AMBULATORY CARE GUIDE FOR MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS PATIENTS AT DISTRICT LEVEL

2024

NATIONAL PROGRAMME FOR TUBERCULOSIS CONTROL AND CHEST DISEASES (NPTCCD)

AMBULATORY CARE GUIDE FOR MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS PATIENTS AT DISTRICT LEVEL

2024

PREFACE

Tuberculosis continues to pose a significant public health challenge globally, and the emergence of drug-resistant forms has further compounded the complexity of its management. In Sri Lanka, although the burden of MDR/RR-TB remains relatively low, the persistent gap between estimated and notified cases, as well as suboptimal treatment outcomes from centralized institutional care, has necessitated a paradigm shift in how care is delivered to patients.

The global move toward patient-centred, decentralized models of care, as endorsed by the World Health Organization (WHO), has demonstrated that drug-resistant TB can be managed safely and effectively in community settings. These approaches not only reduce the burden on tertiary care institutions but also enhance treatment adherence, empower communities, and uphold the dignity and wellbeing of patients.

This Ambulatory Care Guide for Management of Drug-Resistant Tuberculosis Patients at District Level – 2024 has been developed to support this transition in Sri Lanka. It serves as a practical resource for district-level healthcare workers, providing step-by-step guidance on diagnosis, treatment initiation, patient monitoring, drug handling, adverse event management, and the integration of psychosocial support systems. The guide aligns with the existing Programmatic Management of Drug-Resistant TB (PMDT) Guidelines and supplements and provides detailed, district-adaptable operational strategies.

I extend my sincere appreciation to all experts and stakeholders involved in developing this guide, including the editorial panel, contributors from district chest clinics, national institutions, and international technical partners. Their insights and experience have been invaluable in shaping a comprehensive framework tailored to Sri Lanka's evolving TB control landscape.

I hope this guide will enhance the capacity of frontline health workers to deliver compassionate, evidence-based care, bringing us one step closer to our national and global commitments to End TB.

Dr. Pramitha Shanthilatha

Director

National Programme for Tuberculosis Control and Chest Diseases

Ministry of Health, Sri Lanka

EDITORIAL PANEL

International expert contribution

Dr. Muhammad Asif	WHO Consultant for Tuberculosis and Drug Resistant Tuberculosis

National Programme for Tuberculosis Control and Chest Diseases

Dr. Onali Rajapakshe	Consultant Community Physician/ NPTCCD
Dr. Mizaya Cader	Consultant Community Physician/ NPTCCD
Dr. Chamika Herath	Consultant Microbiologist/ NTRL, NPTCCD
Dr. Wathsala Galagedara	Consultant Microbiologist/ NTRL, NPTCCD
Dr. Pramitha Shanthilatha	Director/NPTCCD
Dr. Shiromi Malwatta Mohotti	Consultant Community Physician/ NPTCCD
Dr. Kaushalya Rajapaksha	DTCO – Gampaha
Dr. Ruwanthika Kariyakarawana	Medical Officer/ NPTCCD

Sri Lanka College of Pulmonologists

Dr Bandu Gunasena	Consultant Respiratory Physician
Dr Neranjan Dissanayake	Consultant Respiratory Physician
Dr. Eshanth Perera	Consultant Respiratory Physician
Dr Bodhika Samarasekara	Consultant Respiratory Physician

Coordinators

Dr. Onali Rajapakshe	Consultant Community Physician/ NPTCCD
Dr. Ruwanthika Kariyakarawana	Medical Officer/ NPTCCD

Page Setup and Graphics

Dr. Ahmed Shiyam	Registrar in Community Medicine/NPTCCD

TABLE OF CONTENTS

ISBN 978-624-6511-33-3

Suggested citation
National Programme for Tuberculosis Control and Chest Diseases (2024). *Ambulatory care guide for management of drug-resistant tuberculosis patients at district level 2024*. Ministry of Health, Sri Lanka. ISBN 978-624-6511-26-5

ABBREVIATIONS

aDSM	Active Drug Safety Monitoring and Management
ALLR	All Oral Longer Regimen
ATP	Adenosine Triphosphate
Bdq	Bedaquiline
cfu	Colony Forming Units
CXR	Chest X-Ray
Dlm	Delamanid
DR-TB	Drug-Resistant Tuberculosis
DST	Drug Susceptibility Testing
ECG	Electrocardiogram
Eto	Ethionamide
FBC	Full Blood Count
FQ	Fluoroquinolone
GXP	GeneXpert
HbA1C	Hemoglobin A1C
INH	Isoniazid
LFT	Liver Function Test
Lfx	Levofloxacin
LoD	Level of Detection
Lzd	Linezolid
MDR-TB	Multi-Drug Resistant Tuberculosis
Mfx	Moxifloxacin
MTBC	Mycobacterium Tuberculosis Complex
OLTR	Oral Longer Treatment Regimen
OSSTR	Oral Standard Short-course Treatment Regimen
Pa	Pretomanid
PLHIV	People Living with HIV
PMDT	Programmatic Management of Drug-Resistant TB
RR-TB	Rifampicin-Resistant Tuberculosis
SE/SAE	Side Effect / Severe Adverse Event
SRLN	WHO Supranational Laboratory Network
TPT	Tuberculosis Preventive Treatment
WRD	WHO Recommended Rapid Diagnostics
XDR-TB	Extensively Drug-Resistant Tuberculosis

