MULTI-DRUG RESISTANT TUBERCULOSIS

A POLICY FRAMEWORK ON DECENTRALISED AND DEINSTITUTIONALISED MANAGEMENT FOR SOUTH AFRICA

Directorate: Drug-Resistant Tuberculosis, TB & HIV
Chief Directorate: TB Control and Management

health
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Health
REPUBLIC OF SOUTH AFRICA

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August 2011

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FOREWORD

South Africa is the third highest tuberculosis (TB) burden country in the world, lagging behind only two countries -- China and India, countries that have significantly larger populations than ours.

We have to act decisively to curb the rise of TB and particularly drug-resistant TB (DR-TB) in our country. The rising rate of drug resistance among TB patients is due to poorly managed TB patients by health care providers, treatment defaulters and other challenges ranging from delays in initiation of treatment, inadequate bed capacity and poor infection control. Recent evidence suggests that a significant proportion of DR-TB is due to ongoing transmission of already circulating resistant TB strains.

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 has thus decided to reduce the period of stay for DR-TB patients in centralised DR-TB units and to formally decentralise the services.

Management of DR-TB is complex and requires specific skills and additional resources. This document describes the need for decentralisation, the benefits of decentralised treatment, elements of decentralised care, required organisational structures and human resources requirements, and expected functions of each level of operations. Decentralisation of DR-TB care also implies deinstitutionalisation of care and treatment of patients.

The *Multi-Drug Resistant Tuberculosis: A Policy Framework on Decentralised and Deinstitutionalised Management for South Africa* will 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.

Minister of Health
Dr. Aaron Motsoaledi

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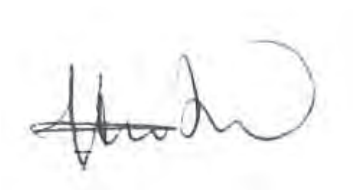

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ABBREVIATIONS

AFB	Acid-Fast Bacilli
ART	Antiretroviral Therapy
ARV	Antiretroviral
DOT	Directly Observed Therapy
DRS	Drug Resistance Surveillance
DR-TB	Drug-Resistant Tuberculosis
DST	Drug Susceptibility Testing
ED-TBR Web	Electronic Drug Resistant TB Register
HAART	Highly Active Antiretroviral Therapy
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
IT	Information Technology
MDR-TB	Multi-Drug Resistant Tuberculosis
NDOH	National Department of Health
NHLS	National Health Laboratory Services
PHC	Primary Health Care
PPM	Public-Private Mix
TB	Tuberculosis
XDR-TB	Extensively Drug-Resistant Tuberculosis
WHO	World Health Organisation

EXECUTIVE SUMMARY

This *Policy Framework* assesses the need for and benefits of decentralisation and deinstitutionalisation of drug-resistant tuberculosis (DR-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 focuses 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. Current guidelines stipulate that all DR-TB patients should be hospitalised for at least six months. The National TB Programme has, in alignment with the guidelines, adhered to the policy of hospitalisation of all DR-TB patients for at least the initial six months of treatment.

> 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 situation in which patients are receiving ambulatory treatment.[1]

A clinical audit of DR-TB services and a World Health Organisation (WHO) led review of the TB programme revealed that the current programme is facing many challenges including delayed initiation of treatment, inadequate bed capacity, poor infection control in hospitals, and poor adherence to treatment, often caused by six months of hospitalisation where patients are forced to relinquish work and home responsibilities. Recent evidence suggests that a significant proportion of DR-TB is due to ongoing transmission of already resistant strains.[2,3]

There is growing evidence from within and outside the country that implementation of a decentralised care model will improve efficiency and effectiveness of the current programme.

To address these challenges, the NDoH has suggested (a) reducing the length of time that MDR-TB patients are required to stay in centralised DR-TB hospitals, and (b) decentralising and deinstitutionalising services.

The following health framework for management of DR-TB patients has been proposed:

1. **Centralised DR-TB unit** also known as "Provincial Centre of Excellence";
2. **Decentralised DR-TB units**;
3. **Satellite MDR-TB units**; and
4. **Community support** through primary health care services to assist with deinstitutionalisation of patients, including:
   a. Mobile teams, and
   b. Community caregivers.

The following suggested changes in the management of DR-TB will require additional resources and specific skills as the treatment process is complex and lengthy:

1. **Centralised MDR-TB units** will be responsible for initiating and monitoring treatment of all extensively drug-resistant TB (XDR-TB) and paediatric patients, and some MDR-TB patients such as those with complications, co-morbidities, or those who live near the unit. The centralised unit will support and advise the provincial TB Directorate regarding the clinical management of DR-TB in the province
2. **Decentralised DR-TB units** will be responsible for initiating and monitoring treatment in MDR-TB, polyresistant and mono-resistant patients. Given the capacity, these units should be allowed to manage XDR-TB patients.
3. **Satellite MDR-TB units** will not initiate treatment of DR-TB cases but will provide treatment, and monitor adherence and side effects for patients that were initiated in either centralised or decentralised units. These units should be capacitated to become decentralised units and to initiate treatment in the future. They will be essentially transitional structures. Satellite units may be located in district and psychiatric hospitals, community health centres, correctional centres, or mining health care facilities.
4. **Mobile teams and community caregivers** will provide treatment and support to MDR-TB patients receiving treatment at home. Provinces and districts should provide enough mobile teams and community caregivers to sustain the deinstitutionalisation. These functions should be integrated with the primary health care (PHC) community outreach teams within the context of re-engineering of PHC services.
5. Recording and reporting will be the responsibility of the centralised and decentralised DR-TB units.
6. The centralised DR-TB unit, in coordination with provincial Department of Health, will be responsible for the overall management of DR-TB in each province. The centralised DR-TB unit will provide clinical support and where possible, managerial support and clinical training for DR-TB in the province. District TB coordinators need to support DR-TB facilities in their areas.
7. The satellite MDR-TB units, mobile teams and community caregivers will be accountable to the decentralised DR-TB units. In turn, the decentralised DR-TB units will be reporting to the centralised DR-TB unit.

This *Policy Framework* stipulates that all MDR-TB smear-negative, TB culture positive patients need to be started on ambulatory treatment. Other MDR-TB patients without extensive disease, stable, smear-positive should be admitted until two negative smear microscopy results are received. Only very sick MDR-TB with extensive disease and XDR-TB patients will be admitted until they have two consecutive TB culture negative results. Criteria for starting treatment either as ambulatory or in facilities are discussed in detail in Chapter 4, Figure II: *Flow of Patients*. Upon introduction of this policy, it is expected that admissions to facilities will drop by 30%, which represents the proportion of TB smear negative, culture positive MDR-TB patients in South Africa's facilities. These admissions rates will continue to decline over the years.

- All smear negative TB culture positive MDR-TB patients should be started on ambulatory treatment.
- MDR-TB patients should be discharged after two consecutive TB negative smear microscopy results.
- Very sick MDR- and XDR-TB patients should be admitted until two consecutive negative TB culture results.

Patients who refuse to be admitted to facilities may not be refused treatment.

1. INTRODUCTION

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 in an attempt 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 the world's third highest burden TB country in the world, only lagging behind countries with significantly larger populations, such as China and India. In addition, the numbers of MDR-TB and XDR-TB patients have increased due to the concurrent HIV epidemic and inadequate management of TB. In 2009 the National Health Laboratory Services (NHLS) diagnosed 9 070 MDR-TB and 594 XDR-TB cases. There has been a steady increase in cases since 2006, possibly due to increased case detection (See Tables I and II). In 2010 the NHLS diagnosed 7 386 MDR-TB cases and 741 XDR-TB cases. It is not clear why a decrease between 2009 and 2010 is seen in the statistics. It is not known how many cases were diagnosed through private laboratories in the country.

