form; and
  - Ensures that the required tests are done (e.g., chest x-ray, blood and sputum samples) before the patient is seen by the MDR-TB Clinician.

- Assists the DTO in assessing and supervising DR-TB DOT Supporters:
  - Conducts a monthly performance evaluation of each DR-TB DOT Supporter (see Section 4.7) and corrects problems that are discovered;
  - Assists in refresher trainings for all DR-TB DOT Supporters (see Section 4.4); and
  - Organises distribution of food packages, transportation reimbursements and DR-TB DOT Supporter compensation (see Section 4.5).
- Ensures that patients are given the right amount of prescribed drugs:
  - Sends prescriptions to pharmacy dispensing area or makes sure that pharmacy personnel have filled prescriptions given to them back at their health centre or district hospital;
  - Informs the central pharmacy of any regimen changes so that they can send the new drugs out to patients' districts; and
  - Educates patients and DR-TB DOT Supporters about regimen changes.
- Ensures that patients receive the correct follow-up appointments.

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### **3.4. Linkages and integrated care for MDR-TB patients**

Patients who suffer from co-morbid conditions should receive care for these other conditions within the MDR-TB programme. This will, among other things, decrease the risk of transmission to other patients because infectious patients are not required to visit multiple clinics.

- Other chronic diseases (HIV, diabetes, etc.) should be managed during the same MDR-TB outpatient clinic visit:
  - The patient drug pack prepared by the pharmacy team should include all medications prescribed for other conditions as well; and
  - The Outpatient MDR-TB Team should be trained in the management of other common chronic diseases in addition to MDR-TB.
- Advantages of integrated care:
  - It is more convenient for the patient. Since many MDR-TB patients are debilitated and struggling with side effects, integrated care decreases the likelihood of them abandoning therapy;
  - It reduces medical errors and drug interactions, as one clinical team manages all of the different medications for the patient; and
  - It decreases risk of transmission to other patients and health workers.

- Integrated care is particularly important in the case of HIV co-infection. All HIV-related services (antiretroviral therapy, screening for opportunistic infection, etc.) should be provided in the MDR-TB clinic or at community level.
- Family planning is a particularly important part of integrated care for MDR-TB patients. MDR-TB patients should not become pregnant while being treated for MDR-TB; therefore, female patients of reproductive age should be counselled and assisted in finding an appropriate family planning method.

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### **3.5. Communication channels**

The DR-TB DOT Supporter and the Focal DR-TB Nurse must communicate on a regular basis. It is recommended that they participate in a check-in phone call every one to two weeks.

The DR-TB DOT Supporter should follow the procedures below in emergency situations:

- Communicate to the nearest peripheral health facility. The facility will be responsible for requesting assistance from the MDR-TB Team, specifically the DTO.
- Directly inform the Focal DR-TB Nurse that there is an emergency.

#### **Communications and Mobile Phones**

The DR-TB DOT Supporter needs a reliable way to communicate with the MDR-TB community team in case of emergencies. All DR-TB DOT Supporters will have a mobile phone and communication allowance (see Section 4.5).

- The Focal DR-TB Nurse should write down the mobile numbers of all members of the DR-TB team (DTO, Clinical Officer, and DOT Supporter) in the DR-TB “DOT Book”.
- The Focal DR-TB Nurse should keep a list of mobile numbers of all DR-TB DOT Supporters and share copies with the MDR-TB team.
- The Focal DR-TB Nurse should keep a list of the nearest health centres and contacts of each MDR-TB patient.
- Patients and families should be instructed to contact the DR-TB DOT Supporter immediately in cases of emergency. The DR-TB DOT Supporter should contact the nearest health centre or the DTO for advice.

The DR-TB DOT Supporter should call the DTO immediately if the patient experiences any of the following:

- Side effects
- Missed doses
- Worsening MDR-TB signs and symptoms
- Running out of drugs early
- Inability to attend a clinic appointment due to weather or travel conditions (e.g., a flooded river)

In areas where there is no mobile network access, the DR-TB DOT Supporter will be expected to travel to the closest area where there is mobile network access. A system of getting a message from the MDR-TB team to the patient or DR-TB DOT Supporter should be set up (i.e., identify someone in the nearest area with mobile network access that can be called or sent a message). In areas with no access, the DR-TB DOT Supporter should travel to an area with access to check in with the Focal DR-TB Nurse once a week.

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### **3.6. Patient appointment and review system**

The Outpatient MDR-TB Team should evaluate each patient once a month in the clinic during the intensive phase, and once every two months during the continuation phase:

- All appointment dates should be communicated to the facility that coordinates the patient's care. The Focal DR-TB Nurse will keep track of all appointments in a calendar (paper or electronic).
- If a patient is too weak to attend his or her monthly clinic visit, the Outpatient MDR-TB Team can conduct home visits with the patient instead. Any monitoring or laboratory test samples can be collected at the patient's home.
- Sputum collections and monitoring blood tests will be conducted on MDR-TB clinic days:
  - Sputum will be collected from the patient for monitoring smear and culture. Sputum will be collected monthly during the injectable phase of the patient's treatment and every other month during the non-injectable phase.
  - Monitoring blood tests for creatinine, potassium, and any adverse effects will be done during the same clinic visit.

- The Outpatient MDR-TB Team may change or adjust the anti-TB drugs during the appointment. Any changes must be communicated to the central pharmacy that dispenses drugs and to the DR-TB DOT Supporter.
- Patients should visit the clinic within one week after being discharged from the hospital. The MDR-TB team should ensure that the clinic appointment is scheduled before the patient is discharged from the hospital.

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### **3.7. TB infection control in the community**

One of the best methods of infection control is effective treatment. Early diagnosis and rapid initiation of treatment are the priorities of the Malawi TB Control Programme.

- The home visit is an excellent opportunity for the Focal DR-TB Nurse to assess and improve infection control in the home:
  - Educate the patient and family about how to determine if the patient is still infectious (patients doing well on therapy are considered highly likely to be non-infectious);
  - Improve natural ventilation and exposure to sun within the home;
  - Screen family members for symptoms of TB;
  - Offer HIV testing to all family members;
  - Advise patients on cough hygiene, such as covering mouths with tissues, handkerchiefs, or surgical masks when coughing;
  - Advise patients to minimise contact with infants and children during the initial months of treatment;
  - Advise patients to sleep in a separate room during the initial months of treatment if at all possible;
  - Advise patients to collect their sputum in a plastic bag or jar and teach them how to bury or dispose of it properly; and
  - Advise patients that if they do spend time with other family members, they should do so outside the home, in open air and sunlight.
- DR-TB DOT Supporters are at increased risk for occupational disease. The following steps should be taken to reduce risk:
  - DR-TB DOT Supporters should know their HIV status and preferably be HIV negative. DR-TB DOT Supporters should be offered HIV testing on a regular basis.

- DR-TB DOT Supporters should know the sputum status of each of their patients. If a patient's sputum culture is positive, this means the patient is still infectious.
- Each DR-TB DOT Supporter should receive two disposable particulate respirators (N95 masks) on a monthly basis if any of their patients is culture-positive. DR-TB DOT Supporters should be trained on how and when to use a mask.