LIST OF TABLES

ANNEXURES

1. Background and Rationale

Sri Lanka is a low burden country for TB. In 2022 WHO estimated that 14,000 (62/100,000) population developed TB and 86 (0.39/100,000 population developed MDR/RR TB in Sri Lanka. However, the notification rate for MDR/RR TB in the country remained far below the WHO estimates over the years. In order to maintain the low notification rate and to prevent the spread of MDR/RR TB, Sri Lanka has been adopted a stringent institutional care for all MDR/RR TB patients since inception. The care was provided in a centralized institution at national level, the National Hospital for Respiratory Diseases (NHRD) until culture conversion or sometimes until end of the treatment. This decision was taken based on the treatment regimens used in the past being injectables lasting 18 to 24 months with considerable toxicity which needed rigorous adverse events monitoring and prevention of spread of the disease by applying optimum IPC measures. However, adoption of such a model in Sri Lanka didn't produce promising outcomes in relation to MDR TB and the treatment success remained very low compared to WHO estimates.

A revolution of MDR TB management is currently observed with the emerging research evidence, and the development of new treatment regimens, especially all oral regimens with treatment durations of 6 to 9 months. The World Health Organization (WHO) recommends that standard treatment for TB, whether drug-susceptible or drug-resistant, should be given as decentralized ambulatory care, with patients remaining within their community and continuing with normal life, so, they feel well enough unless hospitalization is indicated. Pillar one of the End TB Strategy explicitly adopts a patient-centered approach, which puts "patients at the heart of service delivery". A patient-centered approach recognizes that the direct beneficiary of TB care is the individual who is sick, and that strategies must be designed with this individual's rights and welfare in mind. This recommendation provides the basis for development of all approaches to TB care including MDR TB to be decentralized as ambulatory care unless indicated.

Further, the WRD facilities are decentralized currently in the country, which has led to increased case detection of RR/MDR TB. Therefore, strengthening of decentralized ambulatory care is a necessity to minimize the cost incurred and resource requirement when treating the patients institutionalized.

This recommendation itself is underpinned by the knowledge of the infectiousness of individuals affected by TB. Once an effective treatment regimen has commenced, the bacteriological load is rapidly reduced and the patient becomes non-infectious within a few days. Smear conversion is an indicator of cure of the individual patient; it is not an indicator of infectiousness. Patients under treatment represent no danger to other people once they are established on an effective treatment regimen. Furthermore, as TB transmission is not a matter of casual contact, even untreated individuals are of danger only to close contacts or in settings where there is contact over prolonged periods.

As such, considering WHO recommendations and the achievements of the countries that have already adopted provision of shorter treatment regimens through decentralized ambulatory care, Sri Lanka has taken a policy decision to scale up decentralized ambulatory care for MDR/RR TB patients who are currently being institutionalized until culture conversion or throughout the entire treatment period.

2. Existing and proposed district level structure for TB care

The National Program for Tuberculosis Control and Chest Diseases (NPTCCD) functions with a network of District Chest Clinics. Central Chest Clinic Colombo, Chest Clinic Gampaha, Central Drug Stores (CDS) and National Tuberculosis Reference Laboratory (NTRL) are functioning directly under the Director/ NPTCCD while the NHRD which was earlier under the purview of Director NPTCCD, currently functions as a line Ministry institution.

TB service delivery is multimode and provided via curative as well as preventive care institutions. Diagnostic services are provided through the TB labs stationed in 26 DCCs and the peripheral microscopic centers in primary, secondary, and tertiary care institutions (more than 160). WRD facilities are provided in 29 sites, in a range of institutions such as NTRL, selected DCCs and larger hospitals covering each and every district of the country. TB treatment services are decentralized and provided via DCCs and more than 100 branch clinics established in different healthcare institutions. The preventive staff, the Medical Officer of Health and the public health inspectors are involved in case investigation, defaulter tracing and provision of health promotive and preventive services at the community level.

Existing model of care for MDR/RR TB patients

Sri Lanka has been practicing a single model of care for MDR/RR TB patients by providing centralized institutionalized care in the National Hospital for Respiratory diseases. All patients who found to have RR/RH resistant results are transferred to NHRD where specialized management for all MDR/RR TB patients is offered. When such patients are detected at district level, the PMDT focal point stationed in NHRD is informed over the phone and the patients are transferred as per the set guidelines. The transferred patients will be started on RR/MDR TB regimens based on the laboratory confirmation by the National TB Reference Laboratory. The time between the transfer of patients to NHRD and treatment initiation will vary significantly depending on the microbiological and clinical decisions, and this has been identified as a major gap in the existing model during the recent TB programme review. Further, all MDR/RR TB patients remain hospitalized until the decision to transfer out the patients is taken based on culture conversion and clinical decision. During the continuation phase, unless there are complications that need continuous institutional care, all patients are being followed up at the DCCs. PMDT site committee meetings are held at NHRD by the clinical team to discuss overall patient management and regular PMDT meetings are conducted with the

participation of respective DTCOs responsible for follow up care of the patients transferred to districts.

Sri Lanka has adopted below WHO recommendations and plans are underway to shift to a predominantly decentralized ambulatory care model from the current institutional care.

WHO Recommendations for the treatment and care of MDR/RR TB patients:

1. Patients with multidrug-resistant TB (MDR-TB) should be treated using mainly ambulatory care rather than models of care based principally on hospitalization (conditional recommendation, very low certainty of evidence).