Table I Number of MDR-TB Patients, 2004-2010 (Laboratory Diagnosis from NHLS)

PROVINCE	2004	2005	2006	2007	2008	2009	2010	TOTAL
Eastern Cape	379	545	836	1092	1501	1858	1782	7993
Free State	116	151	198	179	381	253	267	1545
Gauteng	537	676	732	986	1028	1307	934	6200
KwaZulu-Natal	583	1024	2200	2208	1573	1773	2032	11393
Limpopo	59	40	77	91	185	204	126	782
Mpumalanga	162	134	139	506	657	446	312	2356
Northern Cape	168	155	188	199	290	631	353	1984
North West	130	203	225	397	363	520	158	1996
Western Cape	1085	1192	1179	1771	2220	2078	1422	10947
South Africa	**3219**	**4120**	**5774**	**7429**	**8198**	**9070**	**7386**	**45196**

Table II Number of XDR-TB Patients, 2004-2010 (Laboratory Diagnosis from NHLS)

PROVINCE	2004	2005	2006	2007	2008	2009	2010	TOTAL
Eastern Cape	3	18	61	108	175	123	320	808
Free State	1	6	3	4	3	3	7	27
Gauteng	5	14	19	38	30	65	37	208
KwaZulu-Natal	59	227	336	241	181	254	201	1499
Limpopo	-	2	5	2	2	6	6	23
Mpumalanga	-	-	-	12	14	18	5	49
Northern Cape	4	10	3	7	19	40	39	122
North West	1	5	9	4	4	13	14	50
Western Cape	12	16	28	42	60	72	112	342
South Africa	**85**	**298**	**464**	**458**	**488**	**594**	**741**	**3128**

The current NDoH policy dictates 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 are hospitalised for many months and waiting lists for patients need to be admitted to the centralised units are long, delaying the initiation of treatment in some provinces for three or four months. In addition, several patients die before starting treatment.

Of approximately 9 070 cases of MDR-TB notified in 2009, fewer than 5 000 were started on treatment in the 9 provinces (See Table III). Of the 7 836 MDR-TB cases diagnosed in 2010, only 5 313 (71%) were started on treatment. This is an improvement in comparison with 2009 data however the gap between number diagnosed and number started on treatment still needs to be narrowed substantially. Thus less than 50% of known MDR-TB cases were hospitalised. Previous estimates showed that up to 73% of diagnosed cases of MDR-TB were admitted and started on treatment.

Table III Number of MDR- and XDR-TB Patients Started on Treatment, 2007-2010

PROVINCE	2007		2008		2009		2010	
	MDR-TB	XDR-TB	MDR-TB	XDR-TB	MDR-TB	XDR-TB	MDR-TB	XDR-TB
Eastern Cape	932	171	772	135	847	135	927	224
Free State	158	7	233	7	148	6	167	5
Gauteng	497	45	414	40	512	25	607	30
KwaZulu-Natal	788	170	1039	163	927	177	1788	235
Limpopo	71	2	104	0	88	3	119	3
Mpumalanga	148	0	272	3	198	5	298	6
Northern Cape	145	11	148	8	253	13	230	37
North West	156	4	159	1	175	9	143	14
Western Cape	439	64	890	34	995	58	1034	61
South Africa	**3334**	**474**	**4031**	**391**	**4143**	**431**	**5313**	**615**

The number of patients diagnosed with MDR- and XDR-TB far exceeds the number of available beds per province (Table IV). It is expected that the number of patients diagnosed with DR-TB will increase in the near future, and thus the demand for beds will continue to increase. In turn, waiting lists will grow which will negatively affect treatment initiation, and infectious and untreated patients may expose family and community members to DR-TB bacilli.

Table IV Patient Load and Bed Availability for MDR- and XDR-TB Patients During 2010

PROVINCE	MDR-TB started on Treatment (2010)	XDR-TB started on Treatment (2010)	Number of Beds Available	Number of Beds Required	Gap
Eastern Cape	927	224	622	688	-66
Free State	167	5	162	89	+73
Gauteng	607	30	266	334	-68
KwaZulu-Natal	1788	235	777	1129	-352
Limpopo	119	3	50	63	-13
Mpumalanga	298	6	130	155	-25
Northern Cape	230	37	65	152	-87
North West	143	14	97	86	+11
Western Cape	1034	61	363	578	-215
South Africa	**5313**	**615**	**2532**	**3274**	**-742**

1.3. Rationale

The current policy prescribing that all DR-TB patients be admitted in specialised TB hospitals is not feasible, and an adjustment to the policy is required. Consequently, the NDOH proposes to decentralise the management of patients with MDR-TB (not XDR-TB). This will shorten the number of days between diagnosis and treatment initiation, increasing treatment coverage, reducing the transmission, and making it possible for patients to be treated closer to their homes, increasing the social acceptability of treatment.

Although each province should maintain at least one specialised MDR/XDR-TB unit, additional DR-TB decentralised units each with a number of satellite units should be established. A recent 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.[4] Patients who refuse admission but who are willing to receive treatment can be treated in the community if they can access the available health services and commit to adhere to proper infection control practices at household and community levels.

Recent studies conducted in South Africa suggest that MDR-TB patients are not being effectively treated and cured[5]; this is contributing to the development of XDR-TB.[6]

The current form of management (centralised in specialised units) has 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.[7]
- 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.[3,8]
- 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.[9]
- 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 is taking place in an uncoordinated and unsystematic manner. Formalisation of decentralised treatment with guidelines on implementation will optimise the chances of successful treatment.

Treatment outcomes for MDR-TB patients in South Africa managed as inpatients are not good. Between 1987 and 1989, Schaaf et al. in Western Cape reported that of 240 MDR-TB patients, 33% were cured, 13% failed treatment and 33% died.[10] A national study ranging from 1999-2001, and focusing on 671 patients, reported that 67 (10%) defaulted treatment.[5] Of the 67 patients that defaulted treatment, 27 (40.3%) had TB culture positive sputum at the time of default, hence infectious. This large proportion of TB culture positive among defaulters underscores the public health importance of minimizing treatment default.[5] At King George V Hospital in Durban treatment success rate of approximately 45% and defaulter rates of 15% were recorded between 2000 and 2006.[11] In a study undertaken at Tugela Ferry in KwaZulu-Natal from 2005 to 2007, the mortality rate among MDR-TB patients after one year's treatment was 75%.[12] A review of the 2007 cohort of MDR-TB patients by the NDOH showed 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.

Participants in a national workshop on MDR-TB community care in July 2009 suggested that the period of stay of MDR-TB patients in centralised MDR-TB hospitals be reduced. In addition, the following decentralised units would ensure treatment closer to patients' homes:

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.

Community-based treatment models for MDR-TB have been successfully implemented in other countries[13,14], but the South African situation is unique. The health services have to take the high burden of HIV and TB[15], high TB-HIV co-infection rates and high incidence of MDR-TB as well as pockets of high incidence of XDR-TB when considering appropriate models.

Decentralised management of MDR-TB patients will benefit the patient by:

- Accommodating their personal responsibilities and needs as they will be closer to their homes;
- Reducing transmission of MDR-TB by initiating treatment sooner, which will make more beds available;
- Improving treatment adherence in community-based programmes as documented in Peru[14], Latvia[13], and some parts of South Africa[16]; and
- Improving cost effectiveness by reducing lengthy hospital stays in specialised hospitals.

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

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2.1. Principles

2.1.1. Need for Clarity of Functions Across all Levels

Effective DR-TB treatment at different levels of the health care system will depend on clear expectations with specific functions for each level of the health care system and a clear referral pathway between these levels. This will facilitate support for community level facilities from experts in DR-TB at the centralised specialised hospitals in each province.

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 recognise 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 district and primary health care levels, is essential to ensure the treatment success for MDR-TB patients.

In addition, linkages with all health services and facilities will be necessary to minimise 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 immuno-compromised 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-infected patients. Every co-infected patient should have both conditions assessed and monitored and repeat medication prescribed at each monthly appointment.

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

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3.1. Key Elements for a Successful Decentralised and Deinstitutionalised MDR-TB Programme include:

- Prompt and accurate MDR-TB diagnoses;
- Trained multidisciplinary teams with adequate and effective mentorship and supervision;
- Guidelines/protocols for clinical management;
- Uninterrupted supplies of second-line anti-TB drugs and ancillary drugs for managing side effects;
- Adequate infrastructure and 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;
- Rigorous monitoring and evaluation; indicators must be defined and operational research conducted; and
- Ring-fenced resources dedicated to ensure the provision of specialised MDR-TB staff.

An essential step in decentralisation of MDR-TB treatment is that district health managers and health workers are appraised of 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 a number of 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.

Table V Requirements for Successful Decentralised and Deinstitutionalised MDR-TB Programme and Means of Achievement

Requirements	Means
Prompt and accurate DR-TB diagnosis	• Ensure good quality culture and drug sensitivity testing and prompt reporting of results; and • Include line probe assay.
Trained multidisciplinary team with adequate and effective mentorship and supervision	• Ensure well trained nurse and MDR-TB counsellor with capacity for daily administration of injections in the community as per agreed model; • Establish tracer teams that conduct home visits, indentify contacts and trace defaulters; • Provide regular support from a doctor familiar with the DR-TB and ART guidelines; • Ensure access to social and mental health support structures; and • Establish clearly defined roles and responsibilities.
Guidelines/protocols for clinical management	• Develop clear guidelines, algorithms and referral pathways; • Ensure that the specialised DR-TB team at the provincial and decentralised sites initiate, manage and evaluate DR-TB treatment in accordance with national guidelines; • 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 • Ensure initiation and support for HAART.
Uninterrupted supply of second-line anti-TB drugs	• Ensure pharmacy support; and • Prescribe and maintain appropriate DR-TB treatment.
Adequate Infrastructure and infection control measures	Good procedures include: • Well ventilated consulting rooms; • Well ventilated waiting areas; • UVGI lights and extractors fans where possible; and • Respiratory protection tools available at all times (e.g., surgical masks for patients and N95 respirators for health care workers).

