

# MULTI-DRUG RESISTANT TUBERCULOSIS

## A POLICY FRAMEWORK ON DECENTRALISED AND DEINSTITUTIONALISED MANAGEMENT FOR SOUTH AFRICA

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Directorate: Drug-Resistant Tuberculosis, TB & HIV  
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# FOREWORD



South Africa is the sixth highest tuberculosis (TB) burden country in the world.

Recent evidence suggests that a significant proportion of DR-TB is due to ongoing transmission of already circulating resistant TB strains. That is why prevention should be our priority.

*This Policy Framework* is based on sound evidence that decentralised DR-TB treatment provides more effective treatment for the patient that takes social and family pressures into consideration. In addition, decentralisation of care will ease the burden placed on hospitals that require lengthy hospital stays.

The National Department of Health decided to reduce the period of stay for DR- TB patients in centralised DR-TB units and to formally decentralise MDR-TB services in August 2011. Between 2011 and March 2019 the number of MDR-TB initiation sites has increased from 17 to 658. MDR-TB treatment success rate has increased from 40 % to 55 % during the same period for patients on longer regimens. Patients receiving shorter treatment regimens have a treatment success rate above 65 % (2017 cohort).

Management of DR-TB is complex and requires specific skills and additional resources. This document has been updated to include key changes to the policy on decentralised and deinstitutionalised management of MDR-TB.

*The Multi-Drug Resistant Tuberculosis: A Policy Framework on Decentralised and Deinstitutionalised Management for South Africa* will continue to guide provinces in the complex process of decentralisation of drug-resistant TB care and treatment. We hope it will receive due consideration and support among all the provincial representatives and health care providers.

A handwritten signature in black ink, which appears to be 'A. Motsoaledi', written over a horizontal line.

**Minister of Health  
Dr. Aaron Motsoaledi**

# ACKNOWLEDGEMENTS



*The Multi-Drug Resistant Tuberculosis: A Policy Framework on Decentralised and Deinstitutionalised Management for South Africa* was coordinated by Dr. Norbert Ndjeka. This document has been reviewed to include major changes to this important policy. Changes have been informed by success observed during implementation as well as changes encountered.

It is hoped that the new version of this policy will enhance TB programme performance.

Our gratitude is extended to the World Health Organisation (WHO) the USAID and the Centre for Diseases Control (CDC) for supporting the policy revision process.

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# ABBREVIATIONS

<b>AFB</b>	Acid-Fast Bacilli
<b>ART</b>	Anti-retroviral Therapy
<b>ARV</b>	Antiretroviral
<b>DOT</b>	Directly Observed Therapy
<b>DRS</b>	Drug Resistance surveillance
<b>DR-TB</b>	Drug-Resistant Tuberculosis
<b>DST</b>	Drug Susceptibility Testing
<b>EDRWeb</b>	Electronic Drug
<b>HAART</b>	Highly Active Antiretroviral Treatment
<b>HCW</b>	Health Care Worker
<b>HIV</b>	Human Immunodeficiency Virus
<b>MDR-TB</b>	Multi-Drug Resistant Tuberculosis
<b>NDOH</b>	National Department of Health
<b>NHLS</b>	National Health Laboratory Services
<b>PHC</b>	Primary HealthCare
<b>PPM</b>	Public-Private Mix
<b>SL</b>	Second Line
<b>TB</b>	Tuberculosis
<b>XDR-TB</b>	Extensively Drug-Resistant Tuberculosis
<b>WHO</b>	World Health Organisation

# EXECUTIVE SUMMARY

This Policy Framework provides guidance to treat MDR-TB patients closer to their homes. It describes the need for and benefits for decentralisation and deinstitutionalisation of multidrug-resistant tuberculosis (MDR-TB) care and treatment. It also describes the necessary organisational structures and human resources requirements and expected functions of each level of operations. The monitoring and evaluation focus on the level and content of recording, reporting and monitoring indicators.

The South African National Department of Health (NDoH) has implemented a DR-TB management programme since early 2000. Previous DR-TB treatment guidelines dictated that all DR-TB patients be hospitalised for at least six months. In 2011, The National TB Programme introduced a policy framework on decentralised and deinstitutionalised management of MDR-TB in South Africa. This policy was revised in 2018, following a successful implementation of decentralised MDR-TB care.

Decentralised management of DR-TB refers to the transfer of responsibility for treating MDR-TB patients to lower levels of the system on condition that they meet specific criteria. It includes the management of DR-TB in decentralised DR-TB units, satellite multi-drug resistant TB (MDR-TB) units, or in the community using mobile teams and community caregivers and households. WHO's MDR-TB guidelines define community-based care and support as any action or help provided by, with or from the community, including situations in which patients are receiving ambulatory treatment.<sup>1</sup>

The revised policy provides the modalities of DR-TB care. The main modalities are admission, ambulatory care or home-based/ community care. All these are applicable. The use of a modality of care is dictated by the patients' condition. The general condition of the patients dictates whether he or she should be admitted or not, not the smear positivity. Very sick patients (RR/MDR-TB and XDR-TB) require admission while those who are not very sick will be treated in ambulatory. Average duration for admission should vary from 2 weeks to 2 months depending on the patient's condition. In some rare circumstances, it may be important to keep an individual patient in the hospital until a negative culture is obtained – but this should be the exception rather than the norm. Recent evidence suggests that a significant proportion of DR-TB is due to ongoing transmission of already resistant strains.<sup>2,3</sup>

We have also noted that XDR-TB patients now have better treatments outcomes than RR/MDR-TB patients.

Before the introduction of the policy framework on decentralised and deinstitutionalised management of MDR-TB there were only 17 DR-TB treatment initiation sites. To date there are 658 sites in 89 % of sub-districts. Treatment success rate has improved from 40 % to 55 % during the same period. We are aiming at establishing and maintaining at least one MDR-TB treatment initiation site per sub-district. The treatment initiation site may be managed by a medical officer, a clinical associate or a clinical nurse practitioner. Each treatment initiation site must have at least access to the following minimum requirements: quality assured medicines, quality assured laboratory services and Electrocardiogram devices (ECGs) as well as a data recording and reporting system in place.

The following health facilities framework for management of DR-TB patients was proposed in the previous policy document:

- **Centralised DR-TB unit** also known as “Provincial Centre of Excellence”;
- Decentralised DR-TB units;
- **Satellite MDR-TB units;** and
- **Community Support** through primary health care services to assist with Deinstitutionalisation of patients, including:
  - a. Mobile teams, and
  - b. Community caregivers.

In this revised policy framework, an emphasis is placed on the importance of the functions of MDR-TB treatment initiation sites. We would like to focus on the patient's initiation aspect due to only some sites having the capacity to initiate and monitor MDR-TB patients while all health care facilities in the country are able to monitor MDR-TB patients. Monitoring patients means adhering to the instructions of the treating health care professional, sourcing medicines and providing them on monthly basis or when necessary, conducting laboratory tests, performing ECGs and report to the treatment initiating facility.

*This Policy Framework* stipulates that all RR/MDR-TB patients in fair to good general condition may be started on ambulatory treatment regardless of their bacteriological status. Such patients are expected to be without extensive disease and stable. RR/MDR-TB that are admitted for treatment initiation may be kept until two negative smear microscopy results are received if they were positive initially or when their general condition improves.

Furthermore, while this document is generally referring to the decentralisation of care for RR/MDR-TB; some key principles in this document are applicable to XDR-TB as well.

# 1. INTRODUCTION

## 1.1 PURPOSE OF THIS DOCUMENT

This document provides a framework for health facilities and communities on how to manage MDR-TB patients closer to their homes. The Policy Framework is based on the South African context and the best evidence available. It also considers the patient's responsibilities at home and at work to make it possible for them to commence treatment as soon as possible and to adhere to the full course of treatment.

## 1.2 BACKGROUND

South Africa is a high burden DR-TB country. In 2017, the World Health Organization estimated that there are 558,000 incident cases of Rifampicin Resistant Tuberculosis (RR-TB) and MDR-TB in the world. Of these, only 139,114 received treatment under programmatic conditions. During the same period, South Africa initiated 10,722 cases of RR-TB and MDR-TB which is approximately 10 % of the global cohort for that year.

Globally, only 25 % of the estimated number of TB cases was initiated on treatment while 75% are missing. In South Africa, we also have missing cases, estimated at approximately 30%. The introduction of GeneXpert for diagnosis of tuberculosis has led to a massive increase in the number of RR/MDR-TB treated in South Africa. The number of RR/MDR-TB newly initiated on treatment yearly increased from 5083 in 2009 (EDR-Web) to 12,640 in 2015. This is a 2-fold increase. Since 2016, there has been a significant decrease in numbers of RR/MDR-TB cases. Currently we initiate approximately 10,000 RR/MDR-TB patients on annual basis.

The previous NDoH policy dictated that all laboratory diagnosed MDR-and XDR-TB patients be hospitalised in centralised MDR- and XDR-TB units until they have two consecutive negative TB cultures taken at least 30 days apart. Consequently, patients were hospitalised for many months and waiting lists for patients to be admitted to the centralised units were long, delaying the initiation of treatment in most provinces for three or four months. This resulted in several patients dying before starting treatment.