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### **3.8. Caring for caregivers**

Health workers are at risk for MDR-TB in high-burden TB settings because they are constantly exposed to infectious TB patients.

- Health workers should be trained in infection prevention and control when they begin work. Training should be in line with the NTP's *Guidelines for Infection Prevention and Control of Tuberculosis*.
- Health workers will be provided with at least four disposable particulate respirators (N95 masks) on a monthly basis. They will also be provided with any other equipment necessary for caring for MDR-TB patients.
- All health workers who are diagnosed with TB should have their sputum sent to the laboratory for drug susceptibility testing.
- Health workers living with HIV are at the highest risk for developing TB and MDR-TB, so regular HIV testing is an important part of occupational safety.
- Health workers living with HIV should not work in TB clinics.
- All health workers should be offered HIV testing before starting to work with TB patients. They should continue to be tested on a regular basis while this work continues, i.e., every 6 months.

# DR-TB DOT SUPPORTERS

## 4.1. Profile of a DR-TB DOT Supporter

In Malawi, during the injectable phase of the patient's treatment, the DR-TB DOT Supporter will be a nurse who lives near the patient or works at a health post or health centre near the patient. If there is no health post or health centre near the patient's home, then arrangements will have to be made for the patient to move close to the health post or centre so that the nurse can meet them every day for DOT. The DR-TB DOT Supporter will visit the patient every day and give him or her an intramuscular injection during the first 6 months or longer of treatment.

During the non-injectable phase of the patient's treatment, the patient may return home if they had to move during the injectable phase. The DR-TB DOT Supporter can be someone chosen from a number of different groups of community health care providers:

- A general nurse (or medical assistant) who lives near the patient (this is the first choice, and is a continuation of the DR-TB DOT Supporter who gave the injectable agent);
- A Health Surveillance Assistant (HSA);
- A Community Volunteer; or
- Any other person working in TB control activities.

A DR-TB DOT Supporter will be paid a monthly incentive in addition to his or her salary.

### **A DR-TB DOT Supporter must:**

- Be acceptable to the patient and his or her family;
- Be active and willing to work hard;
- Be available to support the patient at any time during the day or night for the full duration of treatment;
- Keep confidentiality of the patient's records and conditions;
- Have a stable living situation near where the patient lives;
- Have good literacy skills (be able to read and write);
- Be motivated to care for MDR-TB patients;
- Not have a health condition that could lead to immune-suppression\*;  
and
- Receive basic TB training and MDR-TB-specific training.

*\*The most common cause of immune-suppression is HIV/AIDS, but chronic illnesses, such as diabetes, can also suppress the immune system and are a risk factor for TB infection and disease.*

It is not recommended to appoint a member of the patient's family as his or her DR-TB DOT Supporter. The family relationship may interfere with the Supporter's ability to monitor treatment.

The DR-TB DOT Supporter should live near the patient. This makes twice-daily DOT possible. Additionally, the family should be able to contact the DR-TB DOT Supporter quickly in case of medical emergencies.

DR-TB DOT Supporters will be trained and supervised. It is recommended that DR-TB DOT Supporters receive regular incentives and compensation (the specifics on incentives and compensation will be communicated regularly by the NTP).

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## 4.2. Identification of DR-TB DOT Supporter

A DR-TB DOT Supporter should be someone who meets the profile outlined in Section 4.1.

As mentioned in Section 4.1, the first choice of a DR-TB DOT Supporter is a nurse who is working in a nearby clinic that can make a daily visit to the patient. Nurses are ideal because they are already trained how to give injections. Given the large geographical area of Malawi, many patients may not have a nurse near and arrangements will have to be made for the patient to move near a health facility.

Once the injectable phase of the patient's treatment is over, the nearest HSA can be taught to take over the DOT. HSAs are good candidates because they have often already received some training on TB and HIV.

If there are communities without a nurse or HSA, special arrangements should be made during the injection phase and then a DR-TB DOT Supporter could be chosen from the community. He or she should still meet the profile in Section 4.1. Preference will be given to community volunteers working in TB control.

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## 4.3. Tools for the DR-TB DOT Supporter

The tools for the DR-TB DOT Supporter include:

- Mobile phone (or other means of communication) with adequate airtime
- DOT Book
- Pens or pencils
- Ruler
- Umbrella and rain coat
- LED torch (The DR-DOT provider will be responsible for supplying batteries)
- Waterproof bag
- Lockable container (to keep at home for storing confidential documents and storing medicines out of the reach of children)
- Identification
- Bicycle (if conditions mandate that DOT would be impossible without one)

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#### 4.4. Initial training of DR-TB DOT Supporters

DR-TB DOT Supporters will receive specific training in MDR-TB. This training is necessary in order to provide DOT. Since nurses and HSAs have already been trained in TB and HIV, the training will take place over two or three days.

- Training for DR-TB DOT Supporters is done by the MDR-TB team from the area (although at the start of the programme training may be done by a designated team from the NTP or by the Outpatient MDR-TB Team from a referral clinic). When patient load is low, training is done one-on-one to enable DR-TB DOT Supporters to begin providing treatment. When patient load increases, the DR-TB DOT Supporters can be trained in groups. DR-TB DOT Supporters will receive a small handbook/workbook during the training and a “DOT Book” for each patient. The training will cover:
  - Basic information about TB and HIV;
  - Role and responsibilities of the DR-TB DOT Supporter on an individual basis and as part of the broader Outpatient MDR-TB Team;
  - How to talk to MDR-TB patients during the first encounter;
  - How to give DOT;
  - How to mark the treatment card;
  - How to fill in the DOT Book;
  - About common side effects and how to identify them;
  - About ancillary drugs used to treat side effects;
  - How to encourage the patient to continue coming for TB treatment;
  - What to do if a patient misses a scheduled treatment;
  - How to obtain a resupply of drugs;
  - What to do if the patient or the DR-TB DOT Supporter must be away for a few days;
  - When to send the patient back to the health facility for follow-up;
  - The importance of sputum and blood tests every month;
  - Infection control at home, including universal precautions and needle disposal;
  - How to use and store particulate respirators (N95); and
  - TB screening for adults and children.
- The DR-TB DOT Supporter should also be mentored during the first weeks of providing treatment to patients. The Focal DR-TB Nurse should watch the DR-TB DOT Supporter observe doses in the home while reinforcing the above lessons.

- Monthly on-the-job training by the Outpatient MDR-TB Team is recommended during the routine clinic evaluations at the MDR-TB clinic days. This can be done with groups of patients and their DR-TB DOT Supporters. Topics should include:
  - How MDR-TB develops and how it is transmitted;
  - Drugs used in the treatment of MDR-TB;
  - The distinction between intensive and continuation phases;
  - Roles and responsibilities of all members of the MDR-TB team;
  - How to encourage patients to accept and take treatment;
  - Side effects—how to recognise them and what actions to take;
  - When to refer patients for medical evaluation prior to their next scheduled appointments (e.g., in cases of severe or concerning adverse events or deteriorating health);
  - Importance of monitoring treatment with sputum and blood tests;
  - Risk factors for default;
  - Screening household contacts for TB;
  - Principles of infection control, including disposal of hazardous waste; and
  - Patient rights and confidentiality.
- The Focal DR-TB Nurse should ensure that the DR-TB DOT Supporter also receives a refresher training session every year.