Requirements	Means
Integration with local TB programme activities and HIV and PHC services	• Conduct HIV tests as soon as possible in patients diagnosed with DR-TB; and • Initiate ART within two weeks in HIV-positive patients not already on ART.
Selection of patients who will benefit from completing MDR-TB treatment at district, sub-district or community level.	Establish: • Criteria for patients who need to be treated at the provincial specialised hospital; • Selection criteria for patients eligible for treatment in the community; • Patient needs and his/her preferred option for treatment; and • Decentralised DR-TB units, satellite MDR-TB units and mobile teams and MDR-TB and HAART trained DOTS supporters and caregivers.
Close monitoring of daily treatment, including providing injections and supervising adverse effects.	• Ensure close supervision of mobile teams and clear pathways for feedback to satellite or decentralised units; and • Maintain for early detection and tracking of patients defaulting treatment.
Effective communication between all levels of care.	• Establish communication channels between MDR-TB units; and • Develop clear referral guidelines.
Formulation of a province/ district's Advocacy, Communication and Social Mobilisation (ACSM) plan.	• 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; • Involve public participation, TB Ambassadors, health professionals and other key stakeholders; and • Disseminate relevant IEC materials to clinics, schools, and Thusong community centres in appropriate languages.
Monitoring and evaluation	• Ensure information technology support and database management; • Define indicators; and • Conduct operational research.
Ring fenced resources dedicated to providing specialised MDR-TB staff	• Cost treatment for DR-TB; • Predict number of DR-TB cases per annum; and • Allocate ring-fenced budgeting based on predicted number of DR-TB cases and cost of treatment.

4. TYPES, STRUCTURE, LEVELS AND FUNCTIONS

4. TYPES, STRUCTURE, LEVELS AND FUNCTIONS

This policy framework has been developed based on previous experience in Peru[17] and current efforts at out-patient MDR-TB treatment in KwaZulu-Natal[18] and in the Western Cape.[16] The framework describes the roles of the different levels of patient management.

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 until there are two successive negative TB cultures;
- 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;
- Providing technical assistance and capacity building to decentralised DR-TB units, and feeder clinics on management of DR-TB; and
- Arranging patients' evaluations at provincial patient review committees.

4.1.2. Districts or Sub-Districts

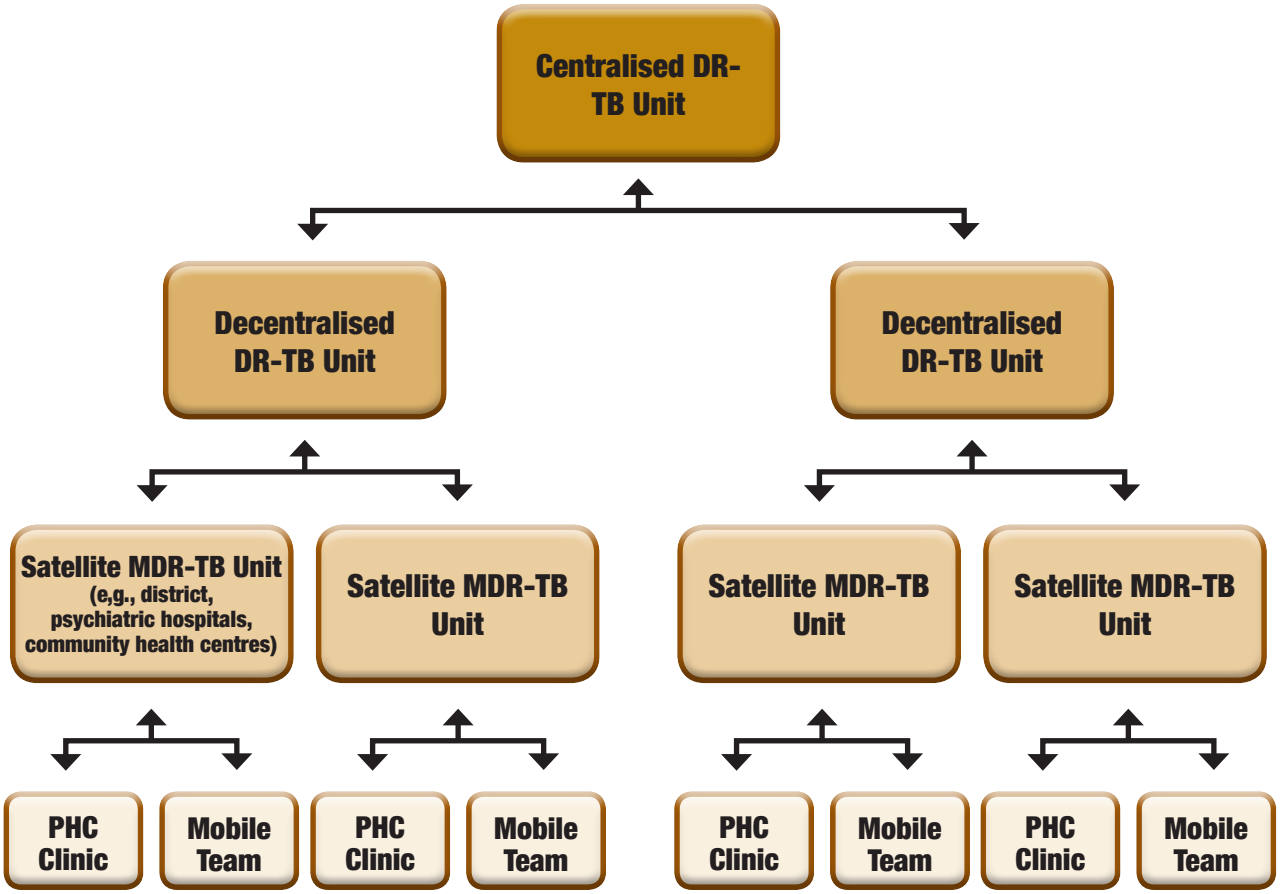
Districts and sub-districts have administrative and management responsibilities in ensuring effective DR-TB services in the area. Their primary function is to:

- Trace all confirmed DR-TB patients and refer 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;
- Arrange transportation 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 two years;
- 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.

Table VI Recommended Staffing Levels for the Centralised DR-TB Unit

Staff	Recommended Staffing Levels
Doctors	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 Unit exist to complement bed capacity of decentralised sites. They are essentially transitional and should be capacitated to become decentralised sites. Mobile teams are to be attached to PHC services but operate within the community.

4.1.3. Decentralised DR-TB Units

There will be a number of 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 cases according to the national and provincial Department of Health's discretion.

Patients diagnosed with MDR-TB who are smear microscopy positive will be hospitalised at the decentralised DR-TB units for up to eight weeks or until they become smear negative on two consecutive tests. This is important given that most patients with MDR-TB in South Africa are co-infected with MDR-TB and HIV and will need to commence treatment for both diseases.

Once a patient's sputum smear microscopy is shown to be negative and they meet the criteria for outpatient treatment (see Figure 2), they can receive treatment while living at home. Smear positive patients who refuse admission but are willing to receive medication should still be treated.

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;
- 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 admitted to 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;
- 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 of DR-TB patients started on treatment, culture conversion and outcomes;
- 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; and
- Tracing all confirmed cases.

Table VII 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.
Part-time Staff: These officers are usually employed by hospitals, and will be required to give 10% to 20% of their time to DR-TB patients	
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 the health of the patient.

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 and is smear negative. 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. The initial period of hospitalisation should be between two and eight weeks.

Initially the patient should return monthly to the decentralised DR-TB 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 DR-TB site.

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

Functions of Satellite MDR-TB Units

- Admitting all MDR-TB cases referred from centralised or decentralised DR-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 patients admitted to hospital;
- Preparing a discharge plan for all patients and ensuring effective down referrals;
- Monitoring treatment side effects; and
- Ensuring referral of patients with XDR-TB, severe adverse events, and complicated disease to the centralised DR-TB site.