In 2011, we had 17 sites initiating MDR-TB treatment in South Africa. As of March 2019, we had 658 treatment initiation sites across all provinces. The policy has helped by treating more patients and getting better treatment outcomes.

## 1.3 RATIONALE

The old policy prescribing that all DR-TB patients be admitted in specialised TB hospitals was found not to be feasible hence the August 2011 policy was put in place.

We can now say that NDOH took an excellent policy decision in 2011. This policy decision has led to shortening of number of days between diagnosis and treatment initiation, it has increased treatment coverage to all districts and to 89% of sub-districts and making it possible for patients to be treated closer to their homes, increasing the social acceptability of treatment as well as favourable treatment outcomes.

A study by Nardell et al. underscores the long-standing evidence suggesting that TB patients on effective therapy rapidly become non-infectious and that unsuspected, untreated TB cases account for most transmission.<sup>4</sup> Other studies conducted in South Africa suggested that MDR-TB patients are not being effectively treated and cured;<sup>5</sup> this is contributing to the development of XDR-TB.<sup>6</sup> The old policy of management (centralised in specialised units) had been fraught with many challenges, including:

- Delays in treatment initiation (due to long waiting lists for admission to specialised hospitals) increases patients' suffering, the risk of death and chance of transmission of DR-TB.<sup>7</sup>
- Nosocomial transmission of MDR/XDR-TB in health facilities when infection control measures are not implemented adequately and substantial evidence that more than half of all XDR-TB infections are acquired in hospitals.<sup>3,8</sup>
- Refusal of hospitalisation or absconding by some patients due to lengthy hospital stays, lack of recreational facilities in hospitals or patients' responsibilities to attend to family needs and demands. A recent study undertaken in KwaZulu-Natal indicated that 70 % of MDR-TB patients' households are headed by females, who cannot be admitted to hospital for a long period due to responsibilities such as caring for young children.<sup>9</sup>
- Patients feel that monthly follow up trips to the centralised hospitals for monitoring and medication are lengthy, arduous and unpleasant, contributing to poor treatment adherence.
- In South Africa, decentralised treatment of MDR-TB patients was taking place in an uncoordinated and unsystematic manner before the year 2011.
- By formalizing decentralised management and guiding it, we are achieving better treatment outcomes.

A review of the 2007 cohort of MDR-TB patients by the NDOH show a treatment success rate of 42 %, a defaulter rate of 9.6 %, a failure rate of 4.8 %, a high death rate of 20.4 %, 5.1 % transferred out while 18 % were still on treatment after two years.

The 2016 cohort of patients treated on longer treatment regimens showed a treatment success rate of 54 % for MDR-TB (n= 11,159) and 58 % for XDR-TB (n=601).

The 2017 cohort of patients on shorter MDR-TB regimen (n=3695) achieved 67 % treatment success rate; 18 % death rate and 12 % loss to follow up.

A further analysis of the patients who received bedaquiline-containing regimen (1936 out of 3695) had 74 % treatment success rate; 13 % death rate and 10 % loss to follow up. These results are similar to outcomes of XDR-TB patients treated on longer regimen that contain bedaquiline. It appears that we are on track to achieve a treatment success rate of 75 % for all our DR-TB patients by 2022.

The following entities have been used to provide MDR-TB care to communities:

1. Decentralised DR-TB units,
2. Satellite MDR-TB units, and
3. Community-based with the support of primary health care services including:
  - a. Mobile teams, and
  - b. Community caregivers.

Following recommendation from the WHO programme review (2014), The DR-TB directorate decided to focus on 2 types of DR-TB services:

- Treatment initiation facilities
- Other facilities that do not initiate but have the responsibility to provide clinical follow up, provide monthly refill of medicines and collect monthly laboratory specimens for patient's evaluation.

This updated policy framework provides more details around these concepts. Several publications have shown that decentralised MDR-TB care is cost-effective and delivers better treatment outcomes. Prior to that, community-based treatment models for MDR-TB had been successfully implemented in other countries,<sup>13,14</sup> although the South African situation is unique.

In this revised version, key changes are discussed in the following areas:

- Modality of delivery of care;
- Human resources and capacity building requirements;
- New targets for decentralisation;
- Eligibility for ambulatory care;
- Duration of admission;
- Role of sub-districts;
- Package of care;
- Emphasis on quality rather than quantity of care and
- Infection control measures at community level.

# 2. DESCRIPTION OF DECENTRALISED AND DEINSTITUTIONALISED MANAGEMENT OF MDR-TB

## 2.1. PRINCIPLES

### 2.1.1. NEED FOR CLARITY OF FUNCTIONS ACROSS ALL LEVELS

Decentralisation of care refers generally to MDR-TB. In this revised document, several key aspects also refer to XDR-TB. XDR-TB patients who are not very sick may be routinely treated in the community.

This policy guidance must be used in conjunction with the report on decentralised management of MDR-TB. The report indicates where all facilities are located and provides the referral pathway at sub-district level. The report also provides incident RR/MDR-TB diagnosed cases (not treatment initiations) for 2016 as an example. All resources available at facility level are indicated in Chapter 7 of this report.

Effective DR-TB treatment at different levels of the health care system will depend on regular consultation of the report on decentralisation that will be updated at least on an annual basis.

**We aim to establish at least one referral MDR-TB treatment site per sub-district for initiation purposes and strengthen the referral pathway so that other non-initiating sites can play their role meaningfully and refer most patients within the sub-district.**

One major inclusion in this policy is the patient-centred approach. This means that the treatment modality is dictated by the patient's needs. All modalities are applicable; which includes ambulatory care, hospital admission, community-based care, hospital-based care; pending on the patient's specific needs.

The very sick patients require admission while those not very sick may be treated in ambulatory regardless of the type of DR-TB (RR/MDR-TB or XDR-TB), and discharge should depend on the clinical condition improving. It is essential to ensure that patients are adequately linked to and supported in outpatient care prior to discharge so their inpatient progress can be maintained, and they can continue to be supported with their therapeutic regimen. Patients who can visit a health facility will do so while those who may not, will be treated at their homes.

### **2.1.2. NEED FOR LINKAGES TO THE ENTIRE HEALTH SYSTEM**

A well-functioning TB programme is essential to prevent further development of DR-TB. A decentralised and deinstitutionalised MDR-TB management system needs to be closely linked to the overall TB control and management programme and the PHC outreach teams if it is to succeed. Health-care workers in all facilities must increase case finding activities in relation to drug sensitive TB and they must recognize that patients who fail to respond to first-line therapy may be drug resistant and need to be managed quickly and appropriately.

Linking MDR-TB management with the overall TB programme, especially at sub-district and primary health care levels, is essential to ensure better treatment success for MDR-TB patients.

In addition, linkages with all health services and facilities will be necessary to minimize nosocomial transmission of DR-TB in these facilities and when TB patients are transported in patient transport vehicles. Health care workers need to be educated about the risk of nosocomial transmission and which patients (e.g., HIV-infected and other immunocompromised patients) are most vulnerable.

Nearly 70 % of patients with MDR-TB are co-infected with HIV, making it important to integrate DR-TB services with those serving HIV/ART-infected patients. Every co-infected patient should have both HIV/AIDS and TB conditions assessed and monitored and repeat medication prescribed at each monthly appointment.

# 3. DESCRIPTION OF ELEMENTS OF DECENTRALISED AND DEINSTITUTIONALISED MDR-TB CARE

## 3.1. KEY ELEMENTS FOR A SUCCESSFUL DECENTRALISED AND DEINSTITUTIONALISED MDR- TB PROGRAMME INCLUDE:

- Prompt and accurate MDR-TB diagnosis;
- Prompt initiation on appropriate SL medicines
- Trained multidisciplinary teams with adequate and effective mentorship and supervision;
- Availability of medical practitioners, clinical associate or NIMDR trained clinical nurse practitioners to lead the teams;
- Updated Guidelines/protocols for clinical management;
- Uninterrupted supplies of second-line anti-TB drugs and ancillary drugs for managing side effects;
- Availability of ECG machines at all treatment initiation sites;
- Adequate infection control measures;
- Integration with local TB programme activities, HIV services and PHC services;
- Careful selection of patients who will receive treatment in the community;
- Functional defaulter tracing mechanisms;
- Communication among the different levels of the health care system;
- Effective TB and DR-TB advocacy, communication and social mobilisation at a community level;
- Availability or access to hearing tests machines at all treatment initiation sites;
- Rigorous monitoring and evaluation;

An essential step in decentralisation of MDR-TB treatment is that district health managers and health workers are appraised on the framework. It is essential to ensure that they will support its implementation.

Effective DR-TB treatment, including highly active antiretroviral treatment (HAART) when indicated, will require close monitoring of side effects, tight control of drug use, and several other requirements outlined in Table V. All requirements listed in this table will have to be met if the MDR-TB decentralised programme is to be effective.

**HIV and the Provision of HAART:** All MDR-TB patients who have not been previously tested for HIV or who are HIV negative will, on admission, be offered an HIV test. Those who are HIV positive and eligible for HAART but not on treatment will be initiated as soon as possible. All decentralised MDR-TB sites must be accredited as antiretroviral treatment (ART) sites and DR-TB staff should be trained in managing HAART side effects.