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## 4.5. Performance-based incentives

Where possible, DR-TB DOT Supporters will be provided with enablers and incentives such as transport reimbursements.

- Incentives are directly tied to performance, as assessed during monthly supervision and evaluation (see Section 4.6). During the monthly evaluation of the patient, the DTO, or Focal DR-TB Nurse will also evaluate each DR-TB DOT Supporter. If his or her performance is acceptable, the DR-TB DOT Supporter will receive the monthly incentives.
  - The Focal DR-TB Nurse will not compensate DR-TB DOT Supporters unless they perform all their responsibilities during the preceding month.
  - If performance is not acceptable for two months in a row, the DTO will immediately find an alternate DR-TB DOT Supporter for the patient.
- If the DR-TB DOT Supporter cannot supervise treatment, he or she should inform the Focal DR-TB Nurse in advance. This will allow the Outpatient DR-TB Team to find another DR-TB DOT Supporter for the patient so that he or she does not miss any doses.

- If the DR-TB DOT Supporter does not fulfil his or her responsibilities, he or she should be replaced immediately. This should be made clear to the DR-TB DOT Supporter before he or she begins work.

#### 4.6. Monthly performance evaluation

The Focal DR-TB Nurse should evaluate the DR-TB DOT Supporter on a monthly basis. The evaluation can be done with both the patient and DR-TB DOT Supporter during the clinic visit at the outpatient facility, or it can be done during a home visit. The specifics of how a supervisor uses the scales for each area of the monthly evaluation are covered during training.

<b>Understands</b>	Circle the appropriate number: 1=poor, 5=excellent	N/A (tick)
The patient's TB treatment regimen (drug names and doses)	1 2 3 4 5	
Common side effects of the TB treatment regimen	1 2 3 4 5	
All other drugs taken by the patient and why	1 2 3 4 5	

<b>Performance</b> (during the past month)	Circle the appropriate number: 1=poor, 5=excellent	N/A (tick)
Treatment card filled properly/in good condition	1 2 3 4 5	
Patient's appraisal of the supporter: punctuality, supportiveness	1 2 3 4 5	
DOT Book filled properly/in good condition	1 2 3 4 5	
Medication bag kept in good condition	1 2 3 4 5	
Provided DOT correctly	1 2 3 4 5	
Notified DTO or health centre in case of any problems	1 2 3 4 5	
Patient missed any doses	1 2 3 4 5	
Household contact screening	1 2 3 4 5	

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## 4.7. Monitoring DR-TB DOT Supporters

The Outpatient MDR-TB Team should make regular visits to the patient's home to ask the patient and his or her family about the DR-TB DOT Supporter. After each visit, the team should contact the DR-TB DOT Supporter to discuss any issues and reinforce teaching points.

- Pills should be counted at monthly evaluations or during spot visits. The DTO should count the remaining pills and compare this number to the amount of pills that should be remaining based on the number of days since the medication bag was replenished. If there are any extra or missing pills, the DR-TB DOT Supporter should explain why.
- The Outpatient MDR-TB Team should regularly ask the patient about the DR-TB DOT Supporter (e.g., "Is the DR-TB DOT Supporter prompt? Does he or she have a good attitude? Does he or she work around the patient's schedule? Is the relationship still a good one?").
- The DR-TB DOT Supporter should be asked to assess his or her own performance at monthly evaluations (e.g., "How do you think you are doing? What are you struggling with?").
- The DR-TB DOT Supporter should keep the treatment card and the anti-TB drugs.
- The DR-TB DOT Supporter should read the exact treatment regimen listed on the card and tick the box immediately after observing each dose.

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## 4.8. The DOT Book

The DOT Book is a record notebook for all medications administered, including side effects, medications, prophylaxis, and ART. It is kept by the DR-TB DOT Supporter.

The DOT book has a page for every day of the week and the DR-TB DOT Supporter must fill in the book daily. Wednesday is a special day in the DOT Book as it requires that the DR-TB DOT Supporter ask about specific side effects and problems. The DR-TB DOT Supporter is expected to ask about side effects every day, but this special form requires them to record the information at least once a week.

Drug Name	Size of tablet, pill, or vial	Morning (number of tablets or mg of injectable)	Evening (number of tablets or mg of injectable)	Signature
<b>MDR-TB Drugs</b>				
<b>Other Antibiotics</b>				
<b>Drugs to treat side effects</b>				

## Side Effects (filled once a week on Wednesdays)

<b>Urgent Side Effects (See or talk to the MDR-TB Team the same day if any present)</b>				
<b>Side Effect</b>	<b>Question to ask the patient</b>	<b>Patient Response</b>		<b>Action Taken</b>
<b>Hearing loss</b>	Has your hearing changed? Are you having trouble with hearing?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b> ringing in the ears and dizziness</b>	Do you have any ringing in the ears or dizziness?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Neuropathy</b>	Have you had pain or burning in your legs?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Low potassium</b>	Have you had leg cramping? Do you feel very weak?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Depression</b>	Do you feel sad?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	Do you have thoughts of committing suicide?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Hepatitis</b>	Have you noticed yellow in the whites of your eyes or your skin tone?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Psychosis</b>	Do you hear voices or see things that may not be there?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Allergy</b>	Do you have any rashes or itching?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

**Non-urgent Side Effects (See or talk to the MDR-TB Team within one week if any present)**

Side Effect	Question to ask the patient	Patient Response		Action Taken
<b>Nausea</b>	Have you had nausea the last week?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Vomiting</b>	Have you vomited the last week?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	Have you vomited up your medications?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Joint pain</b>	Do you have any joint pain?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Diarrhea</b>	Have you had diarrhea in the last week?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Belly discomfort</b>	Have you had pain in your belly or stomach? (Note: if pain is severe, contact the MDR-TB Team.)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Anxiety</b>	Do you feel excessively anxious or agitated?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

**Response to Treatment (See or talk to the MDR-TB Team within one week if any present)**

<b>Improvement or worsening</b>	Are you getting worse? Is cough, fever, or night sweats still present or worsening?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Difficulty breathing</b>	Do you have difficulty when breathing?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Weight loss</b>	Do you have weight loss?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Family members</b>	Does anyone in the family have cough, fever, weight loss, night sweats, or other symptoms?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

# SOCIAL SUPPORT

## 5.1. Home assessment

The Focal DR-TB Nurse together with the DR-TB DOT Supporter should perform a home assessment for all patients at the beginning of treatment. This allows the clinical and public health teams to understand the social and family environment and conditions of TB transmission for each patient. An example of this form is below.

The Home Assessment form is placed in the beginning of the DOT Book. As availability of social support is not universal for all that need it, the Focal DR-TB Nurse will have to work with the MDR-TB Team to help solve social problems. Further instructions on how to solve social and economic problems are given to the MDR-TB team during their training.

The home assessment should be done every 6 months after initiation of MDR-TB treatment to see if conditions have improved.

