Draft

The Development of Harmonised Minimum Standards for the Prevention, Treatment and Management of Tuberculosis in the SADC Region including MDR and XDR TB

Submitted to:

Directorate of Social and Human development and Special Programmes
SADC Secretariat
Private Bag 0095
Gaborone
Botswana

By

University Research Co,. LLC

24 February 2010
TABLE OF CONTENTS

1 BACKGROUND ........................................................................................................................................... 1

2 LESSONS LEARNED FROM 2009-2010 SADC SECRETARIAT TB ASSESSMENT ......................................................... 4

3 PURPOSE AND SCOPE OF MINIMUM STANDARDS/FRAMEWORK ........................................................... 7

4 PROCESS FOR DEVELOPMENT OF MINIMUM STANDARDS/FRAMEWORK............................................. 8

5 FOUNDATION FOR IMPLEMENTING MINIMUM STANDARDS IN THE SADC REGION ......................................................... 9

6 GUIDING PRINCIPLES ............................................................................................................................. 10

6.1 Guiding principles for developing harmonized standards .................................................................................. 10

6.2 Focus for harmonization of policies and guidelines .......................................................................................... 11

7 MINIMUM STANDARDS AND FRAMEWORK FOR THE TB CONTROL PROGRAMME IN THE SADC REGION ......................................................................................................................... 12

7.1 Minimum Standards for Diagnosis .................................................................................................................. 12

7.2 Minimum Standards for Case definitions ........................................................................................................ 12

7.3 Minimum Standards for treatment .................................................................................................................. 13

7.4 Minimum Standards for TB/HIV Collaboration .............................................................................................. 15

7.5 Minimum Standards for Paediatric Care ........................................................................................................... 15

7.6 Minimum Standards for M/XDR TB ................................................................................................................ 16

7.7 Minimum Standards for Cross-Cutting Issues ................................................................................................ 17

8 IMPLEMENTATION MECHANISMS OF THE FRAMEWORK .............................................................................. 21

8.1 Stakeholders Roles and Responsibilities ....................................................................................................... 21

8.2 Financing mechanisms .................................................................................................................................... 23

8.3 Monitoring and Evaluation ............................................................................................................................ 23
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACSM</td>
<td>Advocacy, Communication and Social Mobilization</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>ART</td>
<td>Antiretroviral Treatment</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacille Calmette–Guérin (vaccine)</td>
</tr>
<tr>
<td>CPT</td>
<td>Cotrimoxazole Preventive Therapy</td>
</tr>
<tr>
<td>DOTS</td>
<td>Directly Observed Therapy, Short-Course</td>
</tr>
<tr>
<td>EPTB</td>
<td>Extra pulmonary tuberculosis</td>
</tr>
<tr>
<td>FDC</td>
<td>Fixed Dose Combination</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>HRH</td>
<td>Human Resources for Health</td>
</tr>
<tr>
<td>IDP</td>
<td>Internally Displaced Persons</td>
</tr>
<tr>
<td>IMR</td>
<td>Infant Mortality Rate</td>
</tr>
<tr>
<td>GFATM</td>
<td>Global Fund to fight AIDS, Tuberculosis, and Malaria</td>
</tr>
<tr>
<td>GLC</td>
<td>Green Light Committee</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goals</td>
</tr>
<tr>
<td>MDR TB</td>
<td>Multi-Drug Resistant Tuberculosis</td>
</tr>
<tr>
<td>MS</td>
<td>Member States</td>
</tr>
<tr>
<td>MTEF</td>
<td>Medium-term Expenditure Framework</td>
</tr>
<tr>
<td>NAC</td>
<td>National AIDS Committee</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-Governmental Organization</td>
</tr>
<tr>
<td>NRL</td>
<td>National Reference Laboratory</td>
</tr>
<tr>
<td>NSP</td>
<td>National Strategic Plan</td>
</tr>
<tr>
<td>NTP/NTCP</td>
<td>National TB Programme/ National TB Control Programme</td>
</tr>
<tr>
<td>PHC</td>
<td>Primary Health Care</td>
</tr>
<tr>
<td>PLWHA</td>
<td>People Living with HIV and AIDS</td>
</tr>
<tr>
<td>PRSP</td>
<td>Poverty Reduction Strategy Paper</td>
</tr>
<tr>
<td>RISDP</td>
<td>Regional Indicative Strategic Development Plan</td>
</tr>
<tr>
<td>SADC</td>
<td>Southern African Development Community</td>
</tr>
<tr>
<td>SATCI</td>
<td>Southern African TB Control Initiative</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>TST</td>
<td>Tuberculin Skin test</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>XDR TB</td>
<td>Extensively Drug-Resistant Tuberculosis</td>
</tr>
</tbody>
</table>
1 BACKGROUND

The Southern African countries bear a large share of the global TB burden, which is mainly driven by HIV&AIDS and poor socio-economic conditions. Among the 15 Member States (MS) of the Southern African Development Community (SADC), eight have prevalence rates higher than the African average. The 15 countries of the SADC region also include several of the 22 global TB high burden countries (HBC) identified by the WHO. Together these countries (including DRC, Mozambique, South Africa, Tanzania, and Zimbabwe) account for 80% of the world’s TB cases and have been targeted for increased funding and support from the major donors and the Global Fund. All HBCs in Africa (except Ethiopia and Kenya) are in SADC. However, among those countries in the SADC region not characterized as “high burden” there is also a wide variation in incidence and programmatic support for anti-TB initiatives. There is also a great deal of variation in the level of involvement in Stop TB Partnerships within the region and some HBCs, such as DRC, are not yet fully committed to developing anti-TB partnerships. The SADC region also has some of the highest HIV prevalence rates in the world and accounts for more than 37% of all people living with HIV and AIDS. There is also a wide variation in prevalence rates among countries, with some countries experiencing rates of over 30% amongst pregnant women attending antenatal care (such as Swaziland) and others with less than 5% prevalence (Madagascar). In many SADC countries HIV has been a strong driver of expanding TB epidemics. In some SADC countries the HIV prevalence among TB patients reaches as high as 80%. All of the countries in the world with an estimated HIV prevalence in new TB cases that is over 50% are in the SADC region. Multi-drug resistant tuberculosis (MDR TB) and extensively drug resistant TB (XDR TB) are emerging concerns in the region, shedding light on weaknesses in treatment, case management, infection control, and diagnostic capacities and in some cases weaknesses in the overall health system. SADC MS currently account for half of MDR TB cases in Africa.

