



**East, Central and Southern Africa Health Community (ECSA-HC)**

# **Regional Policy on the Management of Multi-Drug Resistant and Extensively- Drug Resistant Tuberculosis Treatment Failures**



**TB CARE I**

## **Foreword**

Tuberculosis (TB) is the leading cause of death by an infectious disease worldwide despite regional and global efforts and financial investment by governments and non-governmental organizations in disease-control programmes during the past 20 years.

Adequate and timely treatment of TB is the most effective way to reduce the further emergence of acquired drug resistance. In addition, the transmission of Multi/Extensively-drug resistant TB (M/XDR-TB) can be reduced by early diagnosis and treatment, and by using adequate infection control measures. For this reason, national TB control programs (NTPs) need to integrate the programmatic management of drug-resistant TB (PMDT) into routine activities and to link up with private providers, hospitals, and congregate settings such as prisons to ensure a comprehensive response to the M/XDR-TB threat. The situation is worsened by HIV epidemic and cross border transmission of drug resistant strains from neighboring countries.

This policy seeks to guide countries in the management of the challenges of MDR-TB and XDR-TB failures and to put in place strong systems that are able to address these challenges.

ECSA Health Community remains committed to working closely with regional and international partners in supporting Member States to put in place such reliable systems and to raising additional resources to supplement country efforts.



**Prof. Yoswa M. Dambisya**  
**Director General**

## ***Acknowledgements***

ECSCA Health Community wishes to thank the National TB Program Managers who contributed towards the completion of the questionnaires that generated the information that enriched this policy.

Special thanks go to KNCV Tuberculosis Foundation (KNCV) through the United States Agency for International Development (USAID) funded TB CARE I project who made this activity possible by providing financial and technical support that allowed this activity to be completed. Sincere gratitude goes to all our partners and collaborators.

We are indebted to the consultant Dr. Peter Kimuu for the development of the Policy.

A handwritten signature in black ink, appearing to read 'Stephen K. Muleshe', with a stylized flourish at the end.

**Dr. Stephen K. Muleshe**  
**Family Health & Infectious Diseases**  
**East, Central & Southern Africa Health Community**

The Global Health Bureau, Office of Health, Infectious Disease and Nutrition (HIDN), US Agency for International Development, financially supports this publication through TB CARE I under the terms of Agreement No. AID-OAA-A-10-00020. This publication is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of TB CARE I and do not necessarily reflect the views of USAID or the United States Government.

## **Table of Contents**

Foreword.....	ii
Acknowledgements.....	iii
Table of Contents .....	iv
List of Figures and Tables .....	vi
Acronyms.....	vii
Glossary of terms .....	viii
<b>1.0 Introduction &amp; Background.....</b>	<b>1</b>
1.1 Tuberculosis control in the global context .....	1
1.2 Global situation of Drug Resistant Tuberculosis.....	2
1.3 M/XDR-TB Palliative and end of life care .....	4
1.4 Drug Resistant Tuberculosis in ECSA-HC Region .....	5
<b>2.0 RATIONALE .....</b>	<b>6</b>
2.1 Rationale .....	6
2.2 Target audience.....	7
2.3 Policy development process .....	7
<b>3.0 SITUATIONAL ANALYSIS.....</b>	<b>7</b>
3.1 Detection of M/XDR-TB Treatment failures .....	7
3.2 Comprehensiveness of PMDT in member states .....	8
3.3 Infection prevention at the community and household level .....	9
3.4 Discussion .....	9
3.5 Recommendations .....	10
<b>4.0 Policy goal, objectives and strategies .....</b>	<b>11</b>

4.1 Policy goal .....	11
4.2 Policy objectives and strategies .....	11
4.3 Policy implementation framework .....	13
4.3.1 Institutional framework.....	13
4.3.2 Stakeholders in PMDT programmes .....	13
4.3.3 Mechanisms for regional intergovernmental coordination.....	13
<b>5.0 Monitoring and Evaluation .....</b>	<b>14</b>
5.1 Monitoring and evaluation framework.....	14
5.2 Progress indicators .....	14
<b>6.0 Conclusion .....</b>	<b>15</b>
<b>References .....</b>	<b>16</b>

**List of Figures and Tables**

Figure 1: MDR-TB Treatment Outcomes 2012 (Source: Global TB Report 2013) ..... 3

Figure 2: XDR-TB Treatment outcomes (South Africa) (Source: Global TB Report 2013) ..... 3