## Home Assessment Form

General conditions	
How many people are sharing the household with the patient?	
How many rooms are in the house?	
How many are HIV positive or suffer from another chronic disease?	
How many are below 5 or above 50 years of age?	
Is this the patient's only residence?	
Does the patient rent or own the home?	

TB Knowledge		
Do the patient and the family understand how TB is transmitted?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the family understand the need to be screened for TB?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Economics		
Does the patient feel there are days each week when there is not enough food to eat? If yes, how many days a week? _____.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the patient have a source of income (grant/work)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
From what material is the patient's residence constructed?		
Are there visible holes in the roof?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Infection Control		
Does the patient sleep in a separate bedroom?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the house have enough windows?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the patient have lots of visitors?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the patient socialise in outdoor spaces while sputum positive?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

## Home Assessment Form (continued)

Habits		
Does the patient smoke tobacco?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the patient drink alcohol?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Hygiene		
Does the patient know about cough hygiene?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the patient know how to safely dispose of sputum?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the patient's house have a latrine?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:		

### 5.2. Food packages and direct patient support

Food packages and/or direct patient support (often in the form of money) have two purposes for MDR-TB treatment: they improve nutritional status and act as powerful adherence enablers. These enablers are considered as part of the MDR-TB treatment regimen, and are considered to be just as important as medications.

- Because patients often share their food packages with their families, the size of the food package is intended to feed 3 to 4 persons.
- Food packages will be designed according to World Food Programme (WFP) guidelines for HIV patients starting antiretroviral therapy and TB patients starting treatment.

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### 5.3. **Transportation**

MDR-TB patients are asked to make frequent trips to the hospital, clinic, or laboratory. For this reason, they may have more out-of-pocket expenses due to transportation than other TB patients.

- Every effort should be made to consolidate the trips required each month.
- Reimbursement for transport expenses is an important enabler for MDR-TB treatment:
  - Patients will be reimbursed for transportation expenses according to individual need (geographic location and method of transport) or they will be given direct patient support (money) which can be used for transportation;
  - Because DR-TB DOT Supporters are required to accompany the patient to each clinic visit, they also receive reimbursement for transport (see Section 4.5);
  - A patient guardian (or family member) may also need to receive transportation reimbursement.

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### 5.4. **Temporary housing**

While it is usually best for patients to live in the community, there are situations when it will be necessary for the patient to move closer to a health facility so that they can get daily DOT by a nurse or medical assistant experienced in giving intramuscular injections. Because every district will have an MDR-TB Team, patients may need to move near a DR-TB Team during treatment. The National TB Programme and other partners may help to arrange housing for patients.

Temporary accommodation may be needed for MDR-TB patients who:

- Live in very remote areas where there is no nurse to give a daily injection;
- Need to be monitored closely;
- Are too ill to go home, but too well to be in the hospital; or
- Are homeless or have very difficult family situations.

In addition, every district hospital should have the ability to admit patients who are very sick to an isolation room. Isolation rooms can also be used when proper DOT with a DR-TB DOT Supporter has not yet been arranged for outpatient care.

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## 5.5. Work

TB mostly affects patients who are in their most productive age. Nearly all TB patients contribute to their family income and many are responsible for supporting and caring for children and other family members.

- Patients should be sputum culture negative before returning to work.
- Patients should be encouraged to resume work as soon as their sputum is culture negative. This allows patients to reintegrate into society and earn money for their families.
- Some patients will not want to return to work even if they are in good health, for fear of falling sick again. These patients need counselling and psychological support to facilitate their return to the workforce.

Those without skills or jobs should be encouraged to engage in income-generating activities such as:

- Sewing circles
- Gardening
- Raising chickens or pigs
- Operating phones
- Owning shops
- Any other activities they may be able to do

The NTP may implement such social support itself, or may collaborate with other partners to manage income-generating activities, job training, and education projects. Programmes to help with school costs may also help take pressure off the patient who may not be able to generate such income.

# ADHERENCE SUPPORT

Treatment for MDR-TB is long and often complicated. Success of treatment relies heavily on adherence, which in turn relies on:

- A good understanding by the patient of the fundamentals of MDR-TB treatment;
- Commitment from the patient to participate in treatment;
- Support of the patient by the family;
- Good communication between the DR-TB DOT Supporter, the patient, and the family; and
- Commitment of the DR-TB DOT Supporter to the patient.

## 6.1. Directly Observed Treatment (DOT)

Taking of TB medicines must be observed throughout treatment. Doses are administered once a day; however, medicines such as cycloserine and ethionamide can be split into two doses to decrease side effects. When this is done, the DR-TB DOT Supporter must give DOT for both the morning and evening doses.

If a patient misses a dose for any reason, the DR-TB DOT Supporter should notify the Focal DR-TB Nurse the same day.

DOT should be organised in accordance with the needs of the patient.

- The DR-TB DOT Supporter generally supervises doses in the patient's home, but in exceptional cases the patient may visit the home of the DR-TB DOT Supporter, for example, for reasons of confidentiality.
- During the injectable phase of the patient's treatment, a nurse or another qualified individual should inject the patient. This will sometimes need to be done at a mutually agreed upon location, but it is always preferable to do it in the patient's home.

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## 6.2. **Recognising side effects and monitoring response to treatment**

Side effects are the most important reason why patients default from treatment. These can occur at any time during treatment. In most cases side effects are mild, but occasionally they can be severe. It is important to detect and resolve them quickly.

- Daily DOT is an opportunity for early detection of side effects. The patient should be asked about side effects each day and in more detail at least once a week (see Section 4.8). The DR-TB DOT Supporter is trained in recognising potential side effects that could be produced by the regimen his or her patient is receiving. The DR-TB DOT Supporter should have an easy mode of communication with Focal DR-TB Nurse (or any member of the MDR-TB Team) that is open 24 hours a day.
  - If side effects are minor, the DR-TB DOT Supporter can monitor and manage them with pre-established protocols under the supervision of the MDR-TB team.
  - If side effects are serious, the DR-TB DOT Supporter should arrange for appropriate medical referral.
- The DR-TB DOT Supporter should also monitor for signs that the patient is improving or worsening:
  - Signs that treatment is working include weight gain and decreased cough and sputum.
  - If the patient is having fevers or night sweats, difficulty breathing, or haemoptysis (blood in the sputum), the DR-TB DOT Supporter should notify the Focal DR-TB Nurse, who will arrange for appropriate medical referral.
- Patients should have the mobile phone numbers of the Focal DR-TB Nurse and other MDR-TB Team members.

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### 6.3. Support groups

A support group allows DR-TB patients to meet and socialise with other patients and provide emotional support to each other. Informal support groups will be arranged at “clinic days” where patients can meet and give each other support.

When possible, a counsellor or social worker trained to work with support groups will facilitate the support group. The Focal TB Nurse may co-facilitate the group. It is also possible to give ongoing patient education to the groups.

Clear eligibility criteria should be created for participation in each support group:

- Participation is only for patients who are sputum negative and are no longer infectious;
- Cured patients may also be invited to support groups, as they provide hope to patients who are still on treatment;
- More formal groups can be formed for those with serious psychosocial issues and may require a facilitator with psychiatric training; and
- Meetings should be held in an area with excellent ventilation.