Tuberculosis has increasingly become a cross border issue in Southern Africa. The traditionally high level of population mobility between the various countries in the region has been encouraged by SADC policies to promote cross-border trade and economic cooperation. Mobile populations are frequently at a higher risk for all communicable diseases, due to poor integration with host country health services, language and cultural barriers, and generally lower levels of income. The high level of all types of population mobility within the SADC region has been one of the key drivers in the resurgence of TB, along with HIV and AIDS. Those experiencing forced migration, especially women, may be at an elevated risk for TB. In relation to TB, the risk experienced by mobile populations is further compounded by the length of time required to successfully administer DOTS and differing cross-border standards of care for TB. The difficulty of supervising long term treatment for unstable or mobile populations has been one of the factors associated with the rise of MDR TB in the region. There is only limited information on TB amongst children in the region to determine the true burden, though there is cause to believe paediatric TB, as well as paediatric M/XDR TB, are becoming a growing problem as children are increasingly exposed to infected adults. The estimated risk of infection for children in high burden countries who are exposed to an infected adult is 30-50%. Routine TB tests have proved to be imperfect for detecting
TB amongst children and standardized guidelines for the management of children and infants co-infected with HIV are lacking in many facilities.

Although most of the SADC HBCs reported 100% DOTS coverage in 2007, the case detection rates and cure rates need to improve. Some of the main challenges to effective TB control programmes in the region include poor integration of TB with other clinical services; limited capacity of health care workers to increase the index of suspicion for TB in general health services so that TB suspects are identified in the earlier stages of the disease; limited or lack of surveillance data as well as the ability to synthesize and analyze existing data to guide strategic planning; lack of funding and resources including diagnostic and treatment supplies; inadequate numbers of qualified health workers to oversee screening, diagnostic, and treatment; insufficient health sector infrastructure, including TB diagnostic sites; long distances between health facilities; low national management capacity to support scaled up interventions; access to services for mobile populations; poverty and food insecurity; and finally, adherence difficulties associated with long-term TB treatment regimens.

In 2005, the Maputo Resolution of African health ministers declared TB an emergency in Africa. Particularly in the context of HIV, the SADC Regional Indicative Strategic Development Plan (RISDP) recognizes TB as one of the key challenges to improving human development in the Region. A recently completed assessment of the SADC MS examined the existing policies, guidelines and treatment protocols for prevention, management and control of TB, including management of MDR TB and XDR TB, cross border TB, and TB/HIV co-infection in each MS. The assessment also reviewed the capacities (including infrastructure, technical, human and financial resources) available to implement the approved policies, strategies and protocols; and identify critical gaps in the implementation of the policies and guidelines. The assessment found that most SADC MS have made progress towards developing a comprehensive range of necessary TB policies and programmatic interventions. However, although many countries have developed key TB policy documents, the assessment found that NTPs frequently struggle to maintain accurate and up-to-date policies and guidelines. In addition, many countries’ TB policies are not linked to effective plans of action and as a result implementation is inconsistent. As the TB epidemic has grown, many MS have incorporated an increasing number of partners into their TB program, including technical advisory groups, community groups, faith-based organizations, service providers, donors, NGOs, and the private sector. However, although there has been a steady increase in funding for TB activities from a number of sources, primarily bilateral and multilateral donors, funding gaps remain and countries have occasionally struggled to make adequate use of the funding received. In some cases, the increased funding from external sources has strained the absorptive capacity of countries to implement increased activities and manage the constantly multiplying accounting and reporting requirements from donors.

The influx of activity around TB control has created both logjams as NTPs struggle to coordinate among the multiple priorities of different partners, as well as strong examples of what can be achieved when coordination operates effectively. In many countries, progress has been made to integrate TB and HIV activities but this effort needs to be an ongoing and integral part of NTPs implementation plans. The status of MDR TB control
requires significant attention at policy and operational levels and much work needs to be done to strengthen regional diagnostic and infection control capacities. Strong political commitment at the national level, better partnership models for incorporating multiple TB organizations, an increased emphasis on strengthening laboratory systems, and a larger role for the SADC Secretariat in leading cross-border TB collaboration are among the priorities identified.

Based on the assessment, it is evident that the Southern African region requires urgent updating of many key TB policies. It is critical that programmatic interventions are harmonized across the region to facilitate cooperation, ensure programmatic standards, and achieve higher returns on investments. The SADC Secretariat will coordinate a regional task force to assist NTPs in achieving consensus on various policies and help them to harmonize these policies. In addition, the Secretariat will also assist MS to develop operational strategies to implement the harmonized policies, as well as spearhead periodic reviews based on newly available information from technical groups such as the WHO and to incorporate experiences from MS.
2 Lessons Learned from 2009-2010 SADC Secretariat TB Assessment

Over a four month period between the 2009 and 2010, the National TB Control Programmes in each Member State (with the exception of Madagascar) were reviewed to identify gaps in policies affecting quality of TB services and to make recommendations for coordinated action on TB control in the Region.

The key policies each Member State should have in place to accelerate TB prevention and control include: TB treatment (including treatment of adult cases, paediatric cases, and pregnant mothers); TB/HIV integration and management of co-infected patients; Infection Control in TB and HIV settings; MDR/XDR TB; Public Private Mix (PPM); TB in congregate settings; financing; and advocacy, communication, and social mobilization (ACSM). These policies should also be accompanied by operational strategies for ensuring that lower level management and service delivery points are able to comply. Each Member State should have in place a 5-year strategic plan which is linked to a budget plan and strategy for securing funding for implementation and includes a framework for coordinating stakeholders, monitoring and evaluating TB data (including standard indicators and responsibilities for reporting and recording), management and procurement of TB drugs (including an Essential Drug List), and collaboration with the private sector. Other framework guides such as collaborations for cross-border TB control should be included as appropriate in the Member State policies and operational plans.