### 3.2. REQUIREMENTS

The requirements for the successful decentralisation of MDR-TB services are described in the following table following table.

**Table I: Requirements for Successful Decentralised and Deinstitutionalised MDR-TB Programme and Means of Achievement**

REQUIREMENTS	MEANS
Prompt and accurate DR- TB diagnosis	<ul style="list-style-type: none"> <li>• Ensure good quality culture and drug sensitivity testing and prompt reporting of results; and</li> <li>• Include line probe assay.</li> <li>• Have a good specimen transport system</li> </ul>
Uninterrupted supply of second-line anti-TB drugs	<ul style="list-style-type: none"> <li>• Ensure availability of SLDs</li> <li>• Prompt initiation on appropriate SL medicines and treatment regimens</li> <li>• Prescribe and maintain appropriate DR-TB treatment</li> <li>• Ensure appropriate PSM - pharmacy support; and storage</li> <li>• Ancillary medicines</li> </ul>
Trained multidisciplinary team with adequate and effective mentorship and supervision	<ul style="list-style-type: none"> <li>• Ensure well trained medical practitioners, clinical associates and clinical nurse practitioners to lead the teams;</li> <li>• Establish tracer teams that conduct home visits, identify contacts and trace defaulters;</li> <li>• Provide regular support from a doctor familiar with the DR-TB and ART guidelines;</li> <li>• Ensure access to social and mental health support structures; and</li> <li>• Establish clearly defined roles and responsibilities.</li> </ul>
Guidelines/protocols for clinical management	<ul style="list-style-type: none"> <li>• Refer to treatment guidelines and the report on decentralization of MDR-TB services for guidance;</li> <li>• Ensure that the specialized DR-TB team at the provincial and decentralised sites initiate, manage and evaluate DR-TB treatment in accordance with national guidelines;</li> </ul>

REQUIREMENTS	MEANS
Guidelines/protocols for clinical management	<ul style="list-style-type: none"> <li>• Collaborate with HAART programme to ensure provision of HAART and literacy for MDR-TB patients separate from non-TB infected-HIV positive patients to ensure infection control; and</li> <li>• Ensure initiation and support for HAART.</li> </ul>
Adequate Infrastructure and infection control measures	<ul style="list-style-type: none"> <li>• Good procedures include:</li> <li>• Well ventilated consulting rooms;</li> <li>• Well ventilated waiting areas;</li> <li>• UVGI lights and extractors fans where possible; and</li> <li>• Respiratory protection tools available at all times (e.g., surgical masks for patients and N95 respirators for health care workers).</li> </ul>
Equipment	<ul style="list-style-type: none"> <li>• ECG machines at all treatment initiation sites</li> <li>• Access to hearing tests machines at centres of excellence and selected treatment initiation sites (This is no longer compulsory for smaller treatment initiation sites)</li> <li>• Routine biochemistry</li> </ul>
Integration with local TB programme activities and HIV and PHC services	<ul style="list-style-type: none"> <li>• Conduct HIV tests as soon as possible in patients diagnosed with DR-TB; and</li> <li>• Initiate ART within two weeks in HIV-positive patients not already on ART.</li> </ul>
Selection of patients who will benefit from completing MDR-TB treatment at district, Sub-district or community level	<ul style="list-style-type: none"> <li>• Establish criteria for patients who need to be treated at the provincial specialized hospital;</li> <li>• Selection criteria for patients eligible for treatment in the community;</li> <li>• Patient needs and his/her preferred option for treatment; and</li> <li>• Decentralised DR-TB units, satellite MDR-TB units and mobile teams and MDR-TB and HAART trained DOTS supporters and caregivers.</li> </ul>
Close monitoring of daily treatment.	<ul style="list-style-type: none"> <li>• Ensure close supervision of mobile teams and clear pathways for feedback to satellite or decentralised units; and</li> <li>• Maintain a system for early detection and tracking of patients defaulting treatment.</li> </ul>
Effective communication between all levels of care.	<ul style="list-style-type: none"> <li>• Establish communication channels between MDR-TB units; and</li> <li>• Develop clear referral guidelines.</li> </ul>
Formulation of a Province/ District's Advocacy, Communication and Social Mobilization (ACSM) plan.	<ul style="list-style-type: none"> <li>• Implement provincial/ district specific ACSM plans aimed at MDR-TB patients and their communities with a view to educate and dispel the stigma surrounding the disease;</li> <li>• Involve public participation, TB Ambassadors, health professions and other key stakeholders; and</li> <li>• Disseminate relevant IEC materials to clinics, schools, and community Centres in appropriate languages.</li> </ul>
Monitoring and evaluation	<ul style="list-style-type: none"> <li>• Ensure there is information technology support and database management;</li> <li>• Define indicators; and</li> <li>• Conduct operational research.</li> </ul>

# 4. TYPES, STRUCTURE, LEVELS AND FUNCTION

This policy framework has been developed based on previous experience in Peru<sup>17</sup> and current efforts at out-patient MDR-TB treatment in KwaZulu-Natal<sup>18</sup> and in the Western Cape.<sup>16</sup> The framework describes the roles of the different levels of patient management. To date, considerable effort has been made by all provinces throughout South Africa to implement existing decentralisation policies. Western Cape has the largest number of MDR-TB treatment initiation sites while Kwazulu-Natal has the least decentralised MDR-TB services in the country. Other provinces have really done very well seeing that Northern Cape, Free State, Limpopo and Gauteng each have at least one MDR-TB treatment initiation site at sub-district level.

## 4.1. TYPES AND FUNCTIONS OF DR-TB UNITS

A DR-TB unit is a health facility where health professionals have been trained to initiate and manage the treatment of DR-TB patients. A DR-TB unit may be a (stand-alone) hospital, a DR-TB ward in a general hospital, or a DR-TB ward in a TB hospital or other specialised hospital.

### Hospitalisation provides time for:

- Initiating DR-TB and HIV treatment;
- Monitoring the initial response to treatment and possibly adjusting medication;
- Educating and counselling the patient on MDR-TB and HIV;
- Assessing the household in preparation for discharge; and
- Educating and counselling the family and other household members on DR-TB and HIV to optimise family support for the patient in treatment adherence and implementation of household infection control.

### 4.1.1. PROVINCIAL LEVEL

The centralised DR-TB unit is also known as the “Provincial Centre of Excellence”. Each province has at least one hospital that is a specialised unit for DR-TB. This hospital will take a supporting and supervisory role for the MDR-TB outpatient programme in each province, and as the centre of excellence, provide technical advice to the decentralised MDR-TB sites.

### Functions of the Centralised DR-TB Unit

- Initiating treatment of all DR-TB cases after appropriate assessment;
- Admitting DR-TB cases from the geographic area around the unit;
- Ensuring hospitalisation of all XDR-TB cases;
- Assessing all DR-TB patients attending the clinic each month;
- Providing DOT to all DR-TB patients attending the unit each day;
- Recording and reporting to the provincial Department of Health;
- Providing ongoing training, support and supervision for all the facilities in the province;
- Providing social support, rehabilitation, educational and skills building programmes for patients;
- Providing education and counselling to all patients admitted in hospital;
- Preparing a discharge plan for all patients and ensuring effective down-referrals;
- Monitoring DR-TB patients post discharge until completion of treatment and two years post treatment completion;
- Monitoring rational usage of second-line drugs and ancillary drugs for side effects management;
- Establishing and maintaining functional clinical management teams;
- Compiling monthly, quarterly, six-monthly and annual reports of DR-TB patients started on treatment, their culture conversion and outcomes;
- Utilise local data to provide technical assistance and capacity building to decentralised DR-TB units, and feeder clinics on management of DR-TB;
- Arranging patients' evaluations at provincial patient review committees; and
  - Conduct hearing tests for patients who are receiving amikacin or streptomycin.