2. A decentralized model of care is recommended over a centralized model for patients on MDR-TB treatment (conditional recommendation, very low certainty of evidence).

Definitions:

1. **Ambulatory care** refers to the medical care and services provided to the patient on an outpatient basis, without admission to the hospital. It includes diagnosis, treatment, monitoring, any interventions, and rehabilitation services.

2. **Decentralized care** is defined as treatment and care provided in the local community where the patient lives. This could be through peripheral health centers including clinics, community health workers, non-specialized doctors (General practitioners/doctors at primary health care units), community volunteers or treatment supporters. The settings could be clinics/ health centers/ patient's home or workplace.

3. **Centralized care** is defined as inpatient treatment and care provided solely by a defined Centre or teams specialized in drug-resistant TB for the duration of the intensive phase of therapy or until culture or smear conversion.

The model of care can be decided by the district level local PMDT committee doing the initial assessment of the patient. As required, assistance and expert opinion from the central PMDT committee should be sought.

Proposed models of care for MDR/RR TB patients

1. **Community Based care coupled with clinic-based care (branch clinic/ District Chest Clinic):**

Under this model, patients receive full course of treatment under DOT on ambulatory basis, irrespective of their sputum smear/culture status, at a venue in the community. A DOT provider who may come from the same neighborhood, (field health worker, General Practitioner, community volunteer) is selected after considering patient preference & convenience and the ability to take up the responsibility. The venue is agreed between the patient and the DOT provider. These patients need to be monitored for aDSM at a given time frequency (weekly/once in two weeks/ monthly) by a team trained on aDSM monitoring preferably in a clinic setting (branch clinic/DCC) while continuing the daily symptomatic monitoring for aDSM by the community care providers.

The frequency will be decided upon by the PMDT committee under the patient management plan and according to the follow up frequencies outlined in the PMDT supplement 2024 by the NPTCCD and the Chapter 5 of this guide on 'Follow up of MDR/RR TB patients at district level'.

Conditions to be met in order to offer a community based ambulatory care for RR/MDR TB patients

- Presence of community health worker/community volunteer in the same neighborhood and willingness to provide care
- No medical indication for receiving long term care in the hospital
- No social (lack of social support etc.)/ behavioral (substance abuse etc.) implications that need institutionalized care
- All community MDR-TB care providers are trained on DOT & monitoring of aDSM based on signs and symptoms. They should adhere to protocols for community led monitoring and TB infection prevention and control.

- Availability and willingness of community MDR-TB care providers to provide DOT minimum 6 days per week
- Availability of facilities and trained staff on Active TB drug-safety monitoring (aDSM) in the branch clinics/ DCCs on a given time frequency
- Community care providers are trained on ethics to maintain confidentiality and to reduce stigma

Patient and relatives at the household are informed and educated on TB infection prevention and control practices

2. **Decentralized Clinic Based ambulatory care:**

Under this model, patients receive the full course of treatment via daily DOT on ambulatory basis at an outpatient health care facility (District Chest Clinic) irrespective of the sputum smear/culture status. The decision has to be made after considering the overall clinical condition of the patient, patient preference, proximity to clinics, and the cost incurred for transport. This model of care requires the patient to travel from home and receive the medicines under DOT at the clinic, therefore should be entertained for patients who are in close proximity. When the patient receives clinic-based treatment, priority and rapid access to DOT should be ensured to allow a quick departure from the facility.

Conditions to be met in order to offer a clinic based ambulatory care for RR/MDR TB patients

- No medical indication for receiving long term care in the hospital (e.g., co-existing comorbidities requiring close monitoring etc. to be decided by the PMDT committee)
- No social (lack of social support etc.)/ behavioral (substance abuse etc.) implications that need institutionalized care
- Should live in close proximity/ or should be able to spend on transport
- Not too ill to travel every day to the clinic to receive treatment under DOT

- Sufficient staff are available to guarantee DOT for all attending patients
- Each patient is personally allocated to a specific DOT provider to ensure continuation of care and coordination with the DCC
- DOT services are available at least six days a week
- Availability of facilities and trained staff on Active TB drug-safety monitoring (aDSM)
- Periodic evaluation at the DCC/Branch clinic on a predetermined schedule.
- All staff are trained and adhere to administrative protocols for TB infection prevention and control
- Patient and relatives at the household are informed and educated on TB infection prevention and control practices
- Social support to patients covers out-of-pocket and indirect costs, especially transport to and from the clinic.

3. **Decentralized institutional care (hospital-based care) followed by clinic/community based ambulatory care**
4. **Centralized institutional care (hospital-based care) followed by clinic/ community based ambulatory care**

- Adherence to model 3 and 4 has to be considered when the diagnosed RR/MDR TB patients have one or more indications mentioned above that needs institutional care. In the event of a patient requiring institutionalized care, the local PMDT committee should request the opinion from the Central PMDT committee experts. The decision on decentralized or centralized institutional care needs to be taken considering the clinical conditions of the patient and the availability of clinical experts in the district to manage such conditions, and the infrastructure in particular whether the institutions equipped with international standards for respiratory infection control including respiratory isolation rooms. If adequate expertise to manage the patient is not available at the

decentralized institutions, the panel can decide on transferring the patient to the centralized institution with the team specialized for MDR TB care. More importantly, institutionalized care should be able to provide a holistic care for MDR TB patients beyond treatment only management ensuring phycological, social and economic wellbeing of the patients who are under care.