Support groups may need help in inviting participants, finding a safe meeting place and other organisational issues. At the end of each support group meeting, the facilitator and co-facilitator should meet privately to discuss and analyse the proceedings.

---

### 6.4. Preventing default

Patients should be observed closely for signs that they might default from treatment, such as missed visits or refusal to take doses. The following steps should be taken for patients at risk for default:

- 1. Home visit.** During the home visit, it may be possible to identify more clinical problems than during the monthly clinic evaluation.
- 2. Manage side effects.** This is the most common reason for default.
- 3. Counselling and encouragement.** Often the patient may no longer want to continue treatment because he or she feels better. Sometimes the patient has greater confidence in alternative or folk medicine. It is important to build the trust of the patient and continue to offer emotional support and encouragement to continue with treatment until completion.

- 4. Address economic problems.** Many patients are unable to work when they are ill, and they may be the primary breadwinners for their families. Are basic housing, food, and clothing needs covered?
- 5. Address addiction or other social problems.** Is there alcohol or drug abuse in the home? Patients should be encouraged to stop or decrease consumption if it interferes with their treatment.
- 6. Address problems with health personnel or the DR-TB DOT Supporter.** Is the patient mistreated by the health care facility? Does the DR-TB Supporter arrive late?
- 7. Involve the patient's family.** Family is the most important source of psychosocial support for the patient.
- 8. Involve community leaders.** Community leaders can be helpful if there are community-wide issues such as stigma towards DR-TB patients. This step may not be able to be done if confidentiality has to be observed.

# SUPPLY CHAIN MANAGEMENT

## 7.1. Centralised control of second-line TB drugs

Monthly patient drug packs should include anti-TB drugs and ancillary drugs for treatment of side effects that are not readily available at the health centres. Other drugs used to treat co-morbid diseases such as HIV or diabetes and family planning supplies are available at the health centres.

- Second-line drugs are delivered to the district MDR-TB Teams every quarter from the central TB stock based on the number of patients that are enrolled in each district. All of the drugs (second-line anti-TB drugs and ancillary drugs) are kept in one cabinet in the facility where the MDR-TB team is located. Sometimes extra deliveries from the central warehouse to the districts are needed for new patients or when drug regimens are changed.
- The DR-TB DOT Supporter keeps their patient's anti-TB drugs at his or her home, not at the patient's home.
- Once a month at the clinic where the patient receives the medicines:
  - The team will pack the patient's prescribed regimen in approved and sealable bags.
  - A 30-day supply should be packed for each drug. This gives a 2-day buffer that may be used if necessary (e.g., lost doses due to vomiting).
  - The Focal DR-TB Nurse or a member of the MDR-TB Team should verify that the regimen is correct and that any necessary ancillary drugs are also included such as anti-emetics, vitamin B-6, potassium, and any others.
- The referral DR-TB clinic will need to inform the central TB medicine warehouse of any changes. All extra drugs, including those from patients who have died during the month, should be brought back to the pharmacy by the DR-TB DOT Supporter. The drugs will be inspected and will then be used for other patients or will be destroyed in case the drugs are in unacceptable condition.

## 7.2. Standardised prescription form

The logbook should be maintained by the Outpatient MDR-TB Team and kept in the area used to prepare patient drug packs. The Outpatient MDR-TB Team will use it to document when a packet of second-line drugs is prepared and sent.

In addition to a logbook, a standardised prescription form reduces clinician and pharmacy error. The MDR-TB Clinician fills out the form and passes it to the pharmacy team, which prepares the patient drug pack. This form is also part of the MDR-TB clinic follow-up forms and hospital discharge summaries. The prescription form lists the drugs commonly used in the standardised regimen; blank spaces are included at the bottom for less-commonly prescribed medications. An example of the drug form is below:

### Standardised Prescription Form

Drug	DOSE				TOTALS DISPENSED	
	Morning (mg)	Mid-day (mg)	Evening (mg)	Night (mg)	Number of days	Total number of tablets
<b>Pyrazinamide</b>						
<b>Kanamycin</b>						
<b>Capreomycin</b>						
<b>Levofloxacin</b>						
<b>Ethionamide</b>						
<b>Cycloserine</b>						
<b>TDF-3TC-EFZ</b>						
<b>D4T-3TC-NVP</b>						
<b>Vitamin B-6</b>						
<b>Metoclopramide</b>						
<b>Omeprazole</b>						

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### 7.3. Ordering second-line TB drugs

Ordering second-line TB drugs is a very important activity that is done at the central level. It is important to understand that the following facts are considered at central unit when ordering second-line TB drugs:

- Some second-line drugs may take a very long time to arrive in country after being ordered. Ordering of drugs is done at least 9 months in advance to ensure that there will be sufficient supplies.
- Some second-line drugs, such as cycloserine and capreomycin, have short half-lives. Deliveries of these drugs should be staggered in order to avoid expiration.

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### 7.4. Items often forgotten

- **Syringes, needles, and water** must be provided for each injection.
- **Needle disposal containers** must be provided for each DR-TB DOT Supporter who is providing injections.
- **Ancillary drugs for side effects.** Some may be widely available because they are considered essential drugs, but many are not. The NTP should ensure that MDR-TB teams at facility levels have access to sufficient quantities of commonly-used ancillary drugs. A short list is provided below. For more information on the use of ancillary drugs, refer to the clinical guidelines for MDR-TB.
  - Anti-emetics: metoclopramide, prochlorperazine, ondansetron
  - Anti-depressants: sertraline
  - Anti-convulsants: phenytoin
  - Anti-psychotics: haloperidol, risperidol

- Antihistamines: chlorpheniramine
  - Anti-diarrheals: loperamide
  - For neuropathic pain: amitriptyline
  - Family planning: depot medroxyprogesterone acetate
  - For physical pain and air hunger: opioids
- **Monitoring tests.** Most of the basic blood tests for screening and treatment of side-effects are available in any hospital. But additional budgeted funds may be necessary for these tests, especially in hospitals where there are DR-TB inpatients. DR-TB patients often need frequent monitoring of electrolytes and creatinine after being admitted.
  - **Approved particulate respirators (N95)** for hospital staff, laboratory staff, and DR-TB DOT Supporters should be made available at the health facility.

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## 7.5. Storage conditions in the community

For storage packs or containers for second-line TB drugs, consider the following options:

- Wooden boxes are durable, but can be difficult to take back and forth from the pharmacy.
- Canvas bags are light and convenient, but may tear after several months, so a sufficient supply of replacement bags will be necessary.
- Synthetic bags are heavier but more durable than canvas bags. Some are insulated and may help guard against extreme temperatures.

PASER is a brand of PAS (P-aminosalicylic acid) that is available through the Global Drug Facility. PASER should be stored in a refrigerator in the pharmacy, but is stable at room temperature for several weeks. This means that after the monthly drug pack is delivered to the patient's DR-TB DOT Supporter, it does not need to be refrigerated. The patient's DR-TB DOT Supporter should be instructed to keep the drug pack in a part of the house that does not experience extreme cold or heat.