### 4.1.2. DISTRICTS OR SUB-DISTRICTS

Districts and sub-districts have administrative and management responsibilities in ensuring effective DR-TB services in the area. Their primary function is to:

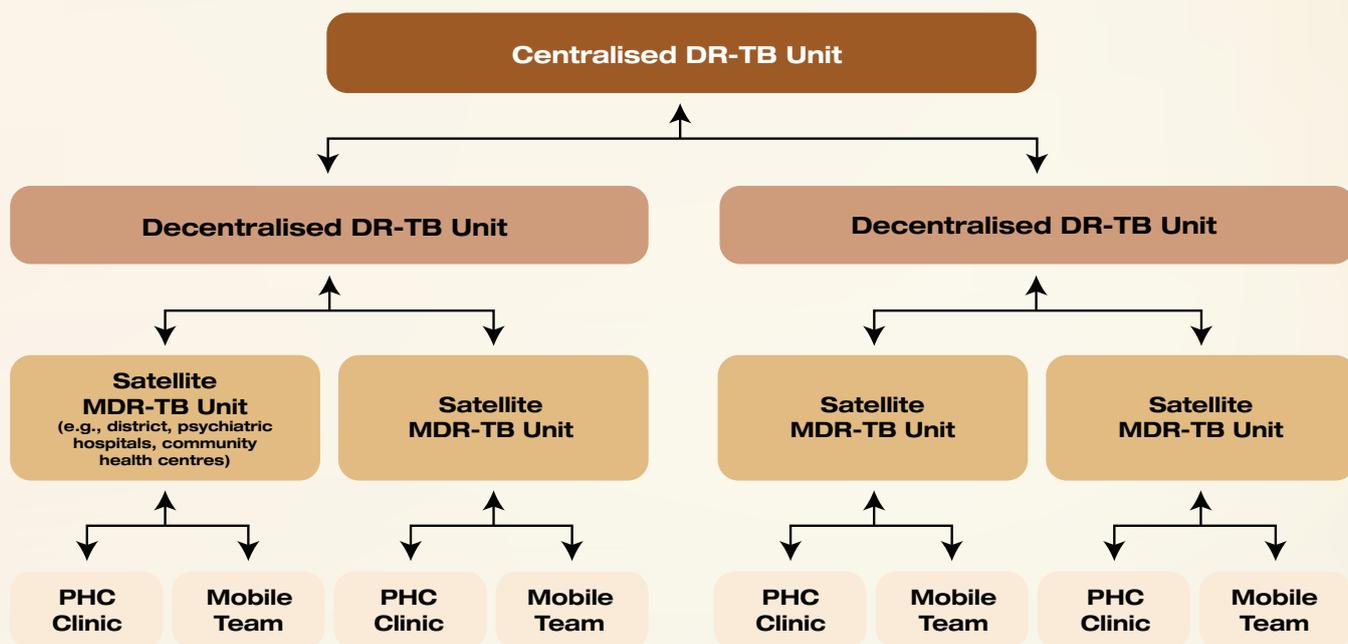
- Trace all confirmed DR-TB patients and initiate the stable patients on treatment. Patient who do not qualify for community-based initiation, should be referred to the DR-TB hospital;
- Ensure availability of drugs for the patient at the clinic or district hospital;
- Establish an efficient patient retrieval system for patients who default DR-TB treatment;
- Patients who are being treated in the community but are having follow up appointment as outpatients at a TB hospital, should have transportation arranged for patient evaluation and follow-up at the DR-TB hospital;
- Appoint disease outbreak teams to conduct contact screening programmes for all close contacts of confirmed DR-TB patients six monthly for one year (12 months);
- Conduct household assessments prior discharging patients from DR-TB units;
- Monitor and evaluate DR-TB programme performance;
- Ensure continuum of care for patients post discharge;
- Ensure ongoing psychosocial support for patients; and
- Increase awareness and education about DR-TB among communities.

We aim to establish and maintain at least one MDR-TB treatment initiation site per sub-district. The sub-district is the unit of treatment and has to adhere to a standard package of care as discussed in this policy document.

**Table II: Recommended Staffing Levels for the Centralised DR-TB Unit**

<b>STAFF</b>	<b>RECOMMENDED STAFFING LEVELS</b>
Doctors/Clinical Associate/NIMDR trained clinical nurse	1 doctor for each 40-bed centralised DR-TB unit (assuming a general occupancy rate of more than 75 %).
Operational Nursing Manager	1 for each unit
Nurses	1 professional nurse for 3 enrolled nurses or nursing assistants. 15 nurses are adequate for a 40-bed unit.
Pharmacist	1 pharmacist for a unit of 100 to 200 beds.
Social worker	1 for a 40-bed unit
Dietician	1 for a 40-bed unit
Clinical psychologist	1 for a 40-bed unit
Occupational therapist	1 for a 40-bed unit
Audiologist	1 for a 100-bed unit
Physiotherapist	1 for a 40-bed unit
Data capturer/ administration clerk	1 for a 40-bed unit
Administration clerk	1 for a 40-bed unit
General Assistants	8 for a 40-bed unit
Housekeeper	1 for each unit
Driver	1 for each 40-bed unit

Figure I: Units for the Decentralised Management of DR-TB



Satellite MDR-TB Units exist to complement bed capacity of decentralised sites. They are essentially transitional and should be capacitated to become decentralised sites. Mobile teams should be attached to PHC services but operate within the community.

**Community: DOTS Supporters and Caregivers**

### 4.1.3. DECENTRALISED DR-TB UNITS

There are several decentralised DR-TB units in each province, depending on the need. These units will be responsible for the initiation and management of DR-TB patients in a defined geographical area, initially as inpatients, but then when appropriate, as outpatients. These units may consist of whole hospitals, wards or sections of existing provincial, district or sub- district level hospitals.

**NOTE:** Decentralised DR-TB units with adequate human resources and infrastructure capacity may initiate treatment and follow up on XDR-TB patients. Provinces need to identify such facilities and inform the National Department of Health.

Patients diagnosed with MDR-TB or XDR-TB who are smear microscopy positive do not have to be hospitalised for treatment initiation. **Criteria for hospital admission will be dictated by the patient's condition, not by smear-positivity.**

## Functions of the Decentralised MDR-TB Units

Primary functions of the decentralised MDR-TB units are:

- Initiating treatment of all MDR-TB cases after appropriate assessment;
- Admitting DR-TB cases when indicated;
- Providing transportation for patient evaluation and monthly follow up of all DR-TB cases attending clinic;
- Tracing confirmed DR-TB patients and referring them to the DR-TB hospital and initiating them on appropriate treatment;
- Providing DOT to all DR-TB patients attending the unit daily;
- Providing social support, rehabilitation, educational and skills building programmes for patients;
- Providing education and counselling to all patients;
- Preparing a discharge plan for all patients and ensuring effective down referrals;
- Monitoring DR-TB patients post discharge until completion of treatment and two years post treatment completion;
- Ensuring availability of drugs and monitoring rational usage of second-line drugs;
- Establishing and maintaining functional clinical management teams;
- Recording and reporting to the provincial Department of Health;
- Compiling monthly, quarterly, six monthly and annual reports for DR-TB patients started on treatment, culture conversion and outcomes;
- Using local DR-TB data to make local plans and interventions to improve DR-TB services;
- Monitoring and evaluate DR-TB programme performance;
- Providing technical assistance and capacity building to satellite MDR-TB units and feeder clinics on management of DR-TB;
- Monitoring treatment side effects;
- Ensuring referral of patients with XDR-TB, severe adverse events and complicated disease to the centralised DR-TB unit;
- Treating XDR-TB patients where capacity exists; and
- Tracing all confirmed TB cases.

**Table III: Recommended Staffing Levels of the Decentralised DR-TB Units**

STAFF	RECOMMENDED STAFFING LEVELS
Doctors	1 doctor for each 40-bed decentralised DR-TB unit (assuming a general occupancy rate of more than 75 %).
Nurses	1 professional nurse for 3 enrolled nurses or nursing assistants. 15 nurses are adequate for a 40-bed unit.
<b>Part-time Staff: These officers are usually employed by hospitals, and will be required to give</b>	
Pharmacist	1 for 10-20 patients
Social worker	1 for 10-20 patients
Dietician	1 for 10-20 patients
Clinical psychologist	1 for 10-20 patients
Occupational therapist	1 for 10-20 patients
Audiologist	1 for 10-40 patients
Physiotherapist	1 for 10-20 patients
Data capturer	1 for 10-20 patients

#### 4.1.4. SATELLITE MDR-TB UNITS

Satellite units may be based at district or psychiatric hospitals, community health centres, or correctional services facilities. These are transitional structures that should be capacitated to become decentralised sites. Satellite MDR-TB units should exist to:

- Make it possible to initiate MDR-TB therapy for all MDR-TB patients as soon as they are diagnosed, regardless of availability of beds; and
- Serve patients who refuse to start treatment unless they can be closer to home.

After the assessment and initiation of MDR-TB therapy (by a centralised or decentralised DR-TB unit) patients may be referred to a satellite MDR-TB unit where they will receive treatment and be monitored daily. Nurses, with the support of a doctor based at the centralised or decentralised DR-TB sites should monitor patients' progress.

An improvement in the patient’s medical condition (e.g., weight gain, no fever, no cough, etc.) indicates that he/she is tolerating all MDR-TB drugs and HAART. Patients can be discharged to the community and continue receiving treatment either from the mobile team or their nearest primary health-care facility.

At times MDR-TB treatment will be administered in institutions such as prisons, mining health facilities or psychiatric hospitals.

Initially the patient should return monthly to the decentralised DR-TB treatment site for ongoing management of their condition. When the programme is established and staff at satellite MDR-TB sites are trained, it may be possible for patients in the continuation phase to be monitored monthly at the satellite MDR-TB site. Until then, the patient should travel once bi-monthly or quarterly to the decentralised treatment DR-TB site.

Satellite MDR-TB units may not initiate MDR-TB treatment. They may become a decentralised MDR-TB unit if they have adequate and trained staff and infrastructure.