Conditions to be met in order to offer decentralized/ centralized institutional care for RR/MDR TB patients.

- Presence of a medical indication for receiving institutionalized care with close monitoring (e.g., uncontrolled DM, extensive TB, CKD requiring close monitoring of vital signs etc.)
- Presence of social (lack of social support etc.)/ behavioral (substance abuse etc.) implications that need institutionalized care
- Basic infrastructure of the hospitals is fully compliant with international standards for respiratory infection control and respiratory isolation rooms are available for all patients who remain smear positive/culture positive.
- Availability of facilities and trained staff on Active TB drug-safety monitoring (aDSM)
- All staff are trained and adhere to administrative protocols for TB infection control.
- Sufficient staff are available to guarantee DOT for all patients.
- Open and safe space is available for patients to socialize and conduct occupational therapy activities.
- Friendly administrative procedures are in place to facilitate regular access of relatives visiting patients.
- Protocols are in place for effective communication and coordination with laboratories providing services during treatment, and with peripheral units receiving patients after discharge from hospital.

- Access of patient progress and treatment details to the relevant District Tuberculosis Control Officer has to be ensured.

- Provisions for TB allowance and other social protection mechanisms to support the families to cope up with income lost and other expenditures

In case of a patient presenting to a DCC/hospital outside of his/her residing district, the relevant district DTCO & CRP also has to be incorporated in decision making from the beginning.

3. Confirmation of diagnosis at district level and coordination with National TB Reference Laboratory

At present GeneXpert testing facilities are established in several hospitals and district chest clinics all around the country. There are 35 GeneXpert machines in the laboratory network.

Truenat MTB Plus and MTB-RIF Dx assays are available in peripheral laboratories in selected districts.

The algorithm 1 in the PMDT supplement 2024 document to be followed up at all GeneXpert/ Truenat testing centres.

Table 1: Recommended action to follow with the reported resistant status

MTB status	**RR status**	**Recommended actions**
MTB detected (High/Medium)	RR detected	Good quality sputum sample to be sent to NTRL for Xpert XDR and liquid culture +DST
MTB detected (Low/Very-Low)	RR detected	Good quality sputum sample to be sent to NTRL for repeat GeneXpert and liquid culture +DST
MTB detected (High/Medium/ Low/Very-Low)	RR Indeterminate	GeneXpert to be repeated with a good quality sputum sample and another sample to be sent to NTRL for liquid culture +DST
MTB detected (Trace)	RR Indeterminate	Good quality sputum sample to be sent to NTRL for liquid culture +DST

Consultant Microbiologist of the relevant district and DTCO to be informed. NPTCCD (PMDT Coordinator and the Consultant Community Physician/PMDT & Lab coordination) and NTRL Microbiologist should be informed via phone /email on the same day by the DTCO. If additional investigations are requested from the NTRL, to coordinate with the NTRL prior to sending the sample for urgent results.

PMDT Coordinator at the central level to follow up on the repeat testing (if done) and inform the NTRL and Consultant Community Physician/PMDT & Lab coordination at NPTCCD regarding the inclusion in to DR TB register and DRTB number.

The patient details should be entered into the PMDT register including the investigation findings at the diagnosis and maintained during the follow up. A copy of the same to be shared with the national level regularly for the central level PMDT register. The monitoring formats are available in the PMDT Supplement 2024 as annexures.

4. Management of a DRTB patient who can be treated ambulatory

Currently the following DRTB categories are treated with different regimen;

1.) MDR/RR TB

2.) INAH resistant TB

3.) PreXDR TB

4.) XDR TB

There is no significant change in the management of INAH resistant TB, PreXDR TB and XDR TB from the previous guideline (refer National guidelines on PMDT 2021, NPTCCD).

MDR/RR TB patients are the most commonly encountered category in Sri Lanka. For the management of MDR/RR TB patients, additional drug regimen (BPaLM) is currently in use in addition to the regimen mentioned in the PMDT guideline, 2021.

1.) **6 months BPaLM** for people above 14 years with MDRTB having susceptibility to fluoroquinolones or when FQ resistance is unknown.

(Still there is no clear evidence supportive of replacing Moxifloxacin with Levofloxacin in this regimen)

2.) **6 to 9 months of BPaL** for patients above 14 years having MDRTB with FQ resistance

3.) **9 to 12 months of oral shorter regimen)** either Ethionamide or Linazolid based regimen if the eligibility criteria are fulfilled (see page 33 national guideline 2022)

Bdq-6, Eto-6 , Hh -6, E-11, Z-11,Cfs-11,Lfx-11 or

Bdq-6, Hh-6, Lzd-2 E-11 Z-11 Cfs-11 Lfx-11

Lzd based regimen is recommended for pregnant or lactating mothers.

4.) **18 months individualized longer regimen** is used when none of the above regimens could be used

The details of the other regimen are given in the PMDT guideline 2021 other than BPaLM.

1.) **6 months BPaLM**

This is the most user-friendly regimen currently available. It consists of four drugs taken orally over a period of 6 months. Currently, this is the priority regimen in use in Sri Lanka.