The recently completed assessment shows that many of the countries in the region have made significant progress in developing the key TB policies. There is a good deal of variation in policy coverage among the MS reflecting differences in capability and relative need; i.e. Swaziland, one of the first countries to experience multiple cases of MDR/XDR TB, has made substantial progress towards developing standard guidelines for management of drug-resistant TB cases. South Africa was the first to develop a recording and reporting system for drug resistant TB, though MDR/XDR TB guidelines are present and in use, they still remain in a draft form. Seychelles has experienced no reported cases of MDR TB and has no specialized policy in place for management. In other countries such as Zimbabwe, despite a strong need, only slow progress has been made towards drafting MDR TB guidelines due to resource and capacity restraints. In Botswana, although the TB/HIV clinical guidelines have yet to be developed, plans are in place to do so in the near future and most other guidelines, including TB training protocols, (which are not yet a universal feature in regional NTPs and should be encouraged) are adequate and available. In Namibia, the only gap identified by the assessment team is the lack of ACSM guidelines which the NTCP has plans to work on. In order to maintain the strong progress made in Tanzania, the NTLP needs to speed up the completion of IC, ACSM and human resource development guidelines which are currently underway. In Zimbabwe, although the TB policy addresses TB/HIV, this is not yet supported by a targeted policy. The CDC has plans to support the development of TB/HIV guidelines and the program is in the process of developing a MDR TB guideline. There are also plans to develop IC guidelines. Future policy requirements for many MS include more clearly defined drug procurement and management policies; in Swaziland the lack of standardized drugs policies may be linked to problems of stock outs. In many of the states where cross-border movement of TB patients is a concern, such as
Zambia, the assessment team found that the national TB strategy does not address cross-border activities and as a result few or no activities are being undertaken.

In recent years, the policy environment for TB control has experienced several important changes and countries have been required to **frequently update policies** to reflect emerging priorities and newly identified best practices. Improvements in treatment regimens (see WHO 2009) and the introduction of new strategies such as WHO’s 3 I’s policy and interventions to increase DOTS coverage require that NTPs are able to flexibly and responsively communicate changes to lower managers, service delivery providers and community support groups. Although many countries have developed key TB policies, the assessment team found that NTPs frequently struggle to maintain accurate and up-to-date policies and guidelines. In Swaziland, for example, the TB treatment guidelines are from 2006 and need updating. This is true for Lesotho as well, where many key policies exist only in draft form and have not been finalized, printed, or disseminated. In the DRC, several critical guidelines, including IC and MDR TB, exist only in draft form. Similarly in South Africa, although there are no major gaps in the current policy and most policies and guidelines were recently updated in line with major international guidelines, the draft MDR guideline is still waiting to be approved and shared with facilities and partners. There is a need in South Africa to re-examine the admissions policy as well, which currently states that all confirmed MDR-TB cases should be admitted to hospital for the intensive phase of treatment or until conversion. TB patients are admitted to the medical wards in single rooms with access limited to staff and a limited number of relatives. With the increase in the number of MDR-TB cases, the South Africa NDOH is planning construction of more MDR-TB hospitals. There might be a need in the future for the Ministry of Health to establish a small unit for the admission of TB patients and guidelines need to reflect these changes. In Malawi, the ACSM guidelines are available but need to be updated and the draft on the MDR TB and Infection control guidelines need to be finalized. In the Seychelles, although TB is not widespread, there is also a need to update the policy which was completed more than 10 years ago. The current guideline is still in draft form and there is very little mention of HIV.

Although most MS have developed the necessary TB control policies, many have had difficulties **implementing policies** especially at the lower levels of the health system. Despite progress, many countries’ TB policies are not linked to effective plans of action and as a result implementation is inconsistent. In Namibia, for example, the team found there is a strong need to monitor and supervise adherence to national guidelines. In Malawi, a system to monitor and reward adherence to guidelines with financial incentives collapsed due to lack of funding. Adherence to standards was found to be difficult especially in relation to infection control and MDR/XDR TB policies. In Botswana for example, IC is not regularly maintained in public facilities and the TB program has struggled to implement high quality or standard MDR TB services. These difficulties are related to and compounded by challenges with collecting routine and accurate data and managing and ensuring the quality of drug and material stores. In Zimbabwe and DRC, even though key policies at the national level have been developed, implementation currently is a main challenge due to staff shortages and the limited partners available in the country to support the program.
In summary, Member States in the SADC region have made tremendous progress in the development of policies and guidelines to manage TB, but implementation is lacking in too many places. NTPs and TB partners need to monitor closely the status of implementation to identify what works and why as well as facilitate channels of communication to address barriers in a timely fashion. Major progress has also been made in increasing funding for TB and TB/HIV activities from donors, yet the majority of the countries have not been able to reduce the incidence rates of TB, or greatly improve case detection rates. There is still a long way to go to reduce TB/HIV co-infection rates and improve collaboration between TB and HIV programs at the facility levels. MDR/XDR TB unfortunately continues to increase in the region and if it is not more forcefully addressed, has the potential to reach epidemic proportions.

Based on the findings of the country assessment teams, it is critical that member states synchronize their TB prevention and control policies in line with the evidence-based guidelines developed by WHO and other international agencies. This synchronization is also critical to ensure that policies and guidelines facilitate the continuity of care for growing migrant and mobile populations.

The SADC Secretariat has the opportunity to exercise a critical role as a catalyst to accelerate the development and implementation of harmonized policies and guidelines by the member states. The Secretariat will need to provide technical assistance to MS in operationalizing the guidelines. In addition, the Secretariat will also have to establish a rapid response team drawing upon technical resources from the region to help MS in dealing with MDR TB outbreaks and to assist MS in developing strategies to control TB in hot zones and high burden areas within specific MS.
3 Purpose and Scope of Minimum Standards/Framework

The purpose of this document is to provide minimum standards for the prevention and control of tuberculosis in the SADC Member States (MS) with the aim of harmonizing the management of TB in the region. The Minimum Standards will integrate and reinforce the strong collaborations that have been forged among regional NTPs and between the SADC Secretariat, the WHO, and technical partners and donors at the country and sub-region level with the goal of improving TB treatment outcomes, reducing morbidity and mortality due to high TB-HIV co-infection rates, and preventing increased MDR TB.