**Functions of Satellite MDR-TB Units**

- Ensuring monthly follow up of all DR-TB patients attending the unit;
- Providing DOT to all DR-TB patients attending daily;
- Educating and counselling all DR-TB patients;
- Preparing a discharge plan for all patients;
- Monitoring treatment side effects and
- Ensuring referral of patients with XDR-TB, severe adverse events, and complicated disease to the centralised DR-TB site.
- Record and report all relevant data accordingly

**Table IV: Recommended Satellite MDR-TB Unit Staffing Levels**

STAFF	RECOMMENDED STAFFING LEVELS
Nurses (professional or staff nurse or nursing assistant)	1 professional nurse for 20 patients
Community Caregiver	1 for 10 patients
PART-TIME STAFF	
Doctor	Optional
Social worker	Optional
Data capturer	Optional

#### 4.1.5. PRIMARY HEALTH-CARE FACILITIES

Primary healthcare (PHC) facilities should play a significant role in providing treatment to all DR-TB patients at the clinics. This must be integrated with the treatment of other TB and HIV patients. The existing TB nurses should be capacitated to handle these activities on an ongoing basis.

Patients who have access to a PHC clinics should utilize the health facility for their DOT. The facility-based staff will monitor side effects and adherence; provide education on the disease, and monitor household infection control practices.

Minor side effects such as nausea, vomiting and diarrhoea should be managed by the nurse at the facility, but the patient will be referred to the decentralised DR-TB unit for management of more serious side effects. In addition, the nurse at the facility should be responsible for contact tracing and serve as the link between the decentralised DR-TB unit and MDR-TB patients treated at the facility.

PHC facilities treating MDR-TB patients will be supported by the nearest decentralised DR-TB unit or the centralised DR-TB unit or provincial centre of excellence if it is closer to the facility.

##### Functions of Primary Health Care Facilities

- Identifying high risk groups;
- Screening and testing symptomatic high-risk groups;
- Tracing patients with a confirmed diagnosis of DR-TB;
- Notifying the district TB coordinator;
- Providing initial counselling and education of the patient and family;
- Preparing patient for hospital admission when indicated;
- Coordinating referrals to the centralised and decentralised DR-TB units;
- Ensuring monthly follow up of all DR-TB cases attending a clinic;
- Providing DOT to all DR-TB patients attending daily;
- Conducting contact screening of close contacts;
- Following up patients initiated to start community-based treatment or patients who are post discharge from hospital;
- Coordinating follow up visits in hospital;
- Tracing treatment interrupters;
- Collecting monthly sputum and other routine tests;
- Monitoring treatment side-effects;
- Ensuring referral of patients with XDR-TB, severe adverse events, and complicated disease to the centralised DR-TB unit; and
- Treating XDR-TB if there is capacity.

##### Contact Tracing and Monitoring

Contact tracing and monitoring is an important role of the PHC facilities through the mobile teams and DOTS supporters.

Measures for contact tracing and monitoring include:

- Listing and examining all contacts and testing those with symptoms in accordance with existing TB protocols;
- Re-testing contacts with symptoms for TB and drug susceptibility 6 monthly for two years
- Ensuring that the MDR-TB patient is continuously screened for signs and symptoms; and
- Offering HIV counselling and testing to contacts.

#### 4.1.6. MOBILE TEAMS

**Table V: Recommended Primary Health Care Staffing Levels**

STAFF	RECOMMENDED STAFFING LEVELS
Doctor	Part-time or full-time depending on patient load
Nurses (professional or staff-nurse or nursing assistant)	Part-time or full-time depending on patient load
Community caregiver	1 for 10 patients
Social worker	Optional
Data capturer	1 for 50 patients

Mobile teams are also called mobile MDR-TB units. These are units based at the PHC facility or a satellite MDR-TB unit. These teams were put in place to provide injections to patients at their homes, supervise intake of oral tablets, and educate families and close contacts about infection control. Now that the injection is no longer provided routinely these teams should focus on other home-based care duties.

Patients who are unable to access a health facility for the first two weeks of treatment should be visited daily (five times a week) at home by a mobile team, which should consist of a driver and a nurse. During these visits the team will observe the patient taking their oral treatment, monitor side effects and adherence, provide education on the disease, and monitor household infection control practices. Minor side effects such as nausea, vomiting and diarrhoea should be managed by the nurse on the mobile team, but the patient should be referred to the decentralised DR-TB site for management of more serious side-effects. The mobile MDR-TB unit should also be responsible for contact tracing and serve as the link between the decentralised DR-TB site and MDR-TB patients in the community.

Existing TB tracer teams may expand their mandate by taking care of MDR-TB patients. Again, these teams need to take care of all TB and HIV patients. Their scope should not be restricted to MDR-TB care.

### Functions of Mobile Teams

- Providing DOT to all DR-TB patients in the area;
- Providing patient, family and community education on TB;
- Monitoring treatment side effects and referring to the nearest health care facility when necessary; and
- Maintaining appropriate records.

### 4.1.7. COMMUNITY LEVEL: DOTS SUPPORTERS/ CAREGIVERS

Table VI: Recommended Mobile Team Staffing Levels

STAFF	RECOMMENDED STAFFING LEVELS
Nurses (professional or staff nurse or nursing assistant)	1 for 20 patients
Community caregiver	1 for 20 patients
Driver	1 for 20 patients

Depending on the local situation the DOTS supporters may be community caregivers, community DOTS volunteers or family members. It should be noted training is crucial for these cadres, and compensation should be considered seriously because DOT is important. Family members should be used only as a last option because they may be coerced by other family members, making them less objective as community caregivers.

Patients and their designated household treatment supporters will be trained in the natural history of MDR-TB and HIV as well as in basic infection control (e.g., cough hygiene and the basic principles of isolation), MDR-TB medications, common side effects/ toxicities, and the role of HIV in TB infection. Family planning during MDR-TB treatment will be encouraged. Community caregivers should provide ongoing daily support to MDR-TB patients who are treated on an out-patient basis.

If the patient is on HAART, the patient and treatment supporter will receive literacy training according to current practice. This will be given by staff trained in MDR-TB and integrated TB and HIV care. Any training that takes place in the clinical setting will be separated in space and time from the HAART programme to avoid nosocomial transmission. In addition, education for the patient, household supporter, and possibly even the treatment supporter should be given at individual patients' home by the mobile MDR-TB unit.

Given the important role of the treatment supporter, he/she should preferably be HIV- negative and have access to a support group and regular TB screening.

### Functions of Community Level Services

- Providing DOT to all DR-TB patients in the area;
- Providing patient, family and community education on TB;
- Monitoring treatment side effects and referring to the nearest health-care facility when required; and
- Maintaining appropriate records.

The following table describes the responsibilities of staff working at various levels of MDR-TB care.

**Table VII: Staff Responsibilities**

STAFF	RESPONSIBILITIES
Doctor	<ul style="list-style-type: none"> <li>• Assess all DR-TB patients for co-morbidities and requesting baseline tests.</li> <li>• Initiate DR-TB treatment regimen for the patient (at centralised and decentralised DR-TB units).</li> <li>• Report adverse drug events to the South African Health Products Regulatory Authority (SAHPRA)</li> <li>• Review treatment of patient and make any necessary adjustments.</li> <li>• Provide clinical monitoring of patients' treatment for adverse events and prompt management.</li> <li>• Provide prompt referral for tertiary care or specialist care when needed.</li> <li>• Ensure necessary laboratory tests are conducted timeously for adequate monitoring of the patient and his/her response to treatment.</li> <li>• Attend meetings and keep up to date about TB and DR-TB management and surveillance.</li> <li>• Educate nurses and other members of the DR-TB team.</li> </ul>
Trained Clinical Associate	<ul style="list-style-type: none"> <li>• Assess RR/MDR-TB patient for co-morbidities and requesting baseline tests.</li> <li>• Initiate DR-TB treatment regimen for RR/MDR-TB patients (at centralised and decentralised DR-TB units).</li> <li>• May initiate treatment to stable pre-XDR-TB patients</li> <li>• Refer very sick RR/MDR-TB and XDR-TB patients to the medical officer</li> <li>• Review treatment of patient and make any necessary adjustments.</li> <li>• Provide clinical monitoring of patients' treatment for adverse events and prompt management.</li> <li>• Report adverse drug events to the South African Health Products Regulatory Authority (SAHPRA)</li> <li>• Provide prompt referral for tertiary care or specialist care when needed.</li> <li>• Ensure necessary laboratory tests are conducted timeously for adequate monitoring of the patient and his/her response to treatment.</li> <li>• Attend meetings and keep up to date about TB and DR-TB management and surveillance.</li> <li>• Educate nurses and other members of the DR-TB team.</li> </ul>