Table VIII 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 health-care (PHC) facilities should play a significant role in providing injectables at the clinics and providing DOT to all DR-TB patients in the area. This must be integrated with the treatment of other TB and HIV patients. The existing TB nurses will be capacitated to handle these activities. It is not necessary to have DR-TB nurses at the primary health care level.

Patients who have access to a PHC clinic should utilise the health facility for their daily injection and 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; and
- Ensuring referral of patients with XDR-TB, severe adverse events, and complicated disease to the centralised DR-TB unit.

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.

Table IX 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

4.1.6. Mobile Teams

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 provide injections to patients at their homes, supervise intake of oral tablets, and also educate family about infection control.

Patients who are unable to access a health facility daily should, for the duration of the injectable phase of treatment, be visited daily (five times a week) at home by a mobile team, which should consist of a driver and nurse. During these visits, the team will administer injectable drugs, observe the patient taking their oral drugs, 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. In some instances the mobile MDR-TB unit will also carry out TB programme activities such as tracing defaulters from the TB programme or giving re-treatment patients streptomycin injections.

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.

Table X 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 10 patients
Driver	1 for 20 patients

4.1.7. Community Level: DOTS Supporters/Caregivers

Depending on the local situation the DOTS supporters may be community caregivers, community DOTS volunteers or family members. It should be noted training is very important for these cadres, and compensation should be considered seriously because DOT is our core business. 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 will provide ongoing daily support to MDR-TB patients who are treated on an outpatient 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 XI Staff Responsibilities

Staff	Responsibilities
Doctor	• Assess patient for co-morbidities and requesting baseline tests. • Initiate DR-TB treatment regimen for the patient (at centralised and decentralised DR-TB units). • Review treatment of patient and make any necessary adjustments. • Provide clinical monitoring of patients' treatment for adverse events and prompt management. • Report adverse drug events to the Medicines Control Council. • Provide prompt referral for tertiary care or specialist care when needed. • Ensure necessary laboratory tests are conducted timeously for adequate monitoring of the patient and his/her response to treatment. • Attend meetings, and keep up-to-date about TB and DR-TB management and surveillance. • Educate nurses and other members of the DR-TB team.
Professional nurse/ Staff nurse or nursing assistant	• Coordinate clinical care with other health professionals. • Monitor inpatients and refer to doctor when appropriate. • Coordinate household assessment, discharge of patient, and linkages to outpatient services. • 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. • Manage and coordinate MDR-TB outpatients. • Support nursing staff in the decentralised DR-TB site. • Monitor patient management (MDR-TB register) and compile a six-monthly report. • Maintain a close relationship with the patient. • Administer treatment to the patient. • Provide ongoing nursing care. • Complete the patient treatment card for treatment dosages given to the patient.

Staff	Responsibilities
Professional nurse/ Staff nurse or nursing assistant	• Provide counselling for HIV testing. • Conduct HIV testing on patients who give consent. • Provide educational talks to patients on a one-on-one basis or in group sessions. • Plan awareness campaigns on different topics to be conducted within the hospital. • Ensure MDR-TB register is updated regularly. • Ensure patients who miss appointments or who default are followed up by tracing team. • Liaise with mobile teams with regard to patients. • Support mobile teams and community caregivers.
Pharmacist	• Ensure availability of second-line anti-TB and ancillary drugs. • Monitor drug stock levels. • Ensure correct storage of the drugs. • Dispatch drugs for patients who have been discharged to the local clinic or hospital.
Admin clerk/ Data capturer	• Retrieve data related to sputum and other lab results from the laboratory and update patient records. • Capture patient data on the Electronic Drug Resistant TB Register (EDRWeb). • Compile and submit six-monthly cohort and other reports as needed.
Clinical psychologist (if available)	• Conduct initial assessment of patients with psychological problems. • Conduct one on one or group therapy sessions for patients. • Refer patients who need expert opinion timeously.
Occupational therapist (if available)	• Conduct initial assessment of patients' psycho-social status. • Develop patients' insight into disease and behaviour through counselling and education. • Provide life skills development programmes. • Provide rehabilitation programmes for patients. • Monitor patient progress. • Facilitate support, stress management, and behaviour modification groups. • Plan pre-vocational training programmes.
Audiologist	• Conduct baseline assessments for all patients prior to initiation of treatment and inform doctor if hearing impaired. • Monitor patients monthly for hearing impairment during the injectable phase and inform doctor if hearing deteriorates. • Recommend management of patient with hearing impairment.
Physiotherapist (if available)	• Conduct initial assessment of patients with co-morbidities and extensive lung disease. • Develop treatment programmes for the individual patients. • Monitor patient progress. • Assist patients with expectoration for monitoring culture conversion.

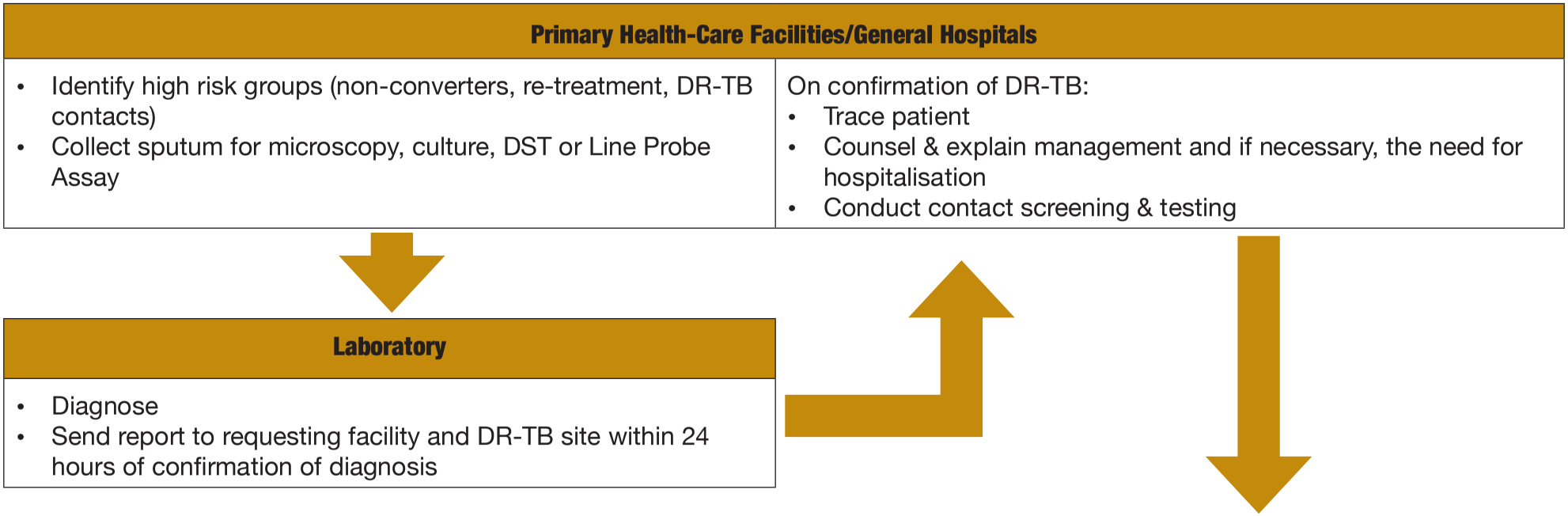
Staff	Responsibilities
Nursing service manager	• Liaise with mobile teams and staff at facilities administering MDR-TB treatment to outpatients. • Ensure recording and reporting procedures are up-to-date. • Liaise with other stakeholders in the geographical area. • Organise and document six-monthly contact screening. • Trace newly identified MDR-TB patients and organise admission to decentralised DR-TB unit. • Organise regular monthly visits for MDR-TB outpatients to decentralised DR-TB units for monthly follow up. • Coordinate activities of the tracing team and monitor their activities. • Participate in district DR-TB team. • Link DR-TB treatment programme with TB programme.
Professional nurse/Staff nurse/nursing assistant at mobile team	• Possess a driving license to provide transportation in the absence of driver. • Administer daily injections to all MDR-TB patients in the intensive phase of treatment, monitor side effects, adherence, and household infection control practices. • Support and supervision of DOTS supporters. • Locate newly diagnosed MDR-TB patients. • Trace MDR-TB defaulters. • Conduct six-monthly contact tracing on all household contacts. • Provide ongoing education on adherence, side effects, and infection control. • Record adherence and side effects and where refer complications or problems in patient management to nurse coordinator.
Driver	• Drive mobile team to administer daily injections to all MDR-TB patients in the intensive phase of treatment. • Transport patients for diagnosis, follow up, and admissions. • Drive mobile MDR-TB unit to trace treatment interrupters and defaulters.
Caregivers/DOTS supporters	• Assist with DOT administration of all doses received outside of health establishments. • Communicate all routine and emergency clinical issues to mobile team. • Provide ongoing education on adherence and infection control. • Recognise side effects, record and report to nurses and doctors.
Family members	• Provide emotional support and nursing care to the patient during treatment. • Report any problems or changes in patient condition to the clinic nurse or community caregiver. • Assist with early identification and testing of symptomatic contacts.