Table 2: Dosing in BPaLM regimen

Drug	Dose	Number of Tablets (26 weeks)
Bedaquiline (100 mg tablets)	400 mg once daily for 2 weeks, followed by 200 mg 3 times per week for 24 weeks	200
Pretomanid (200 mg tablets)	200 mg once daily for 26 weeks	182
Linezolid (600 mg tablets)	600 mg once daily (adjustable only after 9 weeks) for 26 weeks	182
Moxifloxacin (400 mg Tablet)	400 mg once daily for 26 weeks	182

The details of BPaLM regimen and other newer regimen are given in the PMDT Supplement 2024 published by the NPTCCD.

5. Follow up of DRTB patients at district level

Aims of patient follow up are;

1. To ensure treatment adherence
2. To ensure drug regimen effectiveness and disease response to treatment
3. To identify any side effects of drugs and address them
4. To assess overall health of the patient including psychological well being
5. To provide any social support as required

The drug regimen of choice is BPaLM which offers minimal side effects. However, to ensure above goals, following measures have to be adhered to;

1.) DCC follow ups

Initially atleast weekly for two weeks followed up by monthly visits.

However, based on individual patient condition, this should be decided by the treating clinician.

2.) Monitoring of response to drug regimen is to be done as per national guidelines (sputum conversions, BMI improvement and overall clinical improvement etc.)

Monthly Sputum AFB & culture to be carried out as per the National PMDT guidelines.

3.) During each visit, to monitor for aDSM. The Side Effect Monitoring and Management during DR-TB Treatment (Annexure 1: DRTB 7) should be maintained in each DRTB patient file. (This form should be sent along with SE/SAE forms during reporting of adverse events to national level).

4.) Any adverse side effect to be notified via relevant SE/SAE form to NPTCCD (Annexure 2: DRTB 8: Adverse Event Monitoring form; Annexure 3: DRTB 9: Serious Adverse Event Monitoring form). For more information, refer PMDT supplement guidelines 2024, chapter on monitoring and evaluation.

5.) For patients who are on home-based care, it is essential to have a DOT provider.

5.1 Aims of follow up

1.) To ensure treatment adherence

For DRTB patients, despite of the model of care selected, DOT is mandatory. This should be closely followed up by the clinician in charge at the district level or the institutional level.

2.) To ensure drug regimen effectiveness and disease response to treatment

Clinical features as well as investigations are used for this.

i.) Clinical Assessment

For features of patient clinical condition improvement.

ii.) Weight and BMI

With response to treatment, patient's weight and BMI improves. Failure to do so in the follow up visits needs close evaluation by the clinician.

iii.) Microbiological evidence

This is the most important indicator of treatment response. Using smear microscopy or culture to assess the conversion of bacteriological status is an important way to assess treatment response. Sputum smears and culture should be done every month until sputum conversion and every two/three month thereafter until treatment completed and at 6 monthly for 2 years after treatment completion. In the case of repeated positive cultures, repeat testing for drug susceptibility or resistance is important.

3. To identify any side effects of drugs and address them

Side effects monitoring in DRTB is very crucial as most of the drugs used in Second line treatment are known to have side effects.

Major adverse reactions

1) Optic Neuritis
2) Peripheral Neuropathy
3) Myelosuppression
4) Cardiotoxicity
5) Hepatotoxicity

Details of these are provided in the PMDT Supplement 2024 & the National PMDT guidelines 2021.

Table 3: Monitoring schedules for BPaLM/BPaL regimens

Examination	Baseline	2 Weeks	Monthly	End of Treatment	6- and 12-months post-treatment
Clinical Evaluation					
Clinical Assessment	X	X	X	X	X
Weight and BMI	X	X	X	X	X
Peripheral neuropathy	X	X	X	X	
Visual acuity and Ishihara test	X	X	X	X	

Assessment and follow up of Adverse Events	X	X	X	X	X
Outcome evaluation				X	X
Radiology, ECG, and other Lab Tests					
Chest X-Ray	X			X	X
ECG	X	X	X	X	
Full Blood Count (FBC)	X	X	X	X	
Liver Function Tests (LFT)	X		X	X	
Serum electrolytes	X		X	X	
Urea, Creatinine	X				
Serum Amylase *					
S. Lactate *					
Pregnancy Test	X				
HIV /HBV/ HCV	X				
Fasting Blood Sugar/HbA1C	X				

*As indicated

NOTE: More frequent monitoring may be advisable in specific situations, including elderly people, patients infected with HIV, affected by HBV- or HCV-related hepatitis, diabetes mellitus, or with moderate to severe hepatic or renal impairment

4. To assess overall health of the patient including psychological well being

Assessment of psychological wellbeing is very important among TB patients and in particular among MDR/RR TB patients. Psychological disturbance can occur as a response to the disease condition, socio economic conditions and the associated stigma associated with it. However, some psychological side effects are also reported due to the given drugs.

Therefore, psychological assessment is mandatory before initiating the treatment as well as during each patient encounter with the clinician. The DOT provider also should be made aware and trained on assessing psychological status of the patient and to identify when to refer for health care provider. The DOT provider should be able to provide psychological support as required through basic counselling.

5. To provide any social support as required

The patient and the care givers should be made aware of the social support systems available through the NPTCCD as well as through the social services department. During the patient encounters/PMDT meetings, a member from the social welfare department can be invited to sought available services for the patient.

The details of the medical leave are given in National Manual for Tuberculosis Control 2021.