STAFF	RESPONSIBILITIES
Professional nurse	<ul style="list-style-type: none"> <li>• Initiate RR/MDR-TB patients' treatment</li> <li>• Report adverse drug events to the South African Health Products Regulatory Authority (SAHPRA)</li> <li>• May initiate treatment for stable pre-XDR-TB patients</li> <li>• Refer all XDR-TB and very sick DR-TB patients to the medical officer</li> <li>• Coordinate clinical care with other health professionals.</li> <li>• Monitor inpatients and refer to doctor when appropriate.</li> <li>• Coordinate household assessment, discharge of patient, and linkages to outpatient services.</li> <li>• Manage the weekly MDR-TB outpatient clinic, ensuring that there is a functioning filing system and laboratory results are retrieved and recorded before the patient is attended to by a doctor for the monthly review.</li> <li>• Manage and coordinate MDR-TB outpatients.</li> <li>• Support nursing staff in the decentralised DR-TB site.</li> <li>• Monitor patient management (MDR-TB register) and compile a six-monthly report.</li> <li>• Maintain a close relationship with the patient.</li> <li>• Administer treatment to the patient.</li> <li>• Provide ongoing nursing care.</li> <li>• Complete the patient treatment card for treatment dosages given to the patient.</li> </ul>
Staff nurse or nursing assistant	<ul style="list-style-type: none"> <li>• Provide counselling for HIV testing.</li> <li>• Conduct HIV testing on patients who give consent.</li> <li>• Provide educational talks to patients on a one-on-one basis or in group sessions.</li> <li>• Plan awareness campaigns on different topics to be conducted within the hospital.</li> <li>• Ensure MDR-TB register is updated regularly.</li> <li>• Ensure patients who miss appointments or who default are followed up by tracing team.</li> <li>• Liaise with mobile teams with regard to patients.</li> <li>• Support mobile teams and community caregivers.</li> </ul>
Pharmacist	<ul style="list-style-type: none"> <li>• Ensure availability of second-line anti-TB and ancillary drugs.</li> <li>• Monitor drug stock levels.</li> <li>• Ensure correct storage of the drugs.</li> <li>• Dispatch drugs for patients who have been discharged to the local clinic or hospital.</li> </ul>
Admin clerk / Data capturer	<ul style="list-style-type: none"> <li>• Retrieve data related to sputum and other lab results from the laboratory and update patient records.</li> <li>• Capture patient data on the Electronic Drug Resistant TB Register (EDRWeb).</li> <li>• Compile and submit six-monthly cohort and other reports as needed.</li> </ul>

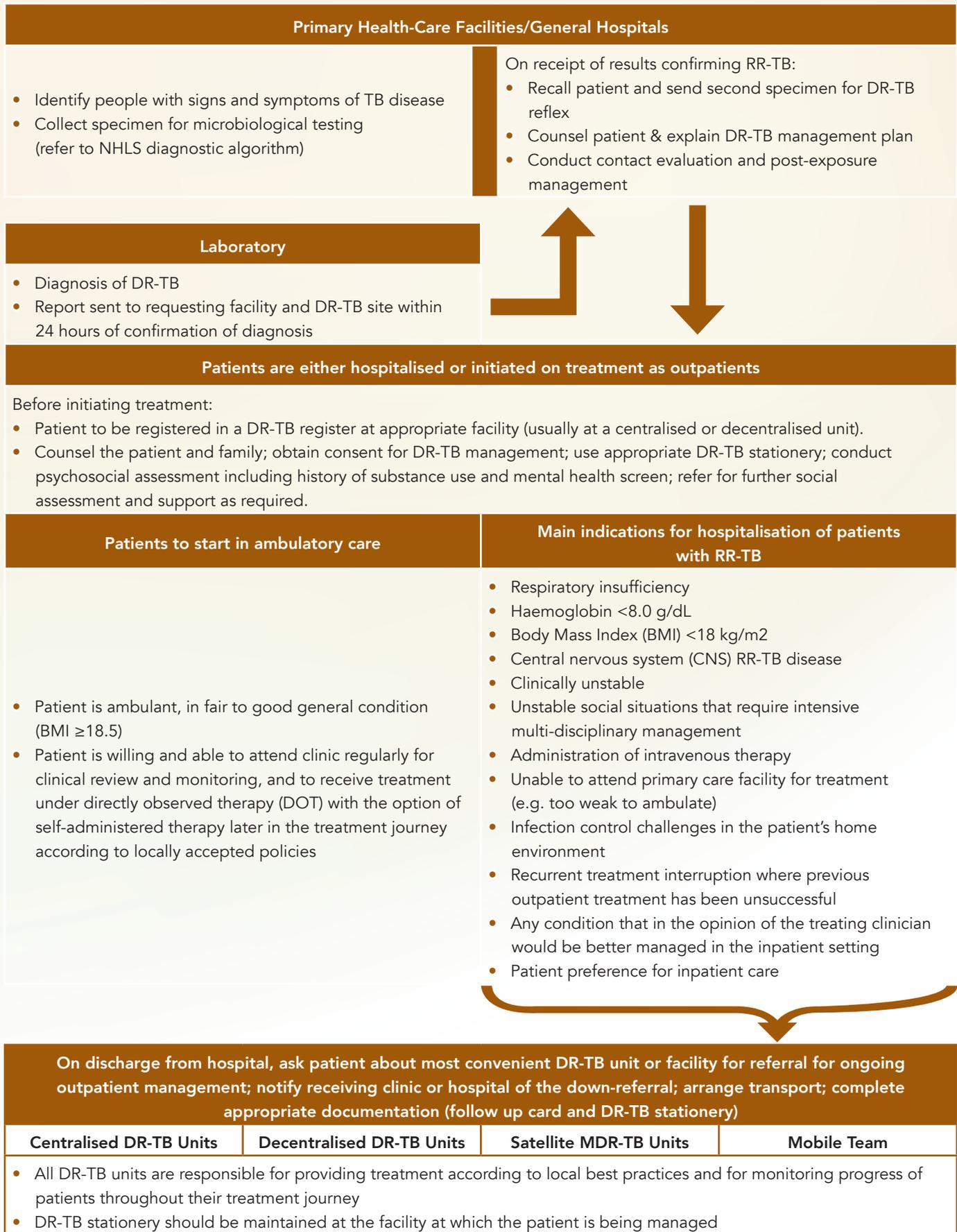
STAFF	RESPONSIBILITIES
Clinical psychologist (if available)	<ul style="list-style-type: none"> <li>• Conduct initial assessment of patients with psychological problems.</li> <li>• Conduct one on one or group therapy sessions for patients.</li> <li>• Refer patients who need expert opinion timeously.</li> </ul>
Occupational therapist (if available)	<ul style="list-style-type: none"> <li>• Conduct initial assessment of patients' psycho-social status.</li> <li>• Develop patients' insight into disease and behaviour through counselling and education.</li> <li>• Provide life skills development programmes.</li> <li>• Provide rehabilitation programmes for patients.</li> <li>• Monitor patient progress.</li> <li>• Facilitate support, stress management, and behaviour modification groups</li> <li>• Plan pre-vocational training programmes.</li> </ul>
Audiologist	<ul style="list-style-type: none"> <li>• Conduct baseline assessments for eligible patients prior to initiation of treatment and inform doctor if hearing impaired.</li> <li>• Monitor eligible patients monthly for hearing impairment and inform doctor if hearing deteriorates.</li> <li>• Recommend management of patient with hearing impairment.</li> </ul>
Physiotherapist (if available)	<ul style="list-style-type: none"> <li>• Conduct initial assessment of patients with co-morbidities and extensive lung disease.</li> <li>• Develop treatment programmes for the individual patients.</li> <li>• Monitor patient progress.</li> <li>• Assist patients with expectoration for monitoring culture conversion.</li> </ul>
Nursing service manager	<ul style="list-style-type: none"> <li>• Liaise with mobile teams and staff at facilities administering MDR-TB treatment to outpatients.</li> <li>• Ensure recording and reporting procedures are up to date.</li> <li>• Liaise with other stakeholders in the geographical area.</li> <li>• Organise and document six-monthly contact screening.</li> <li>• Trace newly identified MDR-TB patients and organise admission to decentralised DR-TB unit.</li> <li>• Organise regular monthly visits for MDR-TB outpatients to decentralised DR-TB units for monthly follow-up.</li> <li>• Coordinate activities of the tracing team and monitor their activities.</li> <li>• Participate in district DR-TB team.</li> <li>• Link DR-TB treatment programme with TB programme.</li> </ul>
Professional nurse/ Staff nurse/nursing assistant at mobile team	<ul style="list-style-type: none"> <li>• Possess a driving license to provide transportation in the absence of driver.</li> <li>• Monitor side effects, adherence, and household infection control practices.</li> <li>• Support and supervision of DOTS supporters.</li> <li>• Locate newly diagnosed MDR-TB patients.</li> </ul>

STAFF	RESPONSIBILITIES
Professional nurse/ Staff nurse/nursing assistant at mobile team	<ul style="list-style-type: none"> <li>• Trace MDR-TB defaulters.</li> <li>• Conduct six-monthly contact tracing on all household contacts.</li> <li>• Provide ongoing education on adherence, side effects, and infection control.</li> <li>• Record adherence and side effects and where refer complications or problems in patient management to nurse coordinator.</li> </ul>
Driver	<ul style="list-style-type: none"> <li>• Drive mobile team to monitor daily treatment to all MDR-TB patients in the intensive phase of treatment.</li> <li>• Transport patients for diagnosis, follow up, and admissions.</li> <li>• Drive mobile MDR-TB unit to trace treatment interrupters and defaulters.</li> </ul>
Caregivers/DOTS supporters	<ul style="list-style-type: none"> <li>• Assist with DOT administration of all doses received outside of health establishments.</li> <li>• Communicate all routine and emergency clinical issues to mobile team.</li> <li>• Provide ongoing education on adherence and infection control.</li> <li>• Recognise side effects, record and report to nurses and doctors</li> </ul>
Family members	<ul style="list-style-type: none"> <li>• Provide emotional support and nursing care to the patient during treatment.</li> <li>• Report any problems or changes in patient condition to the clinic nurse or community caregiver.</li> <li>• Assist with early identification and testing of symptomatic contacts.</li> </ul>