Table XII Responsibilities at Every Level

Functions	Centralised MDR-TB Unit	Decentralised MDR-TB Unit	Satellite MDR-TB Unit	PHC	Mobile Team	Community Caregivers
Admission of all MDR-TB cases till two successive smear negative / culture negative	√	√	NO, Unless no bed availability at centralised or decentralised DR-TB sites	NO	NO	NO
Admission of all XDR-TB cases until two successive culture negatives are obtained	√	NO Unless there is space and capacity	NO	NO	NO	NO
Monthly follow up of all DR-TB cases attending at clinic	√	√	√	√	NO	NO
DOT to all DR-TB patients attending daily	√	√	√	√	√	√
Recording and reporting (DR-TB Register and EDRWeb)	√	√	NO*	NO*	NO*	NO*
Monitoring and supervising DR-TB clinical management in the province	√	NO	NO	NO	NO	NO

* Although these facilities do not have access to EDRWeb, they should still report on their activities.

Figure II Flow of DR-TB Patients



Diagnosed patient referred depending on severity of disease, proximity to hospital and initiation of treatment

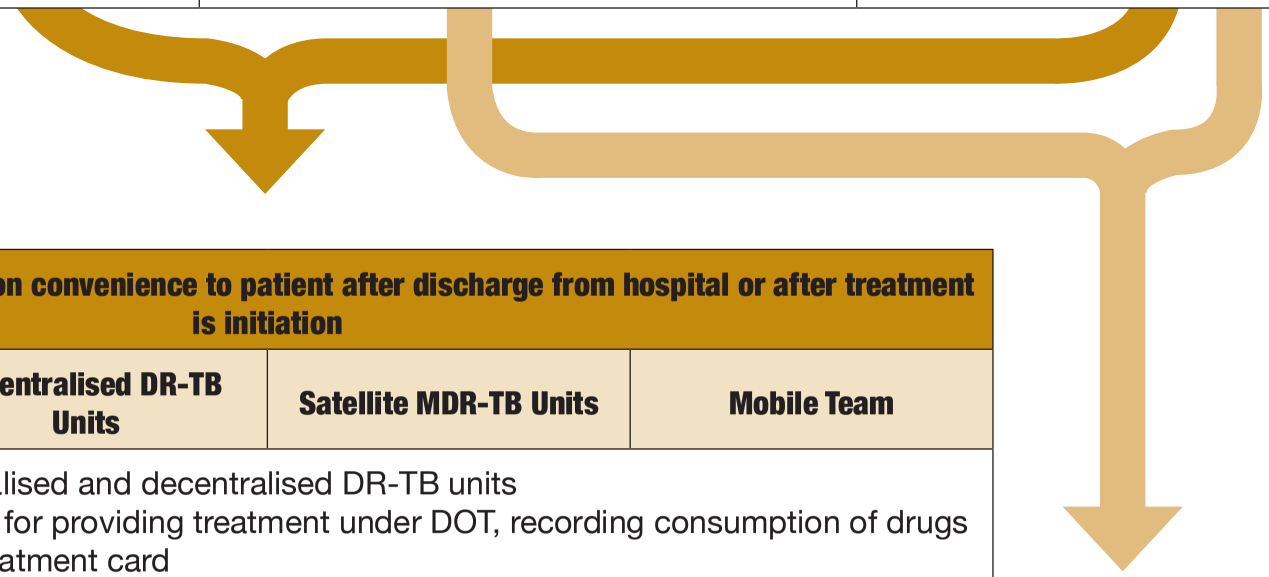
Decentralised DR-TB Unit

Patients are either hospitalised or initiated on treatment as outpatients. Before initiating treatment:

- Conduct an appropriate assessment; Secure written consent; Counsel the patient and family; Prepare a management plan with the patient's consent; Complete DR-TB treatment card, and register in DR-TB register.

Patients to start in ambulatory care	Patients admitted until TWO negative TB smear microscopy	Patients admitted until TWO negative TB cultures (6 months+)
Essential Criteria • Patient is ambulant, in fair to good general condition (BMI > 18.5) • Patient is low grade transmission risk (smear negative)	• Patient with high grade transmission risk (smear positive) • Patients without associated diseases • Patients without extensive resistance pattern	• XDR-TB patients • Very sick MDR-TB patients with extensive resistance patterns, pulmonary cavitations • MDR-TB re-treatments

• Start all GeneXpert positive with resistance to rifampicin on MDR-TB treatment • Patient refuses admission or beds are unavailable **Additional Criteria** • Stable accommodation • Household treatment support • Good reason for not wanting to be hospitalised		• Severe adverse drug reactions • Other associated diseases • May not have access to decentralised or satellite units – until they achieve TB culture conversion



Patients are referred depending on convenience to patient after discharge from hospital or after treatment is initiation			
Centralised DR-TB Units	**Decentralised DR-TB Units**	**Satellite MDR-TB Units**	**Mobile Team**
• Patients registered in centralised and decentralised DR-TB units • All DR-TB units responsible for providing treatment under DOT, recording consumption of drugs and injections on DR-TB treatment card • DR-TB treatment card is at all DR-TB units and with community supporters			

On discharge from centralised/decentralised DR-TB units: • Ask about most convenient facility for referral • Inform patient about management plan	• Notify receiving clinic/hospital of down referral • Arrange transport for the patient • Complete patient treatment follow-up card

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.

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 salvage 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
- Development of provincial criteria on pass-outs.
- 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 co-ordinators 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 DOTS and recording of patients taking drugs and receiving injections. Sputum for smear microscopy and culture should be collected every month for the duration of treatment. Depending on where the patient is receiving care, daily DOTS and recording of patients taking drugs and receiving injections 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 check-list and where necessary reported without delay to supervising unit. Adverse effects must be treated aggressively this will enhance treatment adherence[19,20].

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 XIII Monthly Clinical and Laboratory Evaluations

- **Microbiological assessment (microscopy and culture)**
- **Pregnancy test (on women of childbearing age without documented contraception)**
- **Weight and vital signs**
- **Urea and electrolytes during injectable phase of treatment**
- **Audiometry during injectable phase of treatment or as symptoms warrant**
- **Vision**
- **Adverse events/side effects daily during injectable phase or monthly during continuation phase**
- **Adherence**

4.4. Infection Control

4.4.1. 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;
- Maximising time in open-air environment (e.g., receiving visitors outside);
- Advising all household members and regular contacts to undergo HIV tests;
- Minimising 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.

4.4.2. Infection Control during Patient Transport

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

- Use compartmentalised 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

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. Monthly monitoring is necessary during the injectable phase. Bimonthly monitoring can be done during the continuation phase. Data detailing each step in the patients' treatment journey and where it is taking place should also be captured.

Capturing and maintaining data on patient progress and outcome will require dedicated database 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 (EDRWeb). EDRWeb 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.

All satellite sites, PHC clinics or mobile teams that treat DR-TB patients should provide data to the decentralised site. The decentralised site will collate and analyse all data from the district and send this to the centralised DR-TB unit and the provincial TB directorate. The province will submit data to the NDoH. The province and the NDoH in turn, should provide feedback to the decentralised sites and all teams that will be managing MDR-TB outside the TB institutions.