The rationale for using harmonized standards for treatment and control is to ensure that similar methods are consistently applied by the SADC Member States. This is critical in a region where a significant proportion of the population is routinely engaged in cross-border movement. Harmonized policies will ensure that migrant and vulnerable populations especially are able to receive standardized TB treatment regimens. These guidelines will further ensure that similar prevention strategies are employed by each Member State.

Through participatory assessments with each MS NTP, it was found that most SADC MS have made strong progress towards enacting a comprehensive range of necessary TB policies. In many countries the gaps are slight and plans are already in place to rectify omissions. However, although many countries have developed key documents in TB control and management, the assessment teams found that NTPs frequently struggle to maintain accurate and up-to-date policies and guidelines. Despite progress, many countries’ TB policies are not linked to effective plans of action and as a result implementation is inconsistent. As the TB epidemic has grown, many MS have incorporated an increasing number of partners into their TB programme activities, including community groups, faith-based organizations, supra state companies and service providers, donors, multi-national NGOs, and the private sector. The influx of activity around TB control has created both logjams as NTPs struggle to coordinate among the multiple priorities of different partners, as well as strong examples of what can be achieved when coordination operates effectively. Among some of the priority areas that were determined, it was found that much work needs to be done to strengthen regional diagnostic and infection control capacities. Strong political commitment at the national level, better partnership models for incorporating multiple TB organizations, an increased emphasis on strengthening laboratory systems, and a larger role for the SADC Secretariat in leading cross-border TB collaboration are all necessary for improving regional TB control systems.
4 PROCESS FOR DEVELOPMENT OF MINIMUM STANDARDS/FRAMEWORK

The process of developing minimum standards/framework for TB control in the SADC region has involved the following key steps: literature review, individual country assessments that entailed key informant interviews with various stakeholders (NTP managers, laboratory and pharmacy staff, donors, WHO, partners, private sector and facility staff). Reports of individual MS were compiled, and the review of the SADC Secretariat’s protocols and declarations. In addition, the process has also included the review of international standards for TB control and prevention.

The key documents reviewed include: SADC’s Regional Indicative Strategic Development Plan (RISDP), SADC Protocol on Health and its Implementation Plan, and the Strategic Framework for the Control of TB in the SADC Region. We have also reviewed documents from international sources such as the WHO and Stop TB including “Implementing the Stop TB Strategy – A Handbook for National Tuberculosis Programmes” (2008), Guidelines for the programmatic management of drug-resistant tuberculosis: Emergency update 2008”, and “Promoting the implementation of collaborative TB/HIV activities through public-private mix and partnerships” (2008). The proposed minimum standards/framework also reflects the International Standards for Tuberculosis Care (ISTC) that prescribes widely accepted level of care that public and private practitioners should adhere to in order to achieve the desired outcomes in managing patients who have, or are suspected of having tuberculosis.

A technical review workshop with representatives from 5 MS, technical partners, SADC Secretariat was held from 8-9 February 2010, to discuss the draft of the report of the Minimum Standards. The next step would be a consensus workshop with representatives from all MS to discuss and adopt the proposed Minimum Standards followed by training and implementation in the MS.
5 FOUNDATION FOR IMPLEMENTING MINIMUM STANDARDS IN THE SADC REGION

The articles of the SADC Protocol on Health address the issues relevant to regional cooperation and integration. For example, Articles 9, 10, 11, and 12 related to communicable diseases, call on MS to work together and assist one another and this requires the harmonization of policies and information sharing across the region. In 2006, in response to the Maputo Declaration, a Regional Emergency Response Plan was drafted which laid the groundwork for the Emergency Response Activity Plan and the Strategic Framework for the Control of TB in the SADC Region, 2007-2015. The Strategic Framework recommended the Stop TB Strategy as the basis of the management of TB in the region. The main goals of the Strategic Framework are:

- To achieve universal access to high-quality diagnosis and patient-centered treatment;
- To reduce the suffering and socioeconomic burdens associated with TB;
- To ensure access to prevention, diagnosis and treatment of TB, TB/HIV and MDR/XDR TB in the SADC Region; and
- To support the development and adoption of new tools for TB prevention, diagnosis and treatment in the SADC Region.

To achieve these goals, three primary approaches have been adopted, including strengthening each country’s health system capacity to support expansion of TB services and building stronger partnerships between service providers, TB and HIV programmes, civil society, NGOs and other stakeholders in the SADC region. The final strategic approach is to coordinate and harmonise national TB control policies and guidelines to ensure quality and facilitate the accessibility of TB services to all TB suspects and patients, which is also the goal of this project. This approach is in keeping with the health and social development objectives of the RISDP which instruct states to review and harmonise health policies, co-ordinate and monitor implementation of health interventions, and increase allocation of resources to TB programmes, among others.

The harmonised policies will also be informed by the SADC Regional Policy Framework for Population Mobility and Communicable Diseases, which emphasises the need for “coordinated cross-border referral services and mechanisms for continuity of care for patients (particularly for TB and HIV patients requiring extended treatment regimens)...and joint programming for communicable disease control along common borders".
6 GUIDING PRINCIPLES

6.1 Guiding principles for developing harmonized standards

Among the guiding principles for harmonizing the policy framework in the SADC region include the following:

- **SADC Protocol on Health Article 12:**
  - Develop strategies for the sustained control of tuberculosis, including efficient supply and delivery of drugs; and
  - Ensure, where appropriate, the harmonization of tuberculosis control activities and HIV and AIDS programmes

- The Strategic Plan for the control of TB in the SADC Region 2007 – 2015 recommends that the framework proposed by the Stop TB Strategy be adopted as the basis for TB treatment and control. The goal of the Stop TB Strategy is “To reduce dramatically the global burden of TB by 2015 in line with the Millennium Development Goals and the Stop TB Partnership targets.” The specific objectives are:
  - To achieve universal access to high-quality diagnosis and patient-centred treatment;
  - To reduce the suffering and socioeconomic burden associated with TB;
  - To protect poor and vulnerable populations from TB, TB/HIV and MDR-TB; and
  - To support development of new tools and enable their timely and effective use

Current targets linked to the MDGs and endorsed by the Stop TB Partnership are:
  - by 2015, reduce TB prevalence and death rates by 50% relative to 1990 levels; and
  - by 2050, eliminate TB as a public health problem (<1 case per million population)

- The regional TB policies should be based on internationally agreed upon guidelines and consensus for treating TB, MDR-TB and TB-HIV.