Table 1: Indicators for measuring policy performance ..... 14

## **Acronyms**

**BOD:** Burden of Disease

**DOT:** Directly Observed Treatment

**DOTS:** Directly Observed Treatment Short Course

**DRS:** Drug Resistance Survey

**DST:** Drug Susceptibility Testing

**ECSA:** East, Central and Southern Africa

**ECSA-HC:** East, Central and Southern Africa Health Community (Kenya, Lesotho, Malawi, Mauritius, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe)

**HIV:** Human Immunodeficiency Virus

**HIV/AIDS:** Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome

**ISTC:** International Standards for Tuberculosis Care

**IUTLD:** International Union against Tuberculosis and Lung Disease

**MDR-TB:** Multi-Drug Resistant TB

**M/XDR-TB:** Multi-Drug and Extensively Drug Resistant TB

**NTP:** National TB Programme

**PMDT:** Programmatic Management of Drug resistant TB

**STOP TB Strategy:** A Global strategy for the control of TB

**TB:** Tuberculosis

**TB/HIV:** Tuberculosis and HIV co-infection

**USAID:** United States Agency for International Development

**WHO:** World Health Organization

**XDR-TB:** Extensively Drug-resistant TB

## ***Glossary of terms***

**Extensively drug-resistant TB (XDR-TB)**, also known as Extremely Drug-Resistant TB: TB that is resistant to any fluoroquinolone, and at least one of three injectable second-line drugs (capreomycin, kanamycin and amikacin), in addition to isoniazid and rifampicin.

**High Burden Countries (HBC)**: Countries that account for more than 80% of the global TB burden. These are Afghanistan, Bangladesh, Brazil, Cambodia, China, DR Congo, Ethiopia, India, Indonesia, Kenya, Mozambique, Myanmar, Nigeria, Pakistan, Philippines, Russian Federation, South Africa, Thailand, Uganda, UR Tanzania, Vietnam and Zimbabwe.

**High MDR-TB Burden Countries**: Armenia, Azerbaijan, Bangladesh, Belarus, Bulgaria, China, DR Congo, Estonia, Ethiopia, Georgia, India, Indonesia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Myanmar, Nigeria, Pakistan, Philippines, Moldova, Russian Federation, South Africa, Tajikistan, Ukraine, Uzbekistan and Vietnam.

**Multidrug-resistant TB (MDR-TB)** is defined by resistance to the two most commonly used drugs in the current four-drug (or first-line) regimen, namely isoniazid and rifampicin. WHO treatment standards require that at least four drugs be used to treat TB, in order to avoid the development of further resistance.

**Palliative care**: This is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.



## **1.0 INTRODUCTION & BACKGROUND**

The East, Central and Southern Africa Health Community (ECSA-HC) is a regional intergovernmental health organization set up in 1974 to foster cooperation that will lead to the strengthening of health care programmes in the region, and promote the attainment of the highest possible standards of health among member states. In recognition of the similarities in disease burden, and the potential for joint action on common health challenges in the region, the ECSA-HC works both in member states as well as extending its reach to other countries in terms of activity implementation.

Membership of the ECSA-HC is open to all countries in the East, Central and Southern African region. The current Member States are Lesotho, Kenya, Malawi, Mauritius, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

The programmes and activities of the community are coordinated by the ECSA-HC Secretariat whose operations are overseen by an advisory committee that comprises of Permanent Secretaries of the Ministries of Health of member states. The mandate of the Secretariat is derived from the ECSA-HC Conference of Health Ministers, which is the top governing body responsible for policy guidance, regional health strategies and priorities.

### ***1.1 Tuberculosis control in the global context***

Tuberculosis (TB) is an airborne infectious disease caused by *Mycobacterium tuberculosis* (*M.tb*) that most often affect the lungs, but can also affect other body organs and tissues. Infection spreads from one person to another through droplet nuclei containing *M.tb*. About one third of the world's population is known to have a latent TB infection (LTBI). Such infected people have a lifetime risk of developing TB disease, a risk that is influenced by the body's immune status.

Early TB case finding, initiation and completion of effective treatment are the mainstays of TB control. However, despite more than two decades of implementing the highly effective global Directly Observed Treatment-Short Course (DOTS) and Stop TB strategies, TB remains one of the leading causes of morbidity and mortality globally. According to Global TB Report 2014, 6.1 million TB cases were notified in 2013, this represents about 64% of the estimated 9 million people who developed TB. During the same year,

136,000 cases of the estimated 480,000 cases of MDR-TB were reported. It is estimated that 9% of MDR-TB cases had XDR-TB.