# COMMON LABORATORY ISSUES

## 8.1. Transportation of specimens

The MDR-TB Team should establish a well-structured system for sputum collection and transportation. If specimens are not in well-sealed containers, they can become dried out and can also be a danger to others. Always transport sputum in an approved sputum container.

Sputum samples should be cultured within 4 days of being collected:

- For specimens that cannot be cultured within 4 days: refrigerate at +4 °C until transport and transport to the laboratory for processing as soon as possible. When transporting these specimens, pack in a container with ice.
- Never use cetylpyridinium chloride (CPC) in a specimen that is going to be refrigerated, as the CPC will crystallise.

For areas that are remote from a culture laboratory, new methods appropriate for peripheral laboratories (e.g., Xpert MTB/RIF) are becoming more available. However, these tests often need to be confirmed with conventional culture and DST.

## 8.2. Diagnosing and keeping track of MDR-TB suspects

The following system is established to communicate drug susceptibility testing (DST) results in a timely fashion (as soon as they are available) to clinicians at all levels. This system uses a combination of paper result forms and text messages.

- All diagnostic culture and DST requests (and Xpert MTB/RIF requests) are filled out with the Request for Cultures and Sensitivity Test form for diagnosis. If the form is not filled out correctly, the national TB laboratory may not be able to contact the patient or clinician who originally ordered the DST.

- The NTP focal officer for MDR-TB should regularly review the records of the national TB laboratory for any new patients who have been diagnosed with MDR-TB. These patients should be started on MDR-TB treatment by the district MDR-TB team and arrangements should be made for patients to receive follow up care with the Outpatient MDR-TB Team at the DR-TB referral clinic. Treatment will be under a trained and accepted DR-TB DOT Supporter. The follow up visits at the referral DR-TB clinic must be attended monthly during the injectable phase of the patient's treatment and then every other month thereafter until the completion of treatment.
- In the case of an Xpert MTB/RIF-positive patient, the facility should communicate with the NTP focal officer for MDR-TB. The patient should be started on second-line anti-TB drugs by the district MDR-TB Team trained in MDR-TB.
- Registers can be used at district-level facilities to ensure that all DR-TB suspects are accounted for and that DST results have been received. Staff at the district level should fill in a form to record all DR-TB suspects. Laboratory and treatment registers can be found in Malawi NTP's *Guidelines for the Programmatic Management of Drug-resistant TB* (June 2012 Revision).

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### 8.3. Monitoring cultures

Monitoring cultures are done every month during the intensive phase and every other month during the continuation phase while the patient is in treatment. Samples are collected for monitoring cultures when the patient comes in for his or her monthly visit at the DR-TB referral clinic.

Note that Xpert MTB/RIF should never be used as a monitoring tool as it can detect dead bacilli that do not indicate the patient is failing treatment.

Repeat DST can be done on patients that remain culture positive beyond 3 months of the intensive phase or on any patient considered to be not responding to MDR-TB treatment. Consider requesting DST for both first- and second-line anti-TB drugs.

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## 8.4. Blood tests for side effect screening

The recommended screening blood tests are described in Malawi NTP's *Guidelines for the Programmatic Management of Drug-resistant TB* (June 2012 Revision). These side effects include acute renal failure, hypokalaemia (low potassium), hepatitis, and hypothyroidism. The following blood tests should be done at the monthly visit during the intensive phase unless otherwise noted:

- Creatinine and potassium (monthly while on the injectable agent)
- Full blood count (if anaemia is suspected)
- Thyroid stimulating hormone (every 6 months)
- Pregnancy (if pregnancy is suspected)
- HIV (every 3 months while on MDR-TB treatment)
- Liver function tests (if symptoms of hepatitis occur, or continue monthly if at risk for hepatitis)

Point-of-care testing is an excellent way to improve screening for side effects and it is hoped to be introduced in high-volume clinics. Handheld devices using cartridges allow results to be known instantly and appropriate treatment started quickly. Some testing devices are portable and can even be taken along to home visits. Specific tests depend on the manufacturer, but creatinine, potassium, and haemoglobin tests are available.

# CONTINUITY OF CARE

## 9.1. Indications for hospitalisation at start of treatment

Some patients will need to be hospitalised in a facility designed for the management of MDR-TB patients (such as an isolation room at a district hospital) at the start of treatment. Living conditions while in the hospital should be acceptable. The patient should be provided with sufficient activities to avoid boredom and should also be provided with good nutrition. Strict DOT starts in the hospital for these patients. Patient education on MDR-TB should begin while the patients are in hospital. Reasons for initial hospitalisation are multifold and can include:

- The patient is too sick and fragile to start treatment at home (usually this is determined at the discretion of the MDR-TB Team);
- To have an intensive time period to educate the patient on the disease and its treatment;
- To document that the patient is tolerating the medicines well; and
- To allow time for outpatient home-based care to be arranged.

Despite these benefits from hospitalisations, there are a number of benefits for starting patients on treatment at home that include decreased risk of transmission to hospital staff as well as other patients and keeping the patients close to their family support systems. Most patients, especially those who are relatively healthy, can be started on quality home-based care.

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## **9.2. Indications for a patient on community-based care to be hospitalised**

Occasionally patients will need to be admitted to the hospital after they have started on treatment in the community. The criteria for admission to the hospital are as follows:

- Worsening condition
- Adherence problems or severe side effects
- Immobility
- Vulnerability of patients (e.g., disadvantaged orphans; mentally, socially, or physically handicapped)

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## **9.3. Discharge from the hospital**

Discharge from the hospital will occur only when the patient's condition that resulted in hospitalisation is improved. In general the patient should be tolerating drugs (no major side effects) and showing signs of improving. The Outpatient MDR-TB Team should be ready to provide community-based DOT. The team should also ensure that patient's household is ready to receive the patient and that it has been assessed for infection control.

Patients do not need to be smear and culture negative before discharge if home infection control measures are in place.

When possible, the Focal DR-TB Nurse should perform a home assessment prior to discharge for all patients (see Section 5.1). If adherence issues are identified, then the community nurse will conduct a follow-up home assessment focussing on adherence issues.

For continuity of care, before the patient is discharged, it is essential to ensure that there is good communication between representatives from the hospital (e.g. doctor, clinical officer or hospital nurse); the Outpatient MDR-TB Team (especially the Focal DR-TB Nurse); the DR-TB DOT Supporter; the patient; and the patient's family. All parties should:

- Agree that the patient is medically stable for discharge.
- Agree to where the patient should be sent (home or other housing situation).
- Inform and prepare the family for the patient's arrival.
- Identify (and train if not already trained) the DR-TB DOT Supporter. Discuss

the major issues that occurred during the hospitalisation, including any changes to the treatment regimen.

- Fill out the hospital discharge form and include the original treatment card to be sent to the facility where the MDR-TB team caring for the patient is located. (Note: a copy of the discharge summary and treatment card should stay in the patient's hospital record. The original treatment card will be kept with the DR-TB DOT Supporter and a second copy will be kept in the clinic).
- Ensure the pharmacy prepares the correct patient drug pack before discharge by filling out a prescription form (see Section 7.2).
- Prepare transportation from the hospital.