- While each patient should be diagnosed with smear microscopy, due to the high rates of TB/HIV co-infection rates, access to culture should also be available.

- All patients who require culture and DST according to WHO’s recommendations should be able to access these services.

- The policies should be embedded in local health systems and are capable of being operationalized at all levels of the health systems, from the community to the national levels.
• The policies should facilitate the equitable access of TB services for all those in need, with an emphasis on increasing access for special and vulnerable populations. As stated in the SADC Gender Protocol, there is a need to “ensure universal access to HIV and AIDS treatment for infected women, men, girls and boys” as part of an effort to ensure that all persons, regardless of gender or age, are able to access high quality health care services.

• The policies should promote regional collaboration to ensure the use of standardized treatment regimens, as well as the appropriate screening, treatment and follow-up for the growing numbers of cross-border migrants.

• The Member States will be committed to making adequate resources available for the implementation of the harmonized policies at all levels of the health system.

6.2 Focus for harmonization of policies and guidelines

The key areas for harmonizing and updating policies and guidelines in the region are:

• Standardize the case definition for TB
• Standardize TB and MDR TB treatment regimens as well as treatment strategies for TB/HIV co-infected patients
• Promote access to smear microscopy and culture
• Improve laboratory quality assurance
• Improve infection control at the community and facility levels
• Strengthen monitoring and evaluation systems and to promote TB and MDR TB surveillance
• Strengthen the quality, availability, and sustainability of human resources for health
• Improve cross-border and regional TB prevention, treatment and control
• Involve the private sector in TB prevention and control
• Strengthen management of TB in congregate settings such as prisons and mines
• Promote the integration of new diagnostic tools and treatment regimens as they become available
7    MINIMUM STANDARDS AND FRAMEWORK FOR THE TB CONTROL PROGRAMME IN THE SADC REGION

7.1 Minimum Standards for Diagnosis

Member states shall ensure that:

7.1.1 All persons with unexplained productive cough lasting 2-3 weeks should be investigated for TB.

7.1.2 All persons suspected of having TB should provide sputum specimens for microscopic investigation of AFB according to national guidelines. It is recommended that one of the sputa should be an early morning one. It is also recommended that the first specimen should be taken “on spot.”

7.1.3 For all patients (adults, adolescents and children) suspected of having extra-pulmonary TB, appropriate specimens from the suspected site of involvement should be obtained for microscopy, and where possible for culture and histopathological examination.

7.1.4 All persons with at least 2 negative smear results and TB is still suspected should have a chest X-Ray done.

7.1.5 All persons with chest X-Ray findings suggestive of TB should have sputum specimens submitted for AFB examination.

7.1.6 All HIV+ve clients should be screened for TB based on a standardized screening tool.

7.1.7 All retreatment cases should have a culture and DST taken at the point of diagnosis.

7.1.8 All TB patients failing treatment should have a culture and DST to exclude drug resistant TB.

7.2 Minimum Standards for Case definitions

Member States shall ensure that all case definitions are based on the following:

7.2.1 Site of disease (pulmonary or extrapulmonary)

    7.2.1.1 A patient should be diagnosed as PTB if the disease involves the lung parenchyma.

    7.2.1.2 A patient should be diagnosed as EPTB if the TB involves other organs other than the lungs.
7.2.1.3 A patient diagnosed with both PTB and EPTB should be defined as a PTB case.

7.2.2 Bacteriology (sputum smear and culture results)

7.2.2.1 A single positive smear result is a confirmation of smear positive TB case.

7.2.2.2 Two negative smear results with chest X-Ray abnormalities consistent with TB is a confirmation of smear negative TB.

7.2.2.3 Two negative smear results with a positive culture is a confirmation of smear negative TB.

7.2.2.4 A case of MDR TB is defined as a patient with bacteriologically proven TB whose disease is due to bacilli showing in vitro resistance to rifampicin and isoniazid with or without resistance to other first line anti-TB drugs.

7.2.2.5 A case of XDR TB is defined as a patient with bacteriologically proven TB whose disease is due to bacilli showing in vitro MDR TB together with resistance to any fluroquinolone plus resistance to one or more of the following injectable anti-TB drugs: kanamycin, amikacin, capreomycin.

7.2.3 Severity of TB disease (determined by bacillary load, anatomical site of EPTB and extent of disease)

7.2.3.1 The extent of disease and anatomical site determines the severity and appropriate treatment. Disease should be considered severe if there is significant acute threat to life and risk of serious long term consequences. The forms of EPTB regarded as severe are meningitis, military, pericarditis, peritonitis, bilateral pleural effusions, spinal and intestinal EPTB.

7.2.4 History of previous TB treatment

7.2.4.1 A “new case” is defined as a case of TB who has never taken TB drugs before or has taken anti TB drugs for less than 4 weeks.

7.2.4.2 A “retreatment case” is defined as a case of TB who has taken anti-TB drugs before for 4 weeks or more and either relapsed, defaulted or had treatment failure.

7.3 Minimum Standards for treatment

Member States shall ensure that:

7.3.1 All anti-TB drugs purchased by MS should be of known bioavailability.

7.3.2 Fixed dose combination drugs (FDC) should be the mainstay of TB treatment over single drugs.
7.3.3 The dose of anti-TB drugs should conform to international standards.