Table VIII: Responsibilities at Every Level

FUNCTIONS	CENTRALISED MDR-TB UNIT	DECENTRALISED MDR-TB UNIT	SATELLITE MDR-TB UNIT	PHC	MOBILE TEAM	COMMUNITY CAREGIVERS
Ambulatory care and admission of all MDR-TB cases for clinical reasons	✓	✓	NO, Unless no bed availability at centralised or decentralised DR-TB sites	NO	NO	NO
Ambulatory care and admission of all XDR- TB cases for clinical reasons	✓	NO, unless there is space and capacity	NO, unless there is capacity	NO, unless there is capacity	NO, unless there is capacity	NO, unless there is capacity
Monthly follow up of all DR-TB cases attending at clinic	✓	✓	✓	✓	NO	NO
DOT to all DR-TB patients attending daily	✓	✓	✓	✓	✓	✓
Recording of DR-TB patients in necessary stationery	✓	✓	✓	✓	✓	✓
Reporting (DR-TB Register and EDR-Web)	✓	✓	NO*	NO*	NO*	NO*
Monitoring and supervising DR-TB clinical management in the province	✓	NO	NO	NO	NO	NO

**Figure II: Flow of DR-TB Patients**



## 4.2. MANAGEMENT TEAMS/COMMITTEES AT DIFFERENT LEVELS

The provincial TB directorates are responsible for setting up management teams and committees to oversee the clinical management of DR-TB patients in the province. These committees need to include the audiologists working at DR-TB treatment sites and provincial rehabilitation managers.

### 4.2.1. PROVINCIAL DR-TB REVIEW COMMITTEE

Each province should establish a management team to support and advice in difficult clinical cases, medico-legal and ethical issues such as termination of MDR-TB treatment in a patient who does not respond to treatment. This committee must be multi-disciplinary and ideally should include medical officers and/or professional nurses from the DR-TB hospital, physicians, pathologists, paediatricians, cardio-thoracic surgeons, public health specialists, radiologists, civil society representatives, social workers, provincial management and a specialist in legal and ethical issues. Other representatives from government departments such as Social Development, Correctional Services, Military Health Services, South African Social Security Agency, and the mining industry may be included in this committee.

This committee advises and recommends on the following:

- Appropriate clinical management of individual MDR- and XDR-TB patients;
- Use of “rescue” regimens in individual patients with high-grade resistance;
- Management of chronic drug resistant TB regarding termination of treatment and palliative care;
- Management of patients who refuse treatment;
- Management of infectious patients who do not cooperate with the health professionals and those who abscond from hospital or refuse to be admitted; and
- Identification and resolutions to health systems issues contributing to poor service delivery such as delays in culture results or shortages of medication.

### 4.2.2. DISTRICT AND SUB-DISTRICT LEVEL

At a district and sub-district level co-ordination of DR-TB activities will be done by the district and sub-district TB coordinators and the district TB team if there is one. This team will be responsible for:

- Informing primary health care (PHC) staff of the latest developments regarding DR- TB;
- Disseminating and training PHC staff on the latest guidelines regarding when sputum cultures should be taken so that patients with DR-TB are diagnosed as soon as possible;
- Referring patients diagnosed with DR-TB to the decentralised unit for initiation of treatment;
- Ensuring that PHC staff feel supported in their treatment of patients with DR-TB;
- Ensuring that there are no interruptions in treatment as the patient moves from being an inpatient to receiving care in the community; and
- Monitoring and referring patients receiving treatment in the community;

**Patient support groups** to be formed at all levels of care to enhance adherence.

### 4.3. TREATMENT FOLLOW-UP

DR-TB treatment should be monitored closely through daily DOT and recording of patients taking treatment. Sputum for smear microscopy and culture should be collected every month throughout treatment. Depending on where the patient is receiving care, daily DOT and recording will be done by the decentralised DR-TB site, mobile team or the satellite unit administering medication. Sputum collection and the monitoring of smear microscopy, culture and DST results will be conducted at the decentralised DR-TB site.

Adverse effects should be monitored continuously by the facility where the patient is receiving treatment or the mobile team and DOTS supporters. Adverse effects will be assessed using a checklist and where necessary reported without delay to supervising unit. Adverse effects must be treated aggressively this will enhance treatment adherence.<sup>19,20</sup>

Details of the patient's HIV status and HAART, including the commencement date and treatment regimen must be recorded in the patients' notes. The clinical and laboratory evaluations that should be conducted monthly are listed in Table XIII.

**Table IX: Monthly Clinical and Laboratory Evaluations**

- Microbiological assessment (microscopy and culture)
- Bio-chemistry monitoring
- Pregnancy test (in women of childbearing age without documented contraception)
- Weight and height (BMI), and vital signs
- Urea and electrolytes if indicated
- Electrocardiogram (ECG)
- Audiometry if indicated
- Visual acuity (Snellen Chart) and colour perception (Ishihara test)
- Adverse events/side effects
- Adherence

### 4.4. LIST OF FACILITIES THAT WILL CONTINUE DOING AUDIOMETRY INCLUDE:

Nkqubela Hospital and Jose Pearson Hospital (Eastern Cape); Dr JS Moroka Hospital and Pelonomi Hospital (Free State); Sizwe Hospital (Gauteng); King Dinuzulu Hospital (KZN); Modimolle MDR-TB Hospital (Limpopo); Witbank TB Hospital (Mpumalanga); West End Hospital and Harry Surtie Hospital (Northern Cape); Tshepong Hospital (North West) and Brooklyn Chest Hospital (Western Cape).

All other sites shall stop routine testing of hearing on 31 December 2019.

## 4.5. INFECTION CONTROL

### 4.5.1. HOME INFECTION CONTROL

Mobile teams including DOTS supporters should educate patients, household members. Home infection control will be encouraged and monitored.

Home infection control includes the following:

- Ensuring adequate ventilation/open windows;
- Isolating patient (own bedroom where possible);
- Promoting cough hygiene;
- Ensuring that patients use surgical mask during waking hours while at home or when meeting with others;
- Refraining from close contact with children;
- Maximizing time in open-air environment (e.g., receiving visitors outside);
- Advising all household members and regular contacts to undergo HIV tests;
- Minimizing contact with known HIV positive patients; and
- Ensuring that household members are screened for TB and DR-TB every six months.

#### Infection Control during Home Visits

Mobile teams should decrease the risk of contracting DR-TB by adhering to the following infection control measures:

- Wearing an N95 respirator (health workers and DOTS supporters);
- Keeping home visits or clinical evaluations brief, and whenever possible, conduct these outside or in a well-ventilated room with as much distance as possible from the patient;
- Educating the patient on cough hygiene and avoiding close contact;
- Providing the patient with a surgical mask when close contact is required; and
- Collecting sputum outside, observing prescribed infection control precautions.

### 4.5.2. INFECTION CONTROL DURING PATIENT TRANSPORT

When transporting DR-TB patients, the following infection control measures should be observed:

- Use compartmentalized vehicles separating the airspace of the driver from that of the passengers;
- Open windows in vehicle;
- Provide surgical mask for patient;
- Provide N95 masks for medical staff and driver; and
- Educate patient.

Health workers who have contact with DR-TB patients should know their HIV status. If they do not, they should be encouraged to be tested for HIV. Health workers who are HIV- positive should commence ART when appropriate and be screened every six months for TB and have a TB culture done at the time of ART initiation and on an annual basis.

# 5. MONITORING AND EVALUATION OF THE DECENTRALISED AND DEINSTITUTIONALISED MDR-TB TREATMENT PROGRAMME

Regular monitoring of patients with DR-TB enables clinicians to monitor whether the patient is responding to treatment. Patients who are initiated on treatment need to come back after 2 weeks for a second examination. It is important to assess the extent of side-effects at this stage, review line probe assay results. A third visit should follow 2 weeks (at the end of 4th week of treatment). After that, monthly monitoring is necessary during the entire duration of treatment.

Capturing and maintaining data on patient progress and outcome will require dedicated data base personnel at each decentralised DR-TB site. A data capturer should be appointed at each decentralised MDR-TB unit and will assist in capturing all data related to patient management and monitoring of the programme.

The decentralised DR-TB sites should be responsible for keeping the DR-TB registers up to date, collecting data pertaining to the indicators listed below and capturing data on the Electronic Drug Resistant TB Register (EDR-Web). EDR-Web should be decentralised to lower levels of care in order to support this function. Similarly, case detection of DR-TB should be recorded at all levels of care.

At sub-district level, the referral site is responsible for collating and reporting on DR-TB data for the entire sub-district. If there is no capacity at sub-district level, we expect the district to ensure adequate recording and reporting for all their sub-districts.

The NDOH will conduct clinical audits to the 2 highest DR-TB burden facilities per province once a year at least. Provinces need to audit at least one facility per district every month (3 facilities per quarter) in 3 different sub-districts. A Standard Operating Procedure has been provided to provinces in order to support clinical audits.

Treatment outcomes report need to be reviewed every month.