Table XIV Additional Indicators to be Collected in Each District with a Decentralised DR-TB Unit, or Where DR-TB Treatment is Initiated

Area of Evaluation	Indicators
Patient load	No. of DR-TB beds No. of DR-TB patients admitted No. of DR-TB patients initiated on MDR-TB treatment as outpatients No. of DR-TB patients discharged per month to be treated as outpatients No. of patients receiving injections as outpatients (from a facility or mobile team)
Screening	No. of smear microscopy tests, cultures, LPAs, GeneXpert and DSTs sent No. of patients screened for TB
Average turn-around-time for laboratory tests	Sputum microscopy Cultures and DST
Drug supply	Any drug shortages noted quarterly If so what drug(s) and for how long
Integration with HIV services	No. of patients whose HIV status was known No. tested during quarter and no. of positive tests No. patients on ART and commencement date
Treatment outcomes	Cured, completed, defaulted, died or transferred

Table XV Checklist: Monitoring Activities for Implementation
(To be done every 6 months)

Provinces	DR-TB plan approved by the Provinces	Readiness assessment done for number of units				Number of staff trained			DR-TB services initiated in no. of health facilities
		Centralised DR-TB Units	Decentralised DR-TB Units	Satellite DR-TB units	Mobile teams	Doctors	Nursing staff	Others	
Eastern Cape									
Free State									
Gauteng									
KwaZulu-Natal									
Limpopo									
Mpumalanga									
Northern Cape									
North West									
Western Cape									

Table XVI Checklist: Planning for DR-TB Units/Beds
(To be completed every 6 months)

Provinces	Centralised DR-TB Units				Decentralised DR-TB Units				Satellite MDR-TB Units				Mobile Teams	
	In Place		Planned		In Place		Planned		In Place		Planned		In Place	Planned
	No. of units	No. of beds	No. of units	No. of beds	No. of units	No. of beds	No. of units	No. of beds	No. of units	No. of beds	No. of units	No. of beds	No. of units	No. of units
Eastern Cape														
Free State														
Gauteng														
KwaZulu-Natal														
Limpopo														
Mpumalanga														
Northern Cape														
North West														
Western Cape														

DR- TB HOUSEHOLD GEO MAPPING

Where capacity allows, households with MDR-TB and XDR-TB cases should be mapped to have a geo reference to support the follow up intervention at household level. The mapping should be done with the address reported in the EDRWeb or with GPS in case of rural location or informal settlement.

This type of M&E intervention supports the program in:

- Identifying positive contacts to be initiate on treatment early; and
- Interrupting the chain of transmission at community level.

Data collection and data transmission could be done utilizing “smartphone” technology to have data on real time.

6. CONCLUSIONS AND RECOMMENDATIONS

6. CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

Patients who have negative sputum microscopy and who are clinically not too ill may be initiated on MDR-TB treatment as outpatients if access to daily injections can be organised. It is expected that between 30% and 40% of diagnosed MDR-TB patients in South Africa are smear microscopy negative and meet the criteria for ambulatory treatment.

Ideally patients who have positive sputum microscopy at the time of their MDR-TB diagnosis should be admitted until they get two consecutive negative TB smear microscopy results.

Very sick MDR-TB (patients with extensive resistance patterns, pulmonary cavitations, MDR-TB re-treatments), XDR-TB patients and patients who may not have access to decentralised DR-TB units or satellite MDR-TB units need to be admitted until they achieve TB culture conversion.

It is expected that MDR-TB admissions will decrease by 30% during the first year of effective implementation of the policy framework. However, the admission rate will continue to decrease, which implies that the number of patients treated within the community will need to increase annually.

6.2 Recommendations

Provinces should plan for decentralization, deinstitutionalisation and integration of DR-TB care into HIV, TB and PHC services (including costs involved) with the help of NDoH and the WHO team of experts.

Adequate preparation and planning for decentralised and deinstitutionalised treatment is necessary to ensure the success of DR-TB management. There should be adequate infrastructure and staff should be appropriately trained before they are allowed to look after DR-TB patients.

The provincial and national TB directorates will monitor implementation of decentralization, deinstitutionalisation and integration with TB, HIV into PHC services. Provinces without TB hospitals should consider allocating DR-TB beds within facilities with dedicated TB beds.

7. APPENDICES

APPENDIX I: FACILITY READINESS ASSESSMENT TOOL

A fully functional DR-TB unit should have undergone a readiness assessment using the tool below. Provinces should review the DR-TB diagnosed caseload per district and/or sub-district for the year 2010.

On the basis of the criteria listed above, provincial TB programmes should identify proposed decentralised, satellite, and mobile MDR-TB units. This should be done in consultation with health facilities managers, hospital services directorates, and primary health care services in the provinces. Provincial plans for decentralisation of DR-TB should be made on the basis of the above information.

National and provincial TB programmes will conduct readiness assessments at proposed facilities to finalise decentralisation plan of DR-TB services. The NDOH will send team of experts from WHO to finalise plans for the decentralisation of DR-TB care.

The end product of this process will comprise nine provincial plans and one national plan for implementation of decentralised DR-TB care.

FACILITY READINESS ASSESSMENT TOOL FOR DR-TB UNITS EXPANDING ACCESS TO DR-TB CARE

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

1. Services Provided

No.	Does the health facility provide the following services	Yes	No	Comments
1.1.	General Services • OPD • Inpatients (specify)			
1.2.	• No. of available general beds • No. of isolation beds for TB/ DR-TB			
1.3.	Specialised services (specify) • Chronic disease management (Diabetes, hypertension, respiratory/ asthma) • Reproductive health services (Family planning, PAP smear			
1.4.	HIV services • HCT • PMTCT • PEP • ART • Mx of opportunistic infections			
1.5.	TB services • Outpatient • Inpatient			
1.6.	Laboratory services: • TB microscopy • TB culture • FBC • Other tests (specify):			State turnaround time for: • TB microscopy (48 hrs): y/n if n, specify duration ……..... • TB Culture (6 weeks): y/n if n, specify duration ……..... • FBC (24 hours): y/n if n, specify …….. • Other …….....
1.7.	X-rays			
1.8.	Nutrition counselling, supplements, etc.			
1.9.	Patient Support Services (social worker/support group/ community caregiver			

2. 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 Counselling and Testing (PICT) / Current VCT Policy / HIV Counselling for Children			
2.7.	Nutrition for People Living With HIV and AIDS (check for policies)			
2.8.	IPT Guidelines			
2.9.	STI management guidelines			

3. 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							

4. 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.	Professional nurse/midwife			
4.3.	Staff nurse			
4.4.	Enrolled nurse assistant			
4.5.	Dietician/nutritionist or assistant			
4.6.	Pharmacist or assistant			
4.7.	Clinical psychologist			
4.8.	Occupational therapist			
4.9.	Audiologist			
4.10.	Physiotherapist			
4.11.	Social worker			
4.12.	Lay counsellor			
4.13.	Administrative clerk			
4.14.	Data capturer			
4.15.	Driver			

5. 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)			

6. 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. 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: • Reception area • Waiting area			
7.2.	Adequate space for: • General patient consultation / Counselling			
7.3.	• Infection control compliance (TB, etc) • Infection control facility plan			
7.4.	Adequate secure Storage area for drugs and dispensing			

No.	Does the health facility have	YES	NO	Comments/ Challenges
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			

8. Referral Network

No.	Referral Network	YES	NO	Comments/ Challenges
8.1.	Is there follow up of referred patients • Up referral • Down referral			

9. External Support

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

Skills Audit

Category	Number	MDR-TB trained	TB trained	TB Infection Control	IPT	TB/ HIV	HIV & AIDS Management
Medical doctors							
Prof nurses							
Enrolled nurses							

Enrolled auxiliary nurses							
Lay counsellors							
General assistants							

10. Constraints

11. Recommendations

2. Assessing Team

Full Name and designation	Cell number	Landline	Email

Date .....

APPENDIX II: EXAMPLE OF PROVINCIAL PLAN

PROVINCIAL OPERATIONAL PLAN FOR DECENTRALISATION OF MDR-TB CARE 2011-2012

PROVINCE _____

Current Status of Health Services in the Province

Item No.	Type of Health Facility	Number	No. of beds
1	Centralised DR-TB Unit		
2	Decentralised DR-TB Unit		
3	Satellite DR-TB Unit		
4	TB Hospital		
5	General Hospital		
6	Community Health Centres		
7	Total PHC		
	PHC providing TB services		
	PHC providing DR-TB services		
	PHC having mobile vehicles		
8	Mines Health Services		
9	Correctional Health Service		
10	NGOs working in TB and HIV		
11	Others. Specify ……		
12	Labs providing sputum smear microscopy		
13	Labs providing culture and DST		
14	Labs providing Line Probe Assay		

Current performance and plan of DR-TB Programme

Case Finding			
Type of DR-TB cases	**2010**	**2011**	**2012**
MDR-TB			
XDR-TB			

Treatment outcome (Treatment Success Rate)			
Type of DR-TB cases	**2008**	**2009**	**2010**
MDR-TB			
XDR-TB			