7.3.4 All patients (including those with HIV infection) who have not been treated previously should receive first line treatment based on the national guidelines which consist of the initial phase of two months with isoniazid, rifampicin, pyrazinamide and ethambutol followed by the continuation phase of four months with isoniazid and rifampicin.

7.3.5 The use of a continuation phase with isoniazid and ethambutol is discouraged due to high rate of failure and relapse especially in patients with HIV infection.

7.3.6 All patients who have been treated previously with anti-TB drugs for more than four weeks should receive treatment based on the national guidelines which consist of the initial phase of two months with isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin, followed by another month of isoniazid, rifampicin, pyrazinamide, ethambutol, followed by the continuation phase of five months of isoniazid, rifampicin and ethambutol.

7.3.7 All patients should be monitored for response to therapy by sputum microscopy. In new PTB cases, two specimens should be collected at completion of initial phase of treatment (2 months), thereafter at five months and at end of treatment for new cases. In retreatment PTB cases at the end of three months, then at the end of seven months.

7.3.8 All patients who fail to convert should be further investigated by culture and DST in order to diagnose drug resistance as soon as possible.

7.3.9 A patient-centered approach should be used to promote adherence to the treatment prescribed and to address poor adherence when it occurs. The approach should be tailored to the individual patient circumstances and be mutually acceptable to the patient and the provider, e.g. Direct Observation of Treatment (DOT).

7.3.10 A written record of all medications given, bacteriological response and adverse reactions should be maintained for all patients.

7.3.11 A mechanism of identifying patients who default from treatment early and a system of tracing them is established.

7.3.12 TB drugs are included in the Essential Drug list and establish an effective drug management system.

7.3.13 Address the management of mono and poly resistant TB in their guidelines.

7.3.14 Establish a mechanism of contact tracing once an infectious case of TB has been diagnosed.
7.4 Minimum Standards for TB/HIV Collaboration

Member States shall ensure that:

7.4.1 A TB/HIV collaboration body for TB/HIV activities at national level, such bodies should also be established at lower levels including health facilities.

7.4.2 HIV counseling and testing is provided to all TB patients as part of routine management.

7.4.3 TB screening is provided to all HIV+ve clients as part of routine management.

7.4.4 All co-infected patients receive cotrimoxazole prophylaxis.

7.4.5 All co-infected patients are evaluated (CD4, WHO staging, clinical examination) to determine whether ART is indicated during the course of treatment for TB.

7.4.6 The choice of Anti retroviral drugs for co-infected patients is according to national guidelines.

7.4.7 All HIV+ve clients where active TB has been excluded are provided with isoniazid prophylaxis (IPT).

7.5 Minimum Standards for Paediatric Care

Member States shall ensure that:

7.5.1 National TB paediatrics guidelines are adapted based on the latest 2009 WHO recommendations for pediatric management of TB.

7.5.2 All children under five or HIV infected (irrespective of age) with a positive Tuberculin skin test (TST) are screened for TB disease.

7.5.3 All children under five years of age in close contact with an infectious case of TB who are asymptomatic for TB receive INH to prevent the development of TB disease.

7.5.4 A child presenting with a history of exposure to an infectious TB case or with confirmed infection (positive TST) is regarded as a TB case if there are symptoms of TB and an abnormal chest X-Ray suggestive of TB.

7.5.5 A child presenting with symptoms of TB is regarded as a case of TB if there is history of exposure to an infectious TB case or confirmed infection (positive TST) and an abnormal chest X-Ray suggestive of TB.

7.5.6 Where possible, diagnosis is confirmed by collecting a gastric aspirate or sputum for smear and culture.

7.5.7 Where a chest X-Ray is not available, a case of TB can be diagnosed in children...
presenting with symptoms of TB and a history of exposure to an infectious TB case or a positive TST.

7.5.8 All case definitions presented under 2.0 also apply to children in terms of site of disease, bacteriology, severity and history of previous treatment.

7.5.9 When a child is diagnosed with any form of TB, the parents and household contacts (if not already on TB treatment) should be carefully evaluated to make sure one of them is not the source case.

7.5.10 All children with TB and their parents/caregivers are provided with HIV C&T.

7.5.11 All children diagnosed with TB should be provided with nutritional support.

7.5.12 Children should be treated using the same principles as adults.

7.6 Minimum Standards for M/XDR TB

Member States shall ensure that:

7.6.1 MDR TB management is part of national TB control programmes

7.6.2 Separate guidelines for the “Management of drug-resistant tuberculosis” according to WHO guidelines are developed.

7.6.3 Adequate capacity to diagnose MDR TB (facility with culture and DST capacity)

7.6.4 A “needs assessment” is conducted to establish the capacity of each MS to diagnose drug resistance TB, e.g. number of laboratories needed to diagnose MDR TB, distance from facilities to the laboratories, laboratory capacity in terms of commodities and technical expertise and availability of diagnostic to reduce the turn around times of results.

7.6.5 Invest in introducing new WHO approved diagnostic tools for MDR TB, e.g. line probe essays.

7.6.6 Confirmed cases of MDR TB should have access to culture and DST to monitor response to treatment.

7.6.7 Procurement and availability of second line drugs to those who require them.

7.6.8 Drugs are procured from WHO pre-qualified companies in order to ensure bioavailability and quality assured drugs.

7.6.9 Conduct studies on the prevalence of TB drug resistance to guide management and response as a nation.

7.6.10 Develop a guide for continuum of care for M/XDR TB to ensure that patients have access to care and treatment. This will in turn reduce default and spread of
resistant strains.

7.6.11 Establish formal linkages with supranational laboratories in the region or outside of the region to ensure that they have access to diagnose XDR TB.

7.6.12 Once a case of MDR TB has been confirmed, active case finding amongst close contacts is be conducted.

7.6.13 Where there is limited funding, MS should explore the possibilities of accessing drugs from GDF and from GLC to access second line drugs.