In the event of a death f a DRTB patient, a comprehensive death investigation involving the Con. Respiratory Physician should be carried out within a month and the findings should be submitted to the national level through the relevant format (Annexure 4: DRTB death investigation form). These deaths will be discussed during the following Central PMDT committee. investigation

6. Handling of Second Line Drugs

Central drug store is responsible for distribution of second line drugs to the NHRD and DCCs. In future initiation of second line drugs will be done at district level.

The drug regimen of choice is BPaLM. The drugs for Intensive phase will be made available in three centres as follows.

Table 4: Distribution plan for DRTB drugs in BPaLM/BPaL

	Drug centre	**Districts catered**
1.	Central Drug Stores, Welisara	Gampaha, North Western Province,
2.	Central Chest Clinic, Colombo	Colombo, Kalutara, Southern province, Sabaragamuwa province
3.	Chest Clinic, Kandy	Kandy, Nuwara Eliya, Matale, Northern Province, North Central Province, Eastern Province, Uva province

If other complicated regimen is used, it has to be discussed with the central level PMDT technical group and drugs have to be requested from the central drug stores.

Once a patient is diagnosed, Intensive phase drugs available at the institution will be allocated for that patient and the central PMDT focal has to be informed and a request for drugs to Central Drug Stores has to be made (Annexure 5: Drug request form for DRTB patients) via NPTCCD to aquire the continuation phase drugs for that patient. At the same time, the intensive phase drugs taken out for that patient at the institution will be replenished by the Central Drug stores.

Once a patient is diagnosed, the drugs required for the whole duration for that patient has to be reserved for that patient.

Active drug safety monitoring

1.) Once the PMDT site committee decides upon 2nd line treatment for the patient, initial basic investigations should be performed at the chest clinic. (Chest clinic should be provided the facilities to perform Basic bio chemical investigations, Instruments for neurological examinations, ECG facilities etc.)

a.) Report of the site committee including details of 2nd line regime and other relevant details should be sent to PMDT coordinators and updated to the DRTB register & ePIMS system.

b.) PMDT coordinator should inform drug details to central drug store to provide uninterrupted drug supply. DTCO from the relevant district also should be aware & involved in the process.

c.) DTCO should arrange an educational and counseling session for the patient and family members should find a DOT provider for this patient.

2.) The Side Effects monitoring format (Annexure 1) should be maintained in each DRTB patient file. Regular monitoring of patients for side effects as per the guidelines should be carried out. Details given in PMDT guideline 2021 & PMDT supplement 2024.

3.) Recording and reporting of adverse drug reactions according to the severity and causality. The Adverse Event Monitoring Form (Annexure 2) and the Serious Adverse Event Monitoring Form (Annexure 3) and along with the Side Effects monitoring format should be used when reporting to national level.

The central PMDT focal has to be informed and the forms should be sent to the PMDT focal reporting all the aDSM.

Patient details must be updated in the DRTB register (e version) shared to districts by the PMDT Central Unit. The patient information will be reviewed every quarter through the PMDT committees at national level.

7. Review of DRTB patients

As per the national PMDT guidelines, there are PMDT committees at three levels for review of patients and implementation of the programme.

1. District level PMDT committees
2. PMDT committee at NHRD
3. National PMDT committee

With the ambulatory care implementation, these committees have to be further strengthened.

1. District level PMDT committees

The initial and most important role will be played by the district PMDT committee.

   I. Confirmation of the diagnosis of the patient. If the district PMDT committee feels that more expertise is need, can get the opinion from the members of the PMDT committee members at NHRD.
   II. Regular atleast monthly meetings to discuss progress of the patient
   III. Identify any barriers in treating the patient, and address them

2. NHRD PMDT committees (To review and take decisions on difficult to decide pts at NHRD & other districts)
   I. To review and take decisions on difficult to decide patients at NHRD
   II. To review and give opinion when advise is sought from district level for difficult to decide patients
   III. Regular meetings to discuss progress of the patient
   IV. Identify any barriers in treating the patient, and address them
3. National PMDT committee
   I. Review the programme implementation at district level
   II. Review and discuss reported aDSM incidences
   III. Review and discuss DRTB patient deaths
   IV. Identify barriers for patient centered care and address them

Annexures

Annexure 1: Patient side effect monitoring and management during DRTB treatment

DRTB 7: Side Effect Monitoring and Management during DR-TB Treatment (This form should be sent along with SE/SAE forms during reporting of adverse events to national level)

NOTE: This form should be filled during each monthly follow up or whenever patient reports any side effect and should be part of patient file

Patient Name: **MDR TB registration #** **MDR TB Treatment Site:**

Month of Treatment	Date of SE reporting by patient	New Event in the past 30 days (Include all new events or changes in pre-existing conditions that began in the past 30 days)	Date of onset of SE	Name of the drug(s) that might have caused the side effect	Action taken, management and any adjustment in treatment regimen	Date resolved	Outcome*	Severity†	Seriousness‡	Remarks

National Programme for Tuberculosis Control and Chest Diseases 2024

Please use an additional sheet if extra space is required

*Outcome: **R1** (Recovered/ resolved), **R2** (Recovering/resolving), **S** (Recovered with sequelae), **N** (Not recovered/ not resolved), **D** (Died), **U** (Unknown).

Name of the person filling in this page and initial.....