STRATEGIC GOAL1: TO ADDRESS DR-TB AND HIV								
SPECIFIC OBJECTIVE FOR 2011/12	1	1. Identify health facilities for expansion of MDR-TB services						
INDICATORS	6	1. Available provincial plan 2. DR-TB patient's distribution per district/sub-district 3. Decentralized MDR-TB units identified 4. Satellite MDR-TB units identified 5. PHC clinics that will participate in MDR-TB care identified 6. Mobile MDR-TB units planned						
ACTIVITIES		**PERSONS RESPONSIBLE AND PARTNERS**	**TIME FRAME**				**OUTPUTS**	**BUDGET R'000 (Draft)**
			Q1 (April-Jun 2011)	**Q2 (July-Sept 2011)**	**Q3 (Oct-Dec 2011)**	**Q4 (Jan-Mar 2012)**		
1. Draft a plan for decentralization of MDR-TB care		TB Cluster DRTH directorate Provincial TB Directors WHO		X			Draft plan for decentralisation of MDR-TB care	
2. Establish DR-TB patient's distribution		TB Cluster DRTH directorate Provincial TB Directors	X	X			DR-TB patient distribution	

3. Identify decentralised MDR-TB units	TB Cluster DRTH directorate Provincial TB Directors		X			Number of decentralised MDR-TB units identified	
4. Identify satellite MDR-TB units	TB Cluster DRTH directorate Provincial TB Directors		X			Number of satellite MDR-TB units identified	
5. Identify PHC clinics to participate in MDR-TB care	TB Cluster DRTH directorate Provincial TB Directors		X			Number of PHC facilities to participate in MDR-TB care identified	
6. Identify of areas that will benefit from MDR-TB mobile units	TB Cluster DRTH directorate Provincial TB Directors		X			Number of areas that will benefit from mobile MDR-TB units	
7. Determine resources required for establishment of mobile MDR-TB units (HR, Vehicles and other material resources)	TB Cluster DRTH directorate Provincial TB Directors WHO Partners		X	X		-HR resources required -Number of vehicle required -Material resources required	

STRATEGIC GOAL 1: TO ADDRESS DR-TB AND HIV								
SPECIFIC OBJECTIVES FOR 2011/12	1	1. Conduct facility readiness assessment of all proposed facilities identified for expansion of MDR-TB care						
INDICATORS	3	1. Readiness report for proposed decentralized MDR-TB units available and indicating infrastructural adjustments required, human resources and material resources required 2. Readiness report for proposed satellite units available and indicating infrastructural adjustments required, human resources and material resources required 3. Readiness report for PHC to render MDR-TB care available and indicating infrastructural adjustments required, human resources and material resources required						
ACTIVITIES		**PERSONS RESPONSIBLE AND PARTNERS**	**TIME FRAME**				**OUTPUTS**	**BUDGET R'000 (Draft)**
			Q1 (April-Jun 2011)	**Q2 (July-Sept 2011)**	**Q3 (Oct-Dec 2011)**	**Q4 (Jan-Mar 2012)**		
1. Perform readiness assessment of all proposed decentralised MDR-TB units		TB Cluster DRTH directorate Provincial TB Directors WHO		X			Number of proposed decentralised facilities ready to start service delivery Number of proposed decentralised facilities preparing to start Additional resources required	

2. Conduct readiness assessment of all proposed satellite MDR-TB units	TB Cluster DRTH directorate Provincial TB Directors		X	X		Number of proposed decentralised facilities ready to start service delivery Number of facilities preparing to start Additional resources required	
3. Perform readiness assessment of PHC facilities that will support MDR-TB care	TB Cluster DRTH directorate Provincial TB Directors		X	x		Number of proposed decentralised facilities ready to start service delivery	

STRATEGIC GOAL 1: TO ADDRESS DR-TB AND HIV								
SPECIFIC OBJECTIVES FOR 2011/12	1	1. Strengthen DR-TB/HIV collaboration						
INDICATORS	4	1. Number of doctors trained on DR-TB/HIV co-infection 2. Number of nurses trained on DR-TB/HIV co-infection 3. Proportion of HIV positive, MDR-TB patients started on ART 4. Proportion of HIV positive, XDR-TB patients started on ART						
ACTIVITIES		**PERSONS RESPONSIBLE AND PARTNERS**	**TIME FRAME**				**OUTPUTS**	**BUDGET R'000 (Draft)**
			Q1 (April-Jun 2011)	**Q2 (July-Sept 2011)**	**Q3 (Oct-Dec 2011)**	**Q4 (Jan-Mar 2012)**		
1. Training of doctors and nurses in DR-TB/HIV policy in all identified MDR-TB units		TB Cluster DRTH directorate Provincial TB Directors WHO			X	X	All doctors and nurses identified to manage MDR-TB need to be trained	
2. Initiate all HIV positive, M/XDR-TB patients on ART		TB Cluster DRTH directorate Provincial TB Directors	X	X	X		All co-infected M/XDR-TB and HIV patients to be started on ART	

STRATEGIC GOAL2: WORK COLLABORATIVELY WITH ALL CARE PROVIDERS FOR THE DECENTRALIZED MANAGEMENT OF DR-TB		
SPECIFIC OBJECTIVES FOR 2011/12	1	1. Engage all potential care providers in the decentralised management of DR-TB
INDICATORS	3	1. Mapping of all potential care providers 2. Number of care providers who will sign agreement with the TB Programme to assist in the community MDR-TB care 3. Number of care providers that signed agreement to assist with mobile MDR-TB services

ACTIVITIES	PERSONS RESPONSIBLE AND PARTNERS	TIME FRAME				OUTPUTS	BUDGET R'000 (Draft)
		Q1 (April-Jun 2011)	Q2 (July-Sept 20110	Q3 (Oct-Dec 2011)	Q4 (Jan-Mar 2012)		
1. Mapping of all potential care providers working for TB and HIV	TB Cluster DRTH directorate Provincial TB Directors		X			List and contacts of all potential care providers	
2. Conduct workshop with potential care providers to agree on areas of assistance	TB Cluster DRTH directorate Provincial TB Directors			X		Agreement on areas of assistance	

STRATEGIC GOAL 3: TO EMPOWER PEOPLE WITH TB AND COMMUNITY								
SPECIFIC OBJECTIVE FOR 2011/12	1	1. To implement an ACSM plan relevant to decentralized DR-TB care						
INDICATORS	2	1. Number of IEC materials including DR-TB messages 2. Number of community awareness campaigns organised						
ACTIVITIES		**PERSONS RESPONSIBLE AND PARTNERS**	**TIME FRAME**				**OUTPUTS**	**BUDGET R'000 (Draft)**
			Q1 (April-Jun 2011)	**Q2 (July-Sept 2011)**	**Q3 (Oct-Dec 2011)**	**Q4 (Jan-Mar 2012)**		
1. Production of IEC materials including messages on decentralized MDR-TB care		TB Cluster ACSM Directorate DRTH directorate Provincial TB Directors			X		IEC materials with DR-TB messages	
2. Conduct community awareness campaigns including DR-TB messages		TB Cluster ACSM Directorate DRTH directorate Provincial TB Directors				X	Campaigns awareness including decentralised DR-TB messages	

STRATEGIC GOAL 4: STRENGTHENING MONITORING AND EVALUATION OF DR-TB MANAGEMENT AND PROMOTING OPERATIONAL RESEARCH								
SPECIFIC OBJECTIVE FOR 2010/11	1	1. Establishing system for M&E in newly identified DR-TB units						
INDICATORS	4	1. Number of additional M&E personnel required 2. Number of computers and internet connections required 3. Number of staff trained in M&E 4. Number of areas identified for research in decentralised management of DR-TB						
ACTIVITIES		**PERSONS RESPONSIBLE AND PARTNERS**	**TIME FRAME**				**OUTPUTS**	**BUDGET R'000 (Draft)**
			Q1 (April-Jun 2010)	**Q2 (July-Sept 2010)**	**Q3 (Oct-Dec 2010)**	**Q4 (Jan-Mar 2011)**		
1. Identify resources required for establishing M & E system in newly identified MDR-TB units		TB Cluster RIMES Directorate DRTH directorate Provincial TB Directors			X		IT requirements determined: computers, internet connections and other needs	
2. Training of relevant staff in M & E		TB Cluster RIMES Directorate DRTH directorate Provincial TB Directors			X		Number of staff trained	

APPENDIX III: BUILDING TREATMENT CAPACITY TO MEET THE INCREASING BURDEN OF MDR-TB

It is clear that cases of MDR-TB are on the rise in South Africa. To meet this need, treatment services are being expanded to decentralised treatment facilities and community-based programs are being developed and expanded. It is imperative that innovative approaches to expand access to MDR-TB treatment are explored.