Significant gains towards the elimination of TB that have been made during the last two decades. The Millennium Development Goal 6C to halt and start reversing TB epidemic by 2015 has already been achieved as shown by the falling number of new cases notified (falling at a rate of about 2% between 2010 and 2011), and reduced TB death rate now at 45% of the 1990 rate. Globally, this trend has been observed across all the six WHO regions, as well as in 11 of the 22 high-burden countries (HBC).

### ***1.2 Global situation of Drug Resistant Tuberculosis***

Anti-TB drug resistance is a major public health problem and a threat to progress made in TB care and control worldwide. Drug resistance arises when improper drug regimens are used or when patients do not complete their whole course of treatment. This improper use is a result of a number of actions including, erratic supply of medicines, non-adherence to treatment regimen by patients and incorrect prescribing by providers. In many instances, the health system fails to ensure that patients complete the whole course of treatment. Essentially, drug resistance is a problem in settings characterized by weak health systems and weak TB control programmes. A patient who develops active disease with a drug-resistant TB strain can transmit this form of TB to others.

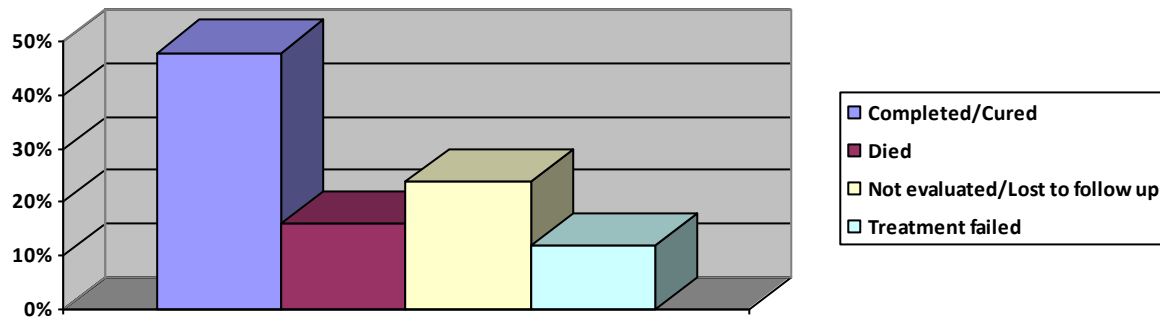
While the TB epidemic has been associated with the HIV epidemic in countries with a high prevalence of HIV, the growing number cases of the more expensive to treat MDR-TB and XDR-TB, and other forms of resistance associated with inconsistent or partial treatment, are a major threat in efforts to control TB due the prolonged duration of infectiousness and poor infection control measures.

The proportion of MDR-TB among new and previously treated TB cases was estimated to be 3.5% and 20.5% respectively in 2013. The WHO/IUTLD Global Project on Anti-TB Drug Resistance Surveillance 2002–2007 report put this at 0-22% and 0-85.9% respectively.

Globally, treatment outcomes for MDR-TB patients remained sub-optimal at 47% treatment success rate, as a result of the high loss to follow up commonly associated with adverse drug reactions, high costs associated

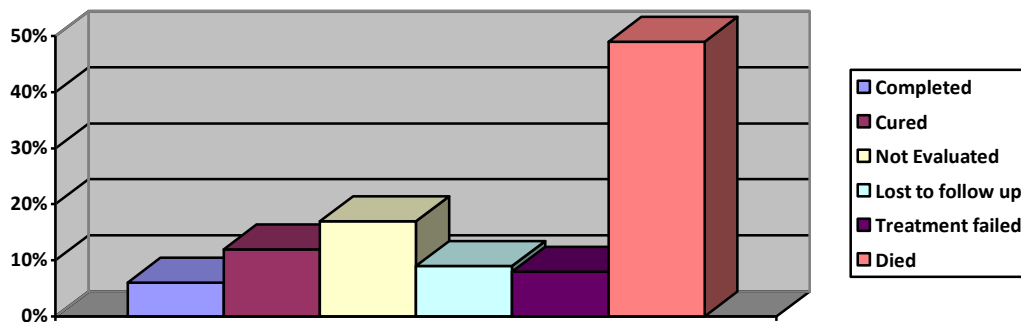
with treatment; and the high frequency of death (Figure 1). Overall, the global treatment success rate target of 75% for MDR-TB was reached by only 30 of the 107 countries that reported treatment outcomes.