7.7 Minimum Standards for Cross-Cutting Issues

Member States shall ensure that each of the following cross-cutting issues are addressed:

7.7.1 Advocacy Communication and Social Mobilization (ACSM)

7.7.1.1 Guidelines for Advocacy, Communication and Social Mobilization are developed.

7.7.1.2 Advocacy in TB control is led at the highest level of the Ministry of Health.

7.7.1.3 ACSM guidelines are accompanied by an implementation plan defining the roles and responsibilities of all stakeholders.

7.7.1.4 NTPs play a leading role in the coordination of ACSM activities with other departments, particularly the HIV and AIDS programmes to ensure that correct and relevant messages are dispatched and to ensure maximum benefit of ACSM activities.

7.7.1.5 NTPs harness and coordinate community involvement in TB control activities through the inclusion of patients, community based organizations, faith-based organizations, donors and other relevant stakeholders.

7.7.2 Laboratory Services

7.7.2.1 Internal and external quality assurance systems are institutionalized.

7.7.2.2 There is an EQA system with blinded re-checking.

7.7.2.3 Laboratories develop a specific TB infection control SOP for the protection of laboratory staff.

7.7.2.4 Funding is secured for the purchase of all laboratory commodities (reagents and consumables).

7.7.2.5 They meet the minimum WHO requirement of at least one laboratory per 100,000 population.
7.7.3 Infection Control

7.7.3.1 Develop a separate TB infection control guideline addressing all components of infection control. (Administrative, environmental and personal protection)

7.7.3.2 All health care facilities develop an infection control plan.

7.7.3.3 All health care facilities establish an infection control committee with a focal person to monitor implementation of infection control plan.

7.7.3.4 Promote of an “open window policy”, cough etiquette and triaging of patients in all health care facilities.

7.7.3.5 Availability of respirators for all health care workers and visitors who come in contact with suspects and confirmed M/XDR TB cases.

7.7.3.6 Establish of a medical surveillance system for TB among health care workers.

7.7.3.7 Promote healthy hygiene practices and cough etiquette in general public areas in the community (e.g. public transport areas, shopping malls, entertainment areas airport).

7.7.3.8 Develop guidelines for TB control in congregate settings according to WHO recommendations.

7.7.3.9 Develop indicators to monitor all elements of infection control in relation to the three broad infection control categories.

7.7.3.10 Promote infection control practices in work place programmes.

7.7.4 Public Private Mix (PPM)

7.7.4.1 Develop guidelines for public private mix according to the WHO recommendations.

7.7.4.2 NTPs develop Memorandum of Understanding with private sector addressing specific areas that the private sector manages in terms of TB control.

7.7.4.3 Develop specific indicators to monitor PPM DOTS based on the service provided by the private sector.

7.7.4.4 Establish linkages with training institutions including Universities.

7.7.5 Cross-border issues

7.7.5.1 Develop and implement a standardized referral form for TB and M/XDR TB patients who move across borders including feedback mechanisms.
7.7.5.2 Establish formal agreements in terms of referral and transfer of patients among MS sharing borders, e.g. Botswana should engage with South Africa and Zimbabwe; South Africa should engage with Lesotho, Botswana, Mozambique, Swaziland and Zimbabwe and; Angola with Namibia, etc.

7.7.5.3 Develop a system of determining the proportion of patients with TB who come outside their borders.

7.7.6 Donor coordination

7.7.6.1 Establish a donor coordinating committee.

7.7.6.2 Identify gaps within the TB control programmes that can be funded by donors.

7.7.7 Policies and guidelines

7.7.7.1 Develop and update guidelines as new information is available according to international standards.

7.7.7.2 Develop plans on dissemination of guidelines to all levels of health service delivery including other sectors that manage TB, e.g. the private sector.

7.7.7.3 Develop training and monitoring plan for staff after the dissemination of guidelines to support implementation.

7.7.7.4 Establish or use the existing TB/HIV coordinating bodies to identify areas of common inter departmental activities within the guidelines in order to improve and harmonize implementation (e.g. TB programme and HIV&AIDS departments).

7.7.8 Human Resources to manage TB control

7.7.8.1 Develop TB staffing policy, coordinated with broader strategies to increase national human resources for health and maintain adequate staffing for TB services.

7.7.8.2 Develop in-service training and refresher courses for all cadres including staff from the laboratories and pharmacy.

7.7.8.3 Develop both short and long term training programmes to accommodate the high turn around and rotation of staff.

7.7.8.4 NTP's are staffed and all key activities related to TB control have staff to manage them. Examples of key programmes under the NTP manager would be the following: TB/HIV, M&E, MDR TB, ACSM, laboratories, drug supply, research coordination, training and PPM.
7.7.8.5 Staff that manage the different activities are capacitated in the different areas of discipline.

7.7.8.6 Provide opportunities for NTP managers to attend courses that are available in the region/globally to improve their skills and knowledge particularly in programmes management and data analysis.

7.7.8.7 Where there are financial constraints, donors should be encouraged to fill in the gaps in terms of appointment of additional staff.

7.7.8.8 Conduct a needs assessment in terms of staffing to manage TB, TB/HIV and MDR TB at all levels of health service delivery.

7.7.9 Monitoring and Evaluation

7.7.9.1 Prioritize strengthening of data collection systems to ensure completeness, integrity, timeliness and consistency of TB data, with an emphasis on integrating related to M/XDR TB and TB/HIV

7.7.9.2 Establish standard and predictable indicators and reporting schedules for TB and TB/HIV data

7.7.9.3 Lead the standardization of M&E indicators, tools, and reporting schedules among TB stakeholders

7.7.9.4 Improve capacities at all levels to capture, record, and analyze TB and TB/HIV data

7.7.9.5 Develop guidelines for providing feedback on TB data to improve accountability
8 IMPLEMENTATION MECHANISMS OF THE FRAMEWORK

8.1 Stakeholders Roles and Responsibilities

8.1.1 SADC Ministers of Health

The SADC Health Ministers will oversee and monitor the implementation of this Framework.