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#### **9.4. Follow-up after completion of treatment**

After completing treatment, each patient should be monitored for the next year with clinical and bacteriological follow-up.

- Patients should be instructed to return to the health facility for evaluation in case they experience recurrence of TB symptoms.
- Household contacts should be informed that the risk of developing MDR-TB continues after the patient has been cured and that they should report to the health facility if they develop any TB symptoms.
- Proper referrals for other medical and social services should be put in place prior to discharge from treatment. Refer patients to the nearest clinic for follow-up of chronic medical problems (such as HIV or diabetes) that were managed by the MDR-TB team during treatment.

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#### **9.5. Additional considerations**

Some types of patients will need special considerations for treatment. These considerations are described in Malawi NTP's *Guidelines for the Programmatic Management of Drug-resistant TB* (June 2012 Revision). This includes patients who are:

- HIV co-infected
- Children
- Diabetics
- Alcohol or substance abusers
- Patients with liver disorders
- Patients with kidney disorders
- Pregnant
- Mentally ill
- Prisoners or institutionalised

# CONTACT TRACING

A list of the patient's close contacts (including those from outside of the household) should be developed upon diagnosis and kept in the patient's clinical record. The DTO screens all household contacts during the initial home assessment. Thereafter, it is the role of the DR-TB DOT Supporter to regularly screen identified household contacts.

- Close contacts of MDR-TB patients are people living in the same household. These may include:
  - People spending nights in the same room as the patient, including spouses, children, caretakers, etc.; and
  - People spending time in common areas (in the workplace, institution, etc.) for several hours on multiple days.
- All household contacts should receive HIV counselling and testing.
- All children five years of age and under should be evaluated by a clinician trained in paediatric TB and DR-TB even if they are asymptomatic.
- Adult close contacts who answer yes to any question on the symptom screen should have:
  - A chest x-ray done;
  - A sputum smear, culture, and drug susceptibility test done; and
  - An evaluation by a clinician, preferably the MDR-TB clinician. The evaluation should include a history and physical examination.
- Close contacts of MDR-TB patients should receive careful clinical follow-up for a period of at least two years, especially if the contacts are children. If active disease develops, appropriate treatment should be initiated. Refer to *Guidelines for the Programmatic Management of Drug-resistant TB* (June 2012 Revision).
- The routine use of second-line drugs for chemoprophylaxis in MDR-TB contacts is currently not recommended.



# RECORDING AND REPORTING

## 11.1. Treatment card for patients receiving second-line TB drugs

There should be three copies of the treatment card for each patient. A copy is provided in the Malawi NTP's *Guidelines for the Programmatic Management of Drug-resistant TB* (June 2012 Revision).

- One copy should be given to the DR-TB DOT Supporter, who is responsible for recording all doses. Generally the patient should not keep the treatment card. This is considered the “original” copy.
- One copy is kept in the clinic outpatient file (often at the health centre where the patient receives treatment).
- One copy is kept with the Outpatient MDR-TB Team.
- The information from the treatment card kept by the DR-TB DOT Supporter should be transferred to the treatment card kept at the clinic at each monthly medical consultation.
- Any changes to the treatment regimen should be written on both treatment cards.

The DOT Book also records the daily drugs given in much more detail than on the treatment card (see Section 4.8).

## 11.2. Quarterly report of community-based activities by the Outpatient MDR-TB Team

This form should be filled out by the Focal DR-TB Nurse each quarter.

### Quarterly Report Form

Quarter \_\_\_\_\_ Year \_\_\_\_\_

Filled by \_\_\_\_\_ Title \_\_\_\_\_

DR-TB Clinic Team Name: \_\_\_\_\_

Focal DR-TB Nurse Name: \_\_\_\_\_

List the patients who stopped MDR-TB treatment this month and their outcomes (include patients who are Xpert MTB/RIF positive but confirmed not to have MDR-TB and who transferred back to first-line treatment):

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### New Patient Enrolment

1. Number started on treatment because of confirmed MDR-TB	
2. Number started because of Xpert MTB/RIF positive result	
3. Total number of new patients started on second-line anti TB drugs (in number 1 plus in number 2) in the quarter	
Number started at home	
Number started in hospital	
4. Number of patients who discontinued second-line TB drugs	
5. Number of new patients (in number 3) who are HIV positive	

Total number of patients on MDR-TB treatment at end of quarter (patients still on treatment plus new patients):

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## Home Visits

Number of home assessments	
Number of home visits for other reasons	

## Emergencies

List of emergencies (provide a brief explanation of each):

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## Deaths

List of patients who died at home:

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### 11.3. **Transfer form**

Patient's name

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Registration number

---

Age

Sex

Date of transfer

---

Receiving clinician

---

Tel.

---

Date discussed with receiving clinician

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Reason for transfer:

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Presenting symptoms and treatment course:

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Please find attached photocopies of the patient's treatment card and most recent bacteriology and drug susceptibility testing results. For additional information, please contact us.

Clinician's name

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Clinician's signature

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Clinician's tel. no.

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# FREQUENTLY ASKED QUESTIONS

## **Does treating patients at home pose a risk to the community?**

The risk of a household contact becoming infected with TB is very small after proper treatment has started. The reality is that by the time the vast majority of patients have been diagnosed with MDR-TB, they have been infectious for months or even years. This means that their close household contacts may already be infected. Taking the patient out of the home does not change this fact. Rather, it is important to explain to the family members how to decrease the risk of developing active TB disease. Explain the symptoms of active TB and implement a system of screening household contacts of MDR-TB patients. Once patients are on effective treatment the risk of transmission is greatly reduced; however, patients failing MDR-TB treatment or those not taking the medicines correctly can still transmit the disease.

## **Isn't it important to isolate patients with MDR-TB?**

Isolation is less important than treatment. It is very difficult to truly isolate a TB patient. Hospitals, even those designated for the treatment of MDR-TB, are usually not adequately equipped for isolation of airborne infections. Transmission in the hospital is very common and this is dangerous for other patients as well as for hospital staff. On the other hand, effective treatment results quickly in the patient becoming non-infectious, no matter where the patient is.

## **Is DOT really necessary?**

DOT is extremely important for MDR-TB treatment. Second-line TB drugs have many side effects and MDR-TB treatment is very long. Treatment with these drugs represents the last possibility for these patients to be cured. Most patients will default if there is no daily support. It is also important to monitor patients for serious side effects. DOT can and should be provided in a supportive rather than punitive manner.

## **Why do DR-TB DOT Supporters need to be compensated for their work?**

Reciprocity is an ethical principal to reward (“compensate”) someone who does a service for benefit of the community. It is true that there are some people who will participate in community health work—even exposing themselves to significant risk—for no compensation. However, in many poor communities, this is not feasible as a long-term strategy, because people need a way to put food on the table.

Compensation of DR-TB DOT Supporters creates a more sustainable community-based programme. It is expensive and time-consuming to continually be recruiting and training new people to replace those who left because their work was not sufficiently rewarded.