**Figure 1: MDR-TB Treatment Outcomes 2012 (Source: Global TB Report 2013)**



Besides MDR-TB, 92 countries reported XDR-TB cases (in many instances a subset of MDR-TB treatment failures), by the end of 2013. Fifteen countries in the African region had identified and reported at least one case of XDR-TB. Treatment outcomes for the 2011 cohort of XDR-TB patients remained poor because of limited treatment regimen, The treatment success was 20% overall and the mortality rate was high at 48% (Figure 2).

**Figure 2: XDR-TB Treatment outcomes (South Africa) (Source: Global TB Report 2013)**



The sub-optimal treatment outcomes result from inadequate treatment programmes; including the capacity to ensure adherence to treatment, that is essential in preventing amplification of drug resistance. It is generally known that adherence to MDR-TB treatment is particularly difficult because of the lengthy (20 months or more) treatment duration, the high daily pill

burden, adverse drug reactions, and the indirect social and economic costs to patients associated with access to care.

As a result of the unsatisfactory M/XDR-TB case holding, the increasing access to second line TB drugs is likely to be associated with amplification and emergence of further resistance; and hence an increasing risk of MDR-TB treatment failures, XDR-TB and XDR-TB treatment failures.

### ***1.3 M/XDR-TB Palliative and end of life care***

While drug-susceptible TB is curable, this is not always true of M/XDR-TB. When M/XDR-TB treatment fails, the anti-TB drugs that are currently being administered might not cure the patient. In addition, other distressing specific and non-specific symptoms, psychosocial and spiritual conditions and situations have an influence on treatment.

With a reported global average MDR-TB cure rate of 47% and at least 150,000 annual deaths, M/XDR-TB can be considered as life threatening conditions from the time of diagnosis.

The WHO Stop TB sponsored palliative care and M/XDR-TB integration meeting of November 2010 declared that “palliative care in the context of M/XDR-TB should be integrated into the management of M/XDR-TB from the time of diagnosis until the patient reaches cure or the end of life”. This may help to improve adherence to M/XDR-TB treatment and cure rates, and help to relieve the suffering of those affected as well as those who have exhausted treatment options, including M/XDR-TB treatment failures. Such care should be based on the international guidelines and principles of palliative care, while paying attention to TB infection control measures to limit exposure and transmission; provided at all levels of care including health institutions, hospices, in households and the community.

The components of palliative and end of life care include:

(i) Physical care to address specific and constitutional symptoms of TB disease, including respiratory symptoms related to compromised lung function. Such symptoms include productive and non-productive cough, dyspnoea, hemoptysis, pain, night sweats, fatigue and cachexia.

(ii) Social support, including stigma reduction: This support is offered within the social network that cares for the patient and focuses on material support

(medicines, food and financial support among others), useful information including training and education that empowers the patient to confront challenges associated with chronic life threatening illness and companionship support.

(iii) Psychological support: Any form of support that is aimed at enhancing mental health, and cognitive, emotional and behavioral wellbeing. According to Standards for psychological support for adults living with HIV, psychological support includes, but not limited to, emotional support and provision of a variety of talking therapies, cognitive rehabilitation and appropriate medication.

(iv) End of life care to promote physical and emotional comfort and open, honest communication as long as it is culturally sensitive and appropriate, especially for those whom treatment options have been exhausted.

(v) Care for the family and caretakers.

(vi) Spiritual care: This relates to values and to a person's search for meaning and purpose in life. Towards the end of life, spiritual care addresses the needs for affirmation and acceptance, forgiveness and reconciliation and the discovery of meaning and direction.

(vii) Bereavement care before and after death.

#### ***1.4 Drug Resistant Tuberculosis in ECSA-HC Region***

Drug-resistant TB is as a major clinical and public health challenge in sub-Saharan Africa, including ECSA-HC member states. As a response to the threat of M/XDR-TB, all ECSA-HC member states have established the Programmatic Management of Drug-resistant Tuberculosis (PMDT) within the NTP to ensure adequate surveillance, case detection, treatment, monitoring, prevention and notification of M/XDR-TB. Member states have invested in all aspects of PMDT including human resource capacity building, rapid drug-susceptibility testing with molecular techniques (line probe assays and Xpert MTB/RIF) to detect TB patients with rifampicin resistance, culture, first and second-line drug susceptibility testing, provision of second-line anti-TB medicines and health infrastructure in general. The member states have predominantly adopted hospitalization and ambulatory models of care for the intensive and continuation phases of treatment respectively, the latter with involvement of community health systems; with an increasing shift to a

shortened admission or full ambulatory in the intensive phase. Although recently established and at different levels of scale, all PMDT programmes in member states are now mature and reporting outcomes for MDR-TB patients on treatment. The Global TB Report 2014 indicates an average of 67% of the 2011 cohort of MDR-TB patients notified from the African Region had treatment outcome data (Global average was 84%). Of the patients with treatment outcomes, 47% successfully completed treatment while the others were accounted for in categories of death, treatment failed, lost to follow up and not evaluated. For ECSA-HC member states, the average treatment success rate was 69%.