†SEVERITY: **1** (Mild), **2** (Moderate), **3** (Severe)

‡SERIOUSNESS: **N** (Not serious), **H** (Hospitalization (caused or prolonged)), **P** (Permanent disability), **C** (Congenital abnormality), **D** (Death)

‡All serious adverse events (SAEs) to be reported per NPTCCD SAE reporting mechanism under aDSM

Additional Comments:

Annexure 2; DRTB 8: Adverse Event Monitoring form

DCC:	
Participant Name:	
Address:	
Contact phone number:	

Adverse Events	**Description**
Optic Neuritis	
Peripheral Neuropathy (PN)	
Myelosuppression	
QT Interval Prolongation	
Hepatotoxicity	
Other adverse events	

Severity	☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4
Action taken on study drug	☐ Dose not changed ☐ Drug discontinued permanently ☐ Drug discontinued temporarily ☐ Unknown
Outcome of AE	☐ Resolved, No Sequelae ☐ Resolved with sequelae ☐ Not resolved ☐ Fatal ☐ Unknown

Date of AE outcome/subsidence	___/____/_____
Causality assessment	☐ Certain ☐ Probable or Likely ☐ Possible ☐ Unlikely ☐ Not related ☐ Unassessable
Remarks	

Attach patient DRTB 6 form on "Side Effect Monitoring and Management during DR-TB Treatment" with the SE form.

Annexure 3: DRTB 9: Serious Adverse Event Monitoring form

DCC:	
Participant Name:	
Address:	
Contact phone number:	

Serious Adverse Events	
Did the participant have any SAE?	○ Yes ○ No
Serious Adverse events	☐ Death ☐ Life-threatening ☐ Inpatient hospitalization or prolongation ☐ Congenital anomaly or birth defect ☐ Persistent or sig. disability or incapacity ☐ Important medical event
Death	
Date of death	____/_____/_____
Cause of death	
Causality assessment	☐ Certain ☐ Probable or Likely ☐ Possible ☐ Unlikely ☐ Not related ☐ Unassessable
Remarks	

Event	
Life Threatening	
In Patient Hospitalization / Prolongation	
Congenital anomaly or birth defect	
Persistent or Sig. Disability or Incapacity	
Important medical event	
Episodes	○ 1 ○ 2 ● 3
Date of onset	___/____/_____

Underlying cause	
Severity	☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4
Action taken on study drug	☐ Dose not changed ☐ Drug discontinued permanently ☐ Drug discontinued temporarily ☐ Unknown
Outcome of SAE	☐ Resolved, No Sequelae ☐ Resolved with sequelae ☐ Not resolved ☐ Fatal ☐ Unknown
Date of SAE outcome / subsidence	___/____/_____
Causality assessment	☐ Certain ☐ Probable or Likely ☐ Possible ☐ Unlikely ☐ Not related ☐ Unassessable
Remarks	

Attach patient DRTB 6 form on "Side Effect Monitoring and Management during DR-TB Treatment" with the SE form

Annexure 4: DRTB 10: Death investigation form

(Death investigation to be carried out by a team at least including the Consultant Respiratory Physician and District Tuberculosis Control Officer)

District		MOH area	
Team		Patient particulars-	
Name	Designation	Name	
		Sex	
		Age	
		Address	
		DRTB no.	
		Date diagnosed/registered	
		Date treatment started	
TB disease information			
Patient registration category			
DRTB category		RR/ MDR/ INH/ Pre XDR/ XDR/……	
Site of TB			
Diagnostic investigations		Date	Result
Xpert/MTB rif result			
Xpert XDR result			
culture and DST result			
Other			
DRTB drug regimen		Drugs	Date started
If any change in drug regimen			
Change made		Reason	Date
DOT provider details			
DOT provision details			

Follow up investigations	Date	Result
Sputum smear		
Culture & DST		
CXR		
Other……..		
Complications during treatment		
Anti TB drug related side effects during treatment		

Co-morbidities

DM		*COPD*	
Chronic renal disease		*IHD*	
Chronic liver disease		*Ca Lung*	
Bronchial Asthma		*Other……..*	

Summary:					
Date of death					
Place of death					
Immediate cause of death					
Underlying cause of death					
Associated causes of death					
Conclusion	Death due to TB		Death not due to TB		Indeterminate
Points discussed		Action to be taken		Responsible person	
CRP:		DTCO:			

Annexure 5: Drug request form for DRTB patients

Drug request form for DRTB patients (2 copies, 1 – CDS, 1 – DCC patient file)

Requesting DCC/institution		
Requested from	**Central Drug Stores**	**Other (mention) …….**
Patient name		
DRTB number		
Date tx starting		
Initial drug regimen		

Initial & follow up drug request details

Date requesting	**Drug**	**Dose**	**Duration**	**Total no. of tablets/capsules requested**	**Requesting officer & signature**	**No. issued**	**Issuing officer & signature**