Nurse-initiated treatment programs are an important option that has proven successful for HIV management throughout the world. Data on nurse-initiated TB/HIV treatment are beginning to emerge in conference proceedings. South African researchers have documented the successful integration of a nurse-based screening algorithm for pulmonary TB compared with physician diagnosis, and a randomised controlled trial is now underway to evaluate PALSA-Plus nurse-led management strategies throughout primary health-care clinics.

The mounting evidence for nurse management coupled with the continued expansion of community-based MDR-TB programs compels key stakeholders to consider the most appropriate approaches to address the epidemiologic circumstances facing the country. To ensure patient safety and a multidisciplinary approach to MDR-TB care and treatment it is essential to explore the regulatory and educational frameworks necessary to produce a skilled nursing workforce capable and willing to assume these added clinical management responsibilities.

The following provides a brief overview of the way forward for nurse-initiated MDR-TB treatment. It is meant to provide a roadmap for discussion and debate as well as a path for the scientific community to appropriately explore the necessary training and clinical requirements.

Educational Preparation and Training Requirements

While management of drug susceptible TB is routinely covered in diploma nursing educational programs, detailed discussions or clinical training on the treatment and care of patients with MDR-TB is not routine. The *Advanced Diploma in Health Assessment, Diagnosis and Care* is an additional year of clinical and didactic training for nurses with a diploma or bachelorette degree who wish to specialize in primary health care. Along with this course of study, a dispensing license and pharmacology course is included. This training enables successful nurses to prescribe drugs from the essential drug list once employed within a primary health centre. This course of study addresses diagnosis and management of TB and HIV, but provides little in the way of MDR-TB treatment.

In order to adequately prepare nurses for the care and management of patients with MDR-TB, the nurse requires training and clinical experiences in TB, HIV, and co-infected populations. It is also essential that the primary health-care needs of these populations are addressed, and it is strongly encouraged that this training can be incorporated into the Advanced Diploma.

Specialty courses and clinical experience specifically for MDR-TB are presently not available for nurses. This is an urgent need and development is underway. MDR-TB treatment and management courses should be available to nurses with an Advanced Diploma in Health Assessment, Diagnosis and Care. Any individual who will provide MDR-TB care should also complete an accredited course of study in HIV treatment and management that includes information on prescribing antiretroviral therapy; integration of this training within an Advanced Diploma course of study would be ideal. Finally, the development of a portfolio of evidence documenting that the nurse has completed clinical trainings with MDR-TB patients is an important consideration.

In summary, the proposed education and training requirements that would allow nurses to actively manage MDR-TB patients would include:

- Diploma or Bachelor's Degree in General Nursing
- Primary Health Care Diploma
- Accredited training program in HIV Treatment and Care
- Accredited training program in MDR-TB Treatment and Care

Regulatory Framework

In addition to educational preparation, the nursing regulatory and legal framework detailing scope of practice must be considered. This is outlined within the South African Nursing Practice Act 33 (2005) under the section entitled, "Special Permissions". The Act as well as current South African Nursing Council (SANC) requirements to expand scope of practice includes the following:

- Registration with the SANC as having completed an Advanced Diploma in Health Assessment, Diagnosis and Care
- Registration with the SANC as having completed a dispensing licensure course
- A written letter by the nurse to SANC requesting permission to prescribe additional agents
- A written letter from the Director General for Health of the province granting permission for the individual to prescribe additional agents

Summary

To increase access to care for MDR-TB patients and to continue expansion of MDR-TB into community-based management models, training in MDR-TB/HIV management for PHC nurses should be strongly considered. A systematic and collaborative approach is necessary to address the both the educational and regulatory infrastructure that will allow PHC nurses to address this important issue.

REFERENCES

REFERENCES

1. World Health Organisation. Guidelines for the programmatic management of drug-resistant tuberculosis Geneva World Health Organisation 2010. Available from: http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf.

2. Cox HS, McDermid C, Azevedo V, Muller O, Coetzee D, Simpson J, et al. Epidemic levels of drug resistant tuberculosis (MDR and XDR-TB) in a high HIV prevalence setting in Khayelitsha, South Africa. PLoS One2010; 5(11): e13901.

3. Basu S, Andrews JR, Poolman EM, Gandhi NR, Shah NS, Moll A, et al. Prevention of nosocomial transmission of extensively drug-resistant tuberculosis in rural South African district hospitals: an epidemiological modelling study. Lancet 2007; 370(9597): 1500-1507.

4. Nardell E, Dharmadhikari A. Turning off the spigot: reducing drug-resistant tuberculosis transmission in resource-limited settings. Int J Tuberc Lung Dis 2010; 14(10): 1233-1243.

5. Holtz TH, Lancaster J, Laserson KF, Wells CD, Thorpe L, Weyer K. Risk factors associated with default from multidrug-resistant tuberculosis treatment, South Africa, 1999-2001. Int J Tuberc Lung Dis 2006;10(6): 649-655.

6. Mlambo C, Warren R, Poswa X, Victor T, Duse A, Marais E. Genotypic diversity of extensively drug-resistant tuberculosis (XDR-TB) in South Africa. Int J Tuberc Lung Dis 2008; 12(1): 99-104.

7. Lawn S, Griffin G. The irreversible cost of delayed diagnosis of tuberculosis in HIV co-infected persons in sub-Saharan Africa. Int J Tuberc Lung Dis 2001; 5(2): 200-203.

8. Mitnick C, Shin S, Seung K, Rich M, Atwood S, Furin J, et al. Comprehensive Treatment of Extensively Drug-Resistant Tuberculosis. N Engl J Med 2008; 359: 563-574.

9. Marra C. Tuberculosis MDR/XDR: The Msinga Experience - Lessons learnt from South Africa 2005 – 2009. Pietermartizburg 2009.

10. Schaaf H, Botha P, Beyers N, Gie R, Vermeulen H, Groenewald P, et al. The 5-year outcome of multidrug resistant tuberculosis patients in the Cape Province of South Africa. Trop Med Int Health 1996; 1: 718-722.

11. Master I. State of M/XDR TB in KwaZulu-Natal. Durban: King George V Hospital, Department of Health 2009.

12. Vella V. Update of the epidemic of XDR and MDR in Msinga sub-district, KwaZulu-Natal: Italian Corporation with KwaZulu-Natal Department of Health, 2008.

13. Lockman S, Kruuner A, Binkin N, Levina K, Chang Wang Y, Danilovitsh M, et al. Clinical Outcomes of Estonian Patients with Primary Multidrug-Resistant versus Drug-Susceptible Tuberculosis. Clinical Infectious Diseases 2001; 32: 373-80.

14. Mitnick C, Bayona J, Palacios E, Shin S, Furin J, Alcantara F, et al. Community-based therapy for multidrug-resistant tuberculosis in Lima, Peru. N Engl J Med 2003; 348(2): 119-128.

15. Lawn S, Churchyard G. Epidemiology of HIV-associated tuberculosis. Curr Opin HIV AIDS 2009; 4: 325–333.

16. de Azevedos V. Community based treatment of MDR-TB patients in Khayelitsha, Western Cape. IAS pre-conference workshop, Cape Town 2009.

17. A DOTS-Plus Handbook Guide to the Community-Based Treatment of MDR TB: Partners in Health Harvard Medical School Bill and Melinda Gates Foundation 2002. Available from: http://parthealth.3cdn.net/1c5a5a5571a916a437_mlbrty0n4.pdf

18. Margot B. Decentralised management of MDR-TB in KwaZulu-Natal. IAS pre-conference workshop, Cape Town 2009.

19. Saravia J, Appleton S, Rich M, Sarria M, Bayona J, Becerra M. Retreatment management strategies when first-line tuberculosis therapy fails. Int J Tuberc Lung Dis 2005; 9(4): 421–429.

20. Furin J, Mitnick C, Shin S, et al. Occurrence of serious adverse effects in patients receiving community-based therapy for multidrug-resistant tuberculosis. Int J Tuberc Lung Dis 2001; 5: 648-655.

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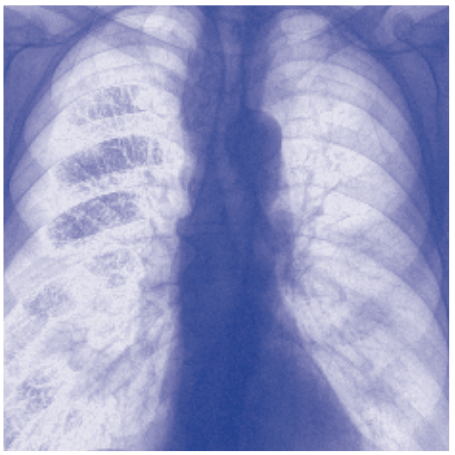
NOTES




TB / HIV
COLLABORATION