## **2.0 RATIONALE**

### **2.1 Rationale**

TB remains one of the leading causes of morbidity and mortality both globally and regionally. Early case finding, initiation and completion of effective treatment are the mainstays of TB control. However, the emergence of resistance to first line TB drugs is a major public health problem that threatens to reverse the gains made in TB care and control worldwide.

The increasing use of second-line drugs in patients with MDR-TB in the region is resulting in increasing levels of drug resistance, contributing to MDR-TB treatment failures and the emergence of XDR-TB, both of which have extremely limited definitive treatment options in low resource settings. Consequently, both are life threatening and an emerging threat to TB control efforts.

This policy responds to the need for guidance in the management of M/XDR-TB treatment failures in the ECSA-HC region with a focus on strengthened MDR-TB case detection and treatment; effective and patient-centered management of M/XDR-TB treatment failures including palliative and end of life care; and a re-emphasis on the strengthened implementation of infection control policies and strategies in health care facilities, congregate settings and households. The integration of palliative care into PMDT programmes has the potential to strengthen the Stop TB Strategy through improved case holding; as well as the new WHO End TB Strategy, the global strategy and targets for TB prevention, care and control after 2015.

The policy is complementary to and in synergy with, the established PMDT guidelines, TB/HIV collaborative activities and overall implementation of Stop TB Strategy in member states.

## **2.2 Target audience**

The policy is intended for managers in the health sector and NTPs, TB physicians and public health specialists, development partners and agencies supporting TB control efforts and health providers in general; as well as other public and private agencies that contribute to TB control efforts in ECSA-HC member states.

## **2.3 Policy development process**

This policy has been formulated under the supervision of the ECSA-HC Secretariat. The technical content has been informed by both global and local actors through studies and the collation of published information and data, as well as by information collected from key informants (MDR-TB patients, NTP managers and TB physicians and public health specialists).

## **3.0 SITUATIONAL ANALYSIS**

### **3.1 Detection of M/XDR-TB Treatment failures**

Member states have integrated PMDT within the NTPs. These programmes have ensured a standard approach to the management of drug-resistant TB, including surveillance, MDR-TB case finding, treatment and related monitoring and reporting.

a) In all countries, MDR-TB case detection is based on conventional culture and drug susceptibility testing, as well as the recently introduced molecular diagnostics, mainly line probe assays and Xpert MTB/RIF, though with varying levels of implementation. However, country specific health system challenges have resulted in under-detection and the late diagnosis of expected MDR-TB cases with an associated delay in the initiation of treatment.

b) Member states have the capacity to enroll MDR-TB patients in treatment programmes under standard treatment regimens informed by first-line drug susceptibility testing. On average, the treatment duration is two years for second-line drug susceptible MDR-TB, but none of the member states

reported 100% enrollment of all MDR-TB cases detected, in part because of weak patient follow up systems, second line drug supply chain management challenges and a lack of adequate isolation facilities for the intensive phase of treatment. Furthermore, unofficial reports show that the treatment of MDR-TB patients by private physicians outside NTPs is a common practice in major cities in the region, and such patients are not notified.

c) Monitoring of patients enrolled in treatment programmes is dependent on sputum smear microscopy and culture in line with locally adapted WHO guidelines. In addition, clinical response is also closely monitored by attending physicians.

d) Although routine surveillance for second line drug resistance among MDR-TB isolates is key to effective treatment and to avoiding amplification of resistance; and emergence and detection of M/XDR-TB treatment failures, this capacity is virtually non-existent in the region, except in Uganda. MDR-TB isolates can be sent out for second line DST, but no member state indicated that this is done routinely.

e) Treatment monitoring is the hallmark of identifying M/XDR-TB treatment failures as the first step in designing and providing comprehensive care for this sub-group. However, with many of the enrolled patients categorized as lost to follow up or not evaluated, PMDT programmes in the region are failing to effectively identify M/XDR-TB treatment failures with serious consequences for TB control.