## **Do enablers such as food packages and transportation reimbursements improve TB treatment outcomes?**

Yes. One of the most important aspects to achieve better outcomes in TB treatment is patient adherence. There is credible evidence that food packages and transportation reimbursements are powerful enablers that improve patient adherence to TB treatment. It is true that there is less evidence of the effect of nutrition on other TB treatment outcomes, compared to the very strong evidence showing that food improves the outcomes of HIV-positive patients. There are a number of ongoing studies that are assessing the effect of nutritional supplements on TB treatment outcomes.

## **How do we best educate and support patients about DR-TB?**

One method is by using the five A's (**Assess, Advise, Agree, Assist, Arrange**).

Patient education starts at the beginning of the treatment and should be repeated when the patient starts community care. Some patients will start treatment in the community and will need a number of sessions with members of the referral team or the MDR-TB Team. Ongoing education will be continued at every clinical visit. The hospital or outpatient team member will prepare the patient for community-based care by using the five A's:

- **Assess** patient's knowledge and ability to take the MDR-TB treatment:
  - How he or she was infected with a drug-resistant strain;
  - His or her understanding of MDR-TB therapy;
  - Ability to adhere with treatment; and
  - Whether he or she can comply with DOT.

- **Advise** and teach:
  - Drug-resistant TB:
    - Is created when TB patients do not take anti-TB drugs regularly or incorrectly;
    - Can be transmitted to family members and friends; and
    - Can be easily transmitted to people living with HIV.
  - MDR-TB treatment lasts for at least 2 years.
  - Second-line anti-TB drugs are weaker/less potent than the first-line anti-TB drugs. Every single dose must be taken under direct supervision (observed by a DR-TB DOT Supporter). If not, there is a chance of treatment failure and development of XDR-TB.
  - There is no other treatment for MDR-TB.
  - Second-line anti-TB drugs have many side effects but these can be managed. The clinical team and the MDR-TB DOT Supporter must communicate closely with each other about side effects.
  - The patient is most infectious during the first few months when he or she is still smear positive. During this period patients need to use surgical masks or handkerchiefs. Windows and doors should be left open in the home to increase ventilation.
- **Agree:**
  - That the patient is willing to undergo at least 2 years of treatment with second-line anti-TB drugs;
  - That the patient is willing to receive directly observed therapy;
  - About who will observe the therapy;
  - That the programme will stop treatment if the patient does not take doses regularly; and
  - That the patient is willing to come once a month during intensive phase and every other month during continuation phase to the MDR-TB clinic at the respective hospital for follow-up.
- **Assist** by:
  - Discussing that DOT medications can be adjusted at clinic or home;
  - Making sure the patient receives the complete socioeconomic support package; and
  - Ensuring support for transportation.

• **Arrange:**

- A DR-TB DOT Supporter for each patient per the guidelines and profile outlined in this document; and
- Education about MDR-TB and how to do DOT for the DR-TB DOT Supporter.

**What are some good reminders that a DR-TB DOT Supporter can give during each visit?**

The DR-TB DOT Supporter should remind the patient about one or more relevant messages during every visit. This is a list of advice a DR-TB DOT Supporter can use for common situations; it is taught in the training of DR-TB DOT Supporters.

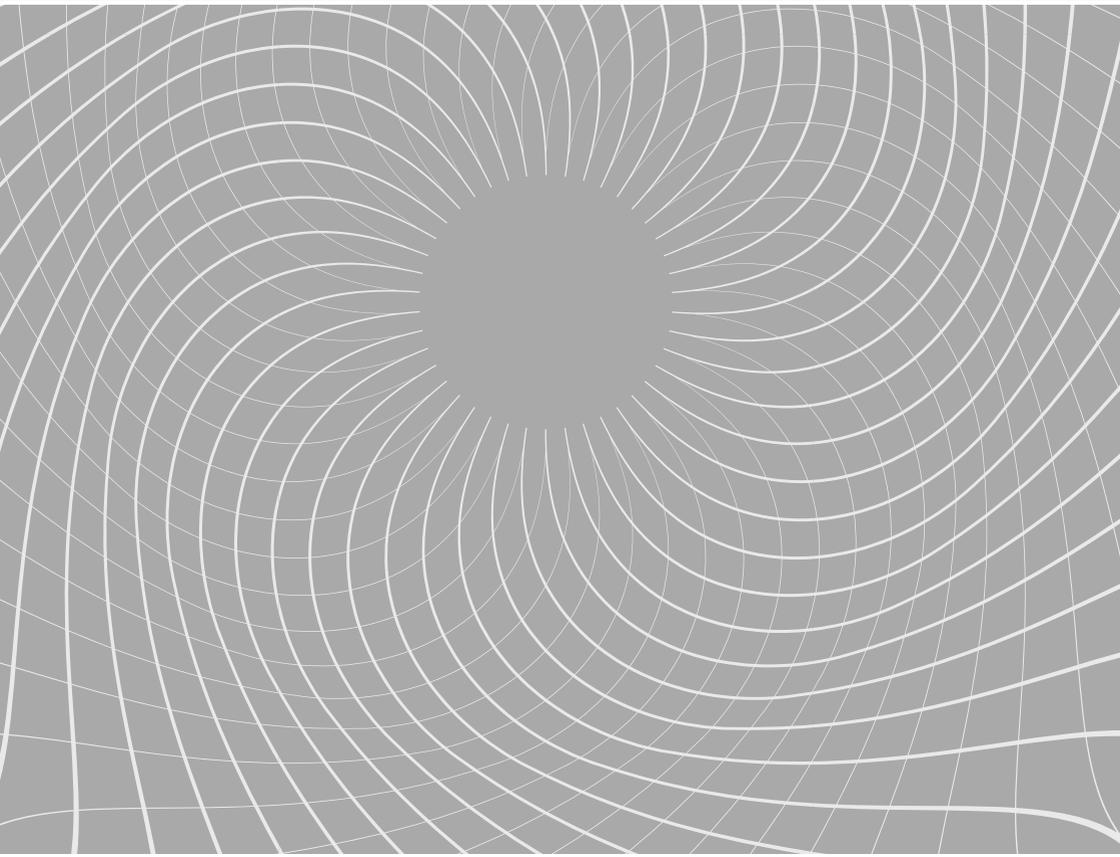
<b>Situation</b>	<b>Advice</b>
<b>If the patient has not yet brought symptomatic household contacts for examination or testing</b>	All household members with cough should be tested.
<b>If the patient is unfamiliar with the drugs, or a change occurs in the regimen</b>	Describe the type, colour, and amount of drugs to be taken by showing the drugs to the patients. Describe how often drugs should be taken and for how long.
<b>If the patient feels better</b>	Say, <i>“Even after you feel better, you must continue taking drugs for the entire treatment period.”</i>
<b>If the patient is planning to travel or move</b>	Say, <i>“If you plan to travel or move from the area, please inform me. We can make arrangements so that you will not miss any dose treatments.”</i>
<b>If the patient has missed a dose</b>	Say, <i>“To be cured, you must take all of the recommended drugs daily until completion of treatment together for the entire duration with completion of the entire dose. If you do not take all of the drugs, you will continue to be ill and spread TB to others and develop almost incurable TB.”</i>











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