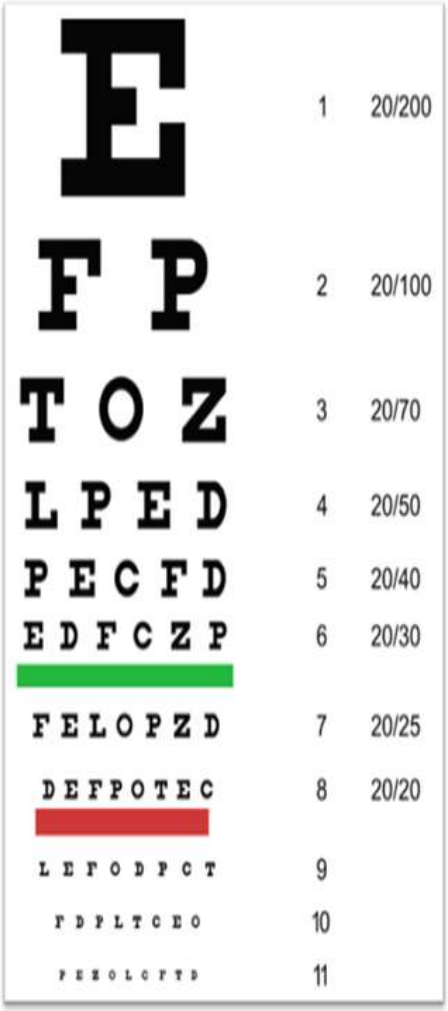
Annexure 6: Testing of visual acuity

Visual acuity

Snellen Chart

- Measures sharpness of central vision
- Chart is standardized for size and contrast
- DO NOT PHOTOCOPY
- 11 rows of capital letters.
- 20 feet away (or 6 meters)

Normal vision = 20/20 (ft) (or 6/6 in m)



Annexure 7: Testing of colour blindness

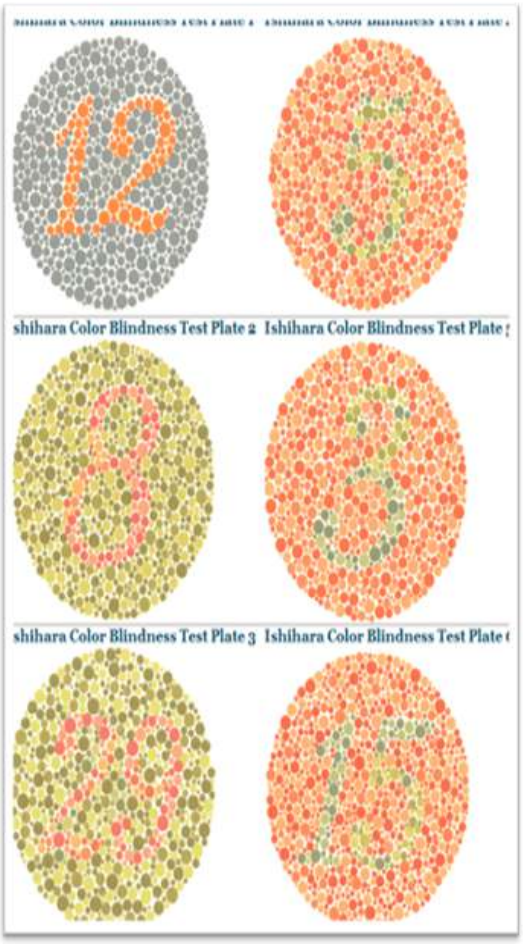
https://www.youtube.com/watch?v=VUq_Y3sUYO4

Color vision test

Ishihara plates

- Color scales are important;
- DO NOT PHOTOCOPY
- 11 plates (Full =38 plates)
- 75 cm away, circles at eye level
- Within 3 (-5) seconds

No. of correctly read plates	Vision
10 plates	**Normal**
8-9 plates	Further testing if patient truly has red/green deficiencies
≤7 plates	Abnormal



Annexure 8: BPNS scoring for peripheral neuropathy

BPNS (Scoring and severity grading)

Normal	Mild ----------Severe								
00	01	02	03	04	05	06	07	07	09	10

Symptoms	Subjective sensory neuropathy score ➡	Right	Left
a.	Pain, aching, or burning in feet, legs	0	0
b.	"Pins and needles" in feet, legs present for at least 2 weeks	3	4
c.	Numbness (lack of feeling) in feet, legs present for at least 2 weeks	0	0

Severity Grade	Grade 1	Grade 2	Grade 3	Grade 4
Neurosensory alteration	Mild discomfort; no treatment required; and/or **BPNS subjective sensory neuropathy score 1-3 on any side.**	Moderate discomfort; non-narcotic analgesia required; and/or **BPNS subjective sensory neuropathy score 4-6 on any side.**	Severe discomfort; or narcotic analgesia required with symptomatic improvement; and/or **BPNS subjective sensory neuropathy score 7-10 on any side.**	Incapacitating; or not responsive to narcotic analgesia

Annexure 9: WHO Classification grading scale for hearing loss

40dB Slight/Mild	41-60 dB Moderate*	61-80 dB Severe	Over 81 dB Profound
Difficulty in hearing and understanding soft speech, speech from a distance, or speech against a background of noise	Difficulty in hearing regular speech, even at close distance.	May only hear very loud speech or loud sounds in the environment, such as a fire truck siren or a door slamming. Most conversation speech is not heard.	May perceive loud sounds as vibrations

Note: In the case of moderate hearing loss, the range for *children is 31-60 dB.

National Programme for Tuberculosis Control and Chest Diseases
4th Floor, Public Health Complex, 555/5, Elvitigala Mawatha,
Narahenpita, Colombo 05
Tel: (94) 011-2368386 | Fax: (94) 011-2368386 |
E-mail: dirnptccd@health.gov.lk