### ***3.2 Comprehensiveness of PMDT in member states***

A mixed hospitalization (intensive phase) and ambulatory (continuation phase) model of care is the predominant approach to the treatment of confirmed MDR-TB patients in nearly all member states. Both the intensive and continuation phases of care comprise of daily administration of treatment; with the involvement of treatment supporters especially during the ambulatory continuation phase. A few member states have incorporated nutritional and financial support.

MDR-TB patient clinical review teams in some member states are involved in decision making including the addition or removal of drugs from standard



treatment regimens based on bacteriological and clinical response but there is no clear guidance on the criteria for determining when to consider treatment options as exhausted, and care for such patients thereafter.

In spite of the widely available body of knowledge that clearly identifies M/XDR-TB in general, and M/XDR-TB treatment failures in particular; as life threatening disease states, none of the member states have specific guidelines on a comprehensive approach to case management for improved case holding and quality of care.

Nearly all PMDT guidelines are programme oriented with gaps in patient-centered care including standards for managing life-limiting and distressing symptoms, physical, psychosocial and spiritual care.

### ***3.3 Infection prevention at the community and household level***

NTPs have defined standards for infection prevention in health care settings. However, written standards for the community and household level settings in view of the widely preferred ambulatory care for MDR-TB patients, and the emerging need for palliative and end of life care at all levels, are not in place in many member states.

### ***3.4 Discussion***

The emergence of drug resistant TB substantially challenges TB control both globally and regionally. M/XDR-TB case detection and treatment is extremely complex, characterized by at least two years of treatment with more toxic and expensive second-line drugs. This complexity and prohibitive cost of MDR-TB treatment limits access to care especially in low resource settings where PMDT programmes are faced with numerous challenges including coordination, a shortage of trained staff, insufficient availability of second line medications, inadequate numbers of health facilities for treatment monitoring and incomplete diagnosis of patients.

As PMDT programmes continue to enroll MDR-TB patients for treatment, increasing numbers of MDR-TB treatment failures, including XDR-TB are being reported. MDR-TB treatment failures are either un-detected XDR-TB at

enrolment for MDR-TB treatment, taking into consideration the fact that about 9% of those with MDR-TB have been reported to have XDR-TB; failures as a result resistance to second-line treatment acquired in the course of MDR-TB treatment; treatment interruptions due to adverse drug effects, inhibitory costs of medicines and other indirect costs to accessing care etc.; or cases reverting to positive status during treatment.

Generally, M/XDR-TB treatment is characterized by low cure rates, high mortality and high loss to follow-up. The global average reported treatment success rate for MDR-TB was 48% for 2011 cohort of patients, with at least 150,000 deaths occurring annually. Patients with XDR-TB are even more difficult to treat and have unfavorable treatment outcomes comprising of loss to follow-up, death and treatment failures in excess of 50%. While MDR-TB and XDR-TB can therefore be considered as life threatening conditions from the moment of diagnosis, M/XDR-TB treatment failures have extremely limited definitive treatment options since the available medicines might not ensure cure. This eventuality may be dictated by other associated clinical, economic and psychosocial conditions specific to the patients.

An effective treatment programme for M/XDR-TB treatment failures that focuses on quality of life and limiting the spread of drug resistant strains need to systematically incorporate palliative care services from diagnosis through to the end of life in line with WHO recommendations for life threatening illnesses.

### **3.5 Recommendations**

1. Scale up PMDT programmes to ensure early detection and universal access to MDR-TB treatment
2. Improve the quality of MDR-TB care by ensuring routine surveillance for resistance to second line drugs, patient-centered care approaches and the integration of palliative and end of life care for patients with limited therapeutic options, particularly M/XDR-TB treatment failures
3. Enhance patient-centered care in MDR-TB treatment programmes by introducing palliative care for M/XDR-TB treatment failures
4. Enhance TB infection prevention in congregate, community and household settings.

## **4.0 POLICY GOAL, OBJECTIVES AND STRATEGIES**

### **4.1 Policy goal**

The policy goal is to reduce the burden of disease attributed to drug-resistant TB in the ECSA-HC region. The goal will be realized by ensuring universal access to quality care for M/XDR-TB with strengthened measures to prevent transmission of drug resistant strains in health facilities, congregate settings and households. The realization of this goal will contribute to The End TB Strategy, the WHO's Global strategy and targets for TB prevention, care and control after 2015.