# 6. CONCLUSIONS AND RECOMMENDATIONS

## 6.1. CONCLUSIONS

Our decentralised and deinstitutionalised management of MDR-TB services are effective. Our aim is to increase access to comprehensive and high-quality DR-TB services through well planned decentralisation of the PMDT programme. We aim to establish and maintain at least one MDR-TB treatment initiation site at each sub-district level.

MDR-TB treatment may be initiated by a medical practitioner, a trained clinical nurse practitioner or a trained clinical associate.

The modality of care must be dictated by the patient's needs hence all modalities model of DR-TB care must be available. TB smear microscopy positive patients in good general condition are also eligible for ambulatory care.

Every treatment initiation site must have access to good quality second-line TB medicines, laboratory tests, ECG machines, hearing tests machines and EDR Web. Access to hearing tests is no longer compulsory. Only, centres of excellence will continue testing hearing function. All other sites shall stop as of 1st January 2020.

Providing improved quality and patient-centred care at all treatment initiation sites is of the highest priority.

Very sick RR/MDR-TB (patients with extensive resistance patterns, pulmonary cavitation, very sick MDR-TB re-treatments), and very sick XDR-TB patients need to be admitted until they achieve smear microscopy conversion, and/or their clinical condition improves. In rare circumstances it may be necessary to admit patients until they get one TB culture negative or TB culture conversion.

Effective implementation of this policy framework will lead to a decrease of MDR-TB admissions.

## 6.2. RECOMMENDATIONS

All Provinces who have not achieved 100 % decentralisation, must fast-track MDR-TB initiation to achieve 100 % sub-district coverage. All Provinces that have achieved 100 % sub-district coverage need to maintain this level of service. All provinces need to continuously work on improving quality of care.

Focus on improvement of quality of care is crucial. All main MDR-TB treatment initiation sites (CoE and high burdened facilities) must be clinically audited at least once a year. NDOH is responsible for auditing 2 facilities per province annually. Provincial TB programmes must audit at least one facility per sub-district once a month (3 facilities per quarter).

NDOH and provinces should continue to plan for decentralisation, deinstitutionalization and integration of DR-TB care into HIV, TB and PHC services. This is necessary in order to maintain what has been achieved so far.

Adequate preparation and planning for decentralised and deinstitutionalised of DR-TB diagnosis, treatment and care services is necessary to ensure the success of DR-TB management. There should be adequate infrastructure and staff should be appropriately trained in order to take care of and provide quality DR-TB patient services.

# 7. APPENDIX: FACILITY READINESS ASSESSMENT TOOL

## 7.1. FACILITY CONTACT DETAILS

Provincial TB programmes are responsible for conducting facilities readiness assessments.

 <b>FACILITY READINESS ASSESSMENT TOOL FOR DR-TB UNITS EXPANDING ACCESS TO DR-TB CARE</b>	
Name of Facility	
Address of Facility	
Province	
District	
Sub-district	
Name of Contact Person	
Telephone	
Fax	
Email	
Type of facility (circle one)	1 = General Hospital                      2 = TB Hospital 3 = MDR-TB Hospital                      4 = Other

## 7.2. SERVICES PROVIDED

No.	Does the health facility provide the following services	YES	NO	Comments
1.1.	General Services <ul style="list-style-type: none"> <li>• OPD</li> <li>• Inpatients (specify)</li> </ul>			
1.2.	<ul style="list-style-type: none"> <li>• No. of available general beds</li> <li>• No. of isolation beds for TB/ DR-TB</li> </ul>			
1.3.	Specialised services (specify) <ul style="list-style-type: none"> <li>• Chronic disease management (diabetes, hypertension, respiratory/ asthma)</li> <li>• Reproductive health services (Family planning, PAP smear)</li> </ul>			
1.4.	HIV services <ul style="list-style-type: none"> <li>• HCT</li> <li>• PMTCT</li> <li>• PEP</li> <li>• ART</li> <li>• Mx of opportunistic infections</li> </ul>			
1.5.	TB services <ul style="list-style-type: none"> <li>• Outpatient</li> <li>• Inpatient</li> </ul>			
1.6.	Laboratory services: <ul style="list-style-type: none"> <li>• TB microscopy</li> <li>• TB culture</li> <li>• FBC</li> <li>• Other tests(specify):</li> </ul>			State turnaround time for: <ul style="list-style-type: none"> <li>• TB microscopy (48 hrs.): y/n if n, specify duration .....</li> <li>• TB Culture (6 weeks): y/n if n, specify duration.....</li> <li>• FBC (24 hours): y/n if n, specify .....</li> <li>• Other .....</li> </ul>
1.7.	X-rays			
1.8.	Nutrition counseling, supplements, etc.			
1.9.	Patient support services (social worker/ support group/ community caregiver)			

### 7.3. POLICY FRAMEWORK AND TREATMENT PROTOCOLS (THE QUICK REFERENCE GUIDES)

No.	Does the health facility have the following guidelines	Yes	No	Comments
2.1.	DR-TB Guidelines			
2.2.	National TB Guidelines, 2009			
2.3.	Management of HIV Guidelines			
2.4.	TB Infection Control Guidelines			
2.5.	Universal Infection Control			
2.6.	Provider-Initiated Counseling and Testing (PICT) / Current VCT Policy / HIV Counseling for Children			
2.7.	Nutrition for People Living With HIV and AIDS (check for policies)			
2.8.	IPT Guidelines			
2.9.	STI management guidelines			

### 7.4. PROJECTED DR-TB LOAD DURING THE FIRST SIX MONTHS (USE AVAILABLE RECORDS)

			Months					
			MDR/XDR-TB patients diagnosed from the area over past 6 months					
			1	2	3	4	5	6
3.1.	Number of MDR-TB patients	Adults						
		Children						
3.2.	Number of XDR-TB patients	Adults						
		Children						

## 7.5. HUMAN RESOURCES (MINIMUM STAFFING LEVELS TO SUPPORT DR-TB SERVICES)

Category of staff		Status of HR		
		Existing number of personnel	Required number of personnel	Gap
4.1.	Medical officer or access to doctor			
4.2.	Clinical Nurse Practitioners trained on NIMDR			
4.3.	Clinical Nurse Practitioners			
4.4.	Clinical Associates			
4.5.	Enrolled nurses and Enrolled nursing assistants			
4.6.	Dietician/nutritionist or assistant			
4.7.	Pharmacist or assistant			
4.8.	Clinical psychologist			
4.9.	Occupational therapist			
4.10.	Audiologist			
4.11.	Physiotherapist			
4.12.	Social worker			
4.13.	Lay counselor			
4.14.	Administrative clerk			
4.15.	Data capturer			
4.16.	Driver			

## 7.6. PATIENT MANAGEMENT INFORMATION SYSTEM (PAPER BASED/ELECTRONIC)

No.	Does the facility have	YES	NO	Specify type available
5.1.	DR-TB data collection tools (registers, forms)			
5.2.	DR-TB data reporting tools			
5.3.	EDR Web system			
5.4.	A person trained on EDRWeb for M&E (at facility/ sub-district/ district)			

## 7.7. COMMUNITY INVOLVEMENT

No.	Is the health facility working with the community	YES	NO	Comments/ Challenges
6.1.	Is the facility engaged in any social mobilization and advocacy activities with the community such as a hospital board? (i.e., any linkage to CBOs, Imbizos, evidence of meetings, referral, care plans, clinic committee?)			

## 7.8. INFRASTRUCTURE: WHAT IS AVAILABLE AND WHAT NEEDS TO BE DONE TO ACCOMMODATE THE ADDITIONAL SERVICES?

No.	Does the health facility have	YES	NO	Comments/ Challenges
7.1.	Adequate (well ventilated) space for: <ul style="list-style-type: none"> <li>• Reception area</li> <li>• Waiting area</li> </ul>			
7.2.	Adequate space for: <ul style="list-style-type: none"> <li>• General patient consultation / Counseling</li> </ul>			
7.3.	<ul style="list-style-type: none"> <li>• Infection control compliance (TB, etc.)</li> <li>• Infection control facility plan</li> </ul>			

No.	Does the health facility have	YES	NO	Comments/ Challenges
7.4.	Adequate secure Storage area for drugs and dispensing			
7.5.	Medical confidential records			
7.6.	Communication systems: Telephone/ transportation to and from the referral services (planned patient transport)			
7.7.	Availability of vehicle			

## 7.9. REFERRAL NETWORK

No.	Referral Network	YES	NO	Comments/ Challenges
8.1.	Is there follow up of referred patients <ul style="list-style-type: none"> <li>• Up referral</li> <li>• Down referral</li> </ul>			

## 7.10. EXTERNAL SUPPORT

No.	Does the Health facility receive any external support?	Define Support Provided
9.1.	List Partners	

## 7.11. SKILLS AUDIT

Category	Number	MDR-TB trained	TB trained	TB Infection Control	IPT	TB/HIV	HIV & AIDS Management
Medical doctors							
Prof nurses							
Clinical Associates							
Enrolled nurses							
Enrolled auxiliary nurses							
Lay counsellors							
General assistants							

### 7.11.1 CONSTRAINTS

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### 7.11.2 RECOMMENDATIONS

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## 7.12. ASSESSING TEAM

Full name and designation	Cell Number	Landline	Email

Date: .....

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