### **4.2 Policy objectives and strategies**

**Objective 1: To ensure early detection and effective treatment of all M/XDR-TB cases. The objective aims to ensuring that all patients with M/XDR-TB are diagnosed early and promptly started on effective treatment.**

#### **Strategies**

1.1. Ensure universal first line Drug Susceptibility Testing (DST) for early MDR-TB case detection and treatment.

1.2. Introduction of routine second-line DST for all MDR-TB isolates for early detection of XDR-TB and the design of treatment options.

1.3. Improved public-private mix for M/XDR-TB diagnosis and treatment.

1.4. Strengthened treatment monitoring, including clinical decision making for M/XDR-TB treatment failures, failing treatment regimens and diminishing therapeutic options; to prevent the amplification of drug resistance.

**Objective 2: To improve the quality of care for M/XDR-TB treatment failures.**

Generally, the treatment of M/XDR-TB is complex and characterized by sub-optimal treatment outcomes in the form of high loss to follow-up commonly associated with adverse drug reactions and high costs associated with treatment; and high frequency of death. As stated in the International Standards for Tuberculosis Care (ISTC), second line treatment is often the last best hope for patients with drug-resistant TB.

This policy objective aims to improve M/XDR-TB case holding, and therefore treatment outcomes; and the quality of life of M/XDR-TB treatment failures.

### **Strategies**

2.1. Emphasis on patient-centered treatment with adequate support to promote adherence to the treatment regimen; as well as addressing poor adherence when it occurs. This individualized care is based on the patient's needs and mutual respect between the patient and the provider.

2.2. Introduce palliative care and end of life care for patients with diminished therapeutic options including those with severely compromised lung function and hence life-limiting states, and affected families; to prevent and relief suffering by means of early identification and impeccable assessment and management of distressing symptoms and other physical, psychosocial and spiritual problems; as well as preventing the transmission of drug resistant TB.

2.3 Introduce new and repurposed drugs and or regimens for patients with limited treatment options.

### **Objective 3: To limit the transmission of M/XDR-TB in all settings.**

Like drug-susceptible TB, the transmission of drug resistant TB is nearly exclusively airborne and is spread to contacts through droplet nuclei containing *M.tb*. Therefore, the effective implementation of TB infection control policies in health facilities, congregate settings and households limits the transmission of drug-resistant *M.tb*.

### **Strategies**

3.1. Implementation of health care facility TB infection control plans comprising of managerial controls, administrative controls, environmental controls and personal protective equipment.

3.2. Ensuring adequate TB infection prevention in conducive environments such as congregate settings (prisons, refugee camps, military barracks and student dormitories, among others) by addressing overcrowding, poor ventilation and by ensuring that patients spend as little time as possible in such settings, among other measures.

3.3. Improve TB infection prevention at the household level by paying special attention to cough etiquette and respiratory hygiene, adequately ventilated rooms, health education and support to ensure the patient spends as much time as possible outdoors, among other measures.

#### **4.3 Policy implementation framework**

##### **4.3.1 Institutional framework**

This policy will largely be implemented by individual member states with NTPs taking a leading role. This calls for collaborative efforts and synergies of in-country actors and stakeholders within the existing country specific institutional frameworks.

##### **4.3.2 Stakeholders in PMDT programmes**

Implementation of this policy will be within the context of Stop TB Strategy with participation of all actors; including state actors at national and sub-national levels, public and private providers, non-state actors (CSOs, NGOs etc.), communities and development partners among others:

1. Ministry of Health and NTPs: Have overall policy responsibility as well as financing, standards, monitoring and evaluation, and technical assistance.
2. Health service providers in both the public and private sector are involved in actual diagnosis, treatment and notification of M/XDR-TB patients.
3. CSOs and NGOs in member states play a major role in mobilizing resources for PMDT, as well as the actual implementation of treatment programmes.
4. Communities and family members are the Directly Observed Treatment (DOT) supervisors in many member states.
5. Development partners and international NGOs and technical agencies have traditionally played a key role in providing financial resources and technical assistance for NTPs.

##### **4.3.3 Mechanisms for regional intergovernmental coordination**

ECSA-HC Secretariat will provide a platform for intergovernmental dialogue and coordination, including cross-border PMDT issues, information sharing

forums, technical support and intergovernmental policy monitoring and evaluation.

## 5.0 MONITORING AND EVALUATION

Implementation of this policy will be tracked using a set of indicators selected from the WHO *Compendium of Indicators for the Monitoring and Evaluation of National TB Programmes, Multi-drug Resistant TB (MDR-TB) Indicators – A minimum set of indicators for the programmatic management of MDR-TB in national tuberculosis control programmes* and other purposefully formulated and selected indicators.

### 5.1 Monitoring and evaluation framework

This regional policy serves as a long term guide for the management of M/XDR-TB treatment failures based on which member states will develop and implement medium term plans with targets for the three policy objectives.

### 5.2 Progress indicators

Table 1 below is an illustration of some policy tracking indicators that may be adopted by member states:

**Table 1: Indicators for measuring policy performance**

Policy area	Domain	Impact level indicators	2014 baseline	2024 Target
Policy goal	BOD attributable to M/XDR-TB	Prevalence of MDR-TB among new PTB cases		
		Prevalence of MDR-TB among retreatment cases		
		Prevalence of XDR-TB among MDR-TB cases		
Policy objectives	M/XDR-TB case detection	TB patients with first line DST result		
		Confirmed MDR-TB cases		
		TB patients with second line DST result		
		Confirmed XDR-TB cases		
	M/XDR-TB treatment outcomes	Treatment success rate		
		Loss to follow-up		
		Treatment failed (M/XDR-TB treatment Failures)		
	TB Infection prevention	M/XDR-TB among contacts		
	Programmatic	TB Palliative and end of life care guidelines available	Yes/No	Yes/No
		TB Palliative and end of life care services available	Yes/No	Yes/No
Proportion of M/XDR-TB treatment failures on palliative and end of life care				

		TB infection control policies and plans available and implemented in:		
		i)Health facilities	Yes/No	Yes/No
		ii)Congregate settings (refugee camps, correctional facilities, military barracks, crowded public places etc)	Yes/No	Yes/No
		iii) Community and household settings	Yes/No	Yes/No

## 6.0 CONCLUSION

This regional policy calls for the scale up of PMDT in member states to ensure universal diagnosis and treatment of M/XDR-TB cases, and therefore facilitating the identification and management of M/XDR-TB treatment failures. The provision of a continuum of care including palliative and end of life care with adequate TB infection control measures to such patients with limited treatment options enhances the quality of life and limits the spread of drug-resistant TB.

## REFERENCES

1. World Health Organization. Multidrug and extensively drug resistant TB (M/XDR-TB): 2010 global report on surveillance and response. Geneva, Switzerland: WHO, 2010.
2. Espinal M, Farmer P. The Cambridge Declaration: towards clinical trials for drug-resistant tuberculosis. *Int J Tuberc Lung Dis* 2009; 13: 1–2.
3. World Health Organization Stop TB Palliative Care and MDR/XDR-TB Integration Meeting, November 18–19, 2010: Declaration on palliative care and M/XDR-TB
4. World Health Organization. Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis. WHO/HTM/TB/2014.11
5. Tuberculosis Coalition for Technical Assistance. International Standards for Tuberculosis Care (ISTC), second edition. Tuberculosis Coalition for Technical Assistance, The Hague, 2009.
6. World Health Organization. Global Tuberculosis Report 2014. WHO/HTM/TB/2014.08
7. Espinal M, Farmer P. The Cambridge Declaration: towards clinical trials for drug-resistant tuberculosis. *Int J Tuberc Lung Dis* 2009; 13: 1-2
8. World Health Organization. Multidrug and extensively drug resistant TB (M/XDR-TB): 2010 global report on surveillance and response.
9. Kyasnovsky C L et al. Extensively drug resistant TB in Eastern Cape, South Africa: high mortality in HIV-negative and HIV-positive patients. *J Acquir Immune Defic Syndr* 2011; 57: 146-152.
10. Harding R et al. Embracing palliative and end-of-life care in the global response to multidrug-resistant tuberculosis. *Lancet Infect Dis* (in press).
11. British Psychological Society, British HIV Association, Medical Foundation for AIDS and Sexual Health: Standards for psychological support for adults living with HIV, November 2011.



12. World Health Organization. WHO definition of palliative care. Geneva, Switzerland: WHO, 2012. Medics Sans Frontiers: Blogs, photos and stories. <http://blogs.msf.org/en/patients/blogs/tb>
13. World Health Organization. Global Tuberculosis Report 2013. WHO/HTM/TB/2013.11
14. Worldwide Palliative Care Alliance: Global Atlas of Palliative Care at the End of Life. 2014
15. World Health Organization. Compendium of indicators for monitoring and evaluation of National TB Programmes. WHO/HTM/2004.344
16. World health Organization. MDR-TB Indicators. A minimum set of indicators for the programmatic management of MDR-TB in National Tuberculosis Control Programmes.