8.1.2 SADC Secretariat

The SADC Secretariat will coordinate the overall implementation and monitoring of these minimum standards on behalf of the Ministers of Health. The SADC Secretariat will also assist in guiding resource mobilization. Specific responsibilities will include:

8.1.2.1 Advocacy for implementation of effective TB prevention and control programmes in the region in relation to the commitments made by MS (SADC protocol for health, Maputo Declaration). The SADC Secretariat has a role in streamlining the adoption of the harmonized Minimum Standards.

8.1.2.2 Facilitate the harmonization of policies guidelines and protocols for the prevention and control of TB, TB/HIV and MDR TB.

8.1.2.3 Facilitate skills transfer and sharing of good/innovative practices, benchmarking of MS amongst each other and provide a platform of sharing of good practices.

8.1.2.4 Coordination of partners for resources mobilization in the region.

8.1.2.5 Facilitate the establishment of rapid response system for MDR-TB epidemic and in dealing with TB and TB-HIV hot zones in the region.

8.1.2.6 Facilitation of inter-country and cross border TB prevention and control.

8.1.2.7 Coordinate regional training programmes on TB, TB/HIV and M/XDR TB.

8.1.3 Member States

Member States shall ensure that the first step towards the implementation of the “Harmonized Minimum Standards” is the adoption of the Minimum Standards by the SADC MS. In order for these standards to be an effective tool in improving TB prevention and control in the SADC region, endorsement of these Standards at the highest level of the Ministries of Health in MS is necessary. MS shall ensure that adequate resources are assigned to facilitate the implementation of activities described in the minimum standards. MS will lead coordination of multi-sector TB control activities. It is important that the Minimum Standards should be viewed as a platform from which additional TB care and control measures can be built. Some MS will be able to go beyond what the Minimum Standards have proposed.

Member States shall:
8.1.3.1 Conduct analyses of the current TB control activities in the individual MS to identify areas that need improvement, including human resource allocation, and strengthen or maintain the NTP programmes.

8.1.3.2 Convene national workshops with various departments in the Ministries of Health (e.g. laboratories, HIV&AIDS, Pharmacy) and key stakeholders in the public and private sector (e.g. donors, WHO, partners, community-based organizations (CBOs), training Institutions).

8.1.3.3 During the workshop, each standard should be reviewed to determine compliance, discuss each standard in detail and identify the resources and skills that must be available to meet the standard.

8.1.3.4 Identify challenges to implementation of each standard, identify the specific shortcomings that prevent the standards from being met, identify the threats, and opportunities for each standard.

8.1.3.5 The outcome of this workshop should identify key activities to be implemented, (who, timelines, how, and resources) by all stakeholders.

8.1.3.6 Develop a detailed financial plan for supporting the harmonized minimum standard.

8.1.3.7 Develop a detailed M&E plan.

8.1.4 Other Stakeholders

Other stakeholders include UN Agencies, bilateral donors and development partners, Local and International NGOs, CBOs and communities, the private sector and research and training institutions. All are essential for the successful implementation of the Framework.

8.1.4.1 UN Agencies and other Development Partners

Their roles will vary but will include:

- Identifying the TB burden in each MS, through mechanisms such as modelling
- Assisting in updating and developing new programmatic/clinical guidelines
- Linking MS with new technologies and tools for diagnostics
- Supporting resource mobilization to assist in implementing TB control activities
- assisting with inputs in harmonizing the management protocols to support implantation, including routine reporting and recording of TB, TB/HIV, and M/XDR TB data
- Assisting MS and the Secretariat to coordinate TB cross-border issues
- Assisting in ensuring access to TB services for mobile populations, women, and other vulnerable populations.
8.1.4.2 Local and international donors and NGOs

These will:

- Assist in implementation of agreed on minimum standards
- Advocate for strengthening of TB control, including DOTS
- Augment resources to ensure implementation of the minimum standards
- Assist in disseminating best practices within the region
- Provide additional human resources as needed to support implementation of minimum standards
- Support integration of TB control within HIV prevention, care, and treatment as well as other primary health care services
- Work with Member States to establish formal cross-border TB control mechanism
- Provide feedback on the status of implementation of the minimum standards

8.2 Financing mechanisms

Implementation of these minimum standards will require additional financial resource allocation by each MS. Funding for the activities required to meet the minimum standards will be allocated with the national budget of each MS, if these activities are not currently provided for in TB control budgets.

Member States shall ensure that:

8.2.1 Areas that need additional financial resources will be identified, with the participation of all relevant stakeholders, including UN agencies, donors, development partners, and NGOs.

8.2.2 Each area that needs improvement should be costed. Examples could be the costing of implementing the ACSM strategy, expansion of the laboratory network, procurement of second line drugs to manage drug resistant TB.

8.2.3 NTPs get endorsement from their Ministries of Health where additional finances are required.

8.3 Monitoring and Evaluation

8.3.1 Monitoring and Evaluation mechanisms within the MS:

The successful implementation of the harmonized minimum standards should be supported by a monitoring and evaluation plan. Any monitoring and evaluation plan developed for these minimum standards should link with and reinforce currently existing monitoring and evaluation systems for TB, TB/HIV, M/XDR TB and other primary health care systems (please refer to section X)

Member States shall ensure that:

- Hold bi-annual meetings to monitor progress with all relevant stakeholders.
- MS will monitor case finding, smear conversion and treatment outcomes of
patients and ensure the completeness of TB data

- Data will be shared with the SADC Secretariat on an annual basis or better
- MS will produce annual reports on the status of TB control and TB/HIV collaborative activities
- In developing an M&E plan, MS will reference relevant SADC frameworks, including the November, 2009 draft document “SADC harmonized Surveillance Framework for HIV and AIDS, TB and Malaria”.

### 8.3.2 Monitoring and Evaluation mechanisms by the SADC Secretariat

The SADC Secretariat will play a key role in supporting MS M&E and ensuring the standards are implemented and adhered to through routine reporting and recording of relevant indicators.

Responsibilities will vary but include:

- Producing annual reports on the status of TB in the region
- Supporting information sharing of TB data between the MS
- Supporting the adoption of standard indicators such as the following:
  - Number of countries with developed plans to meet the Minimum Standards
  - Number of countries with established policies for sharing information on migrants and mobile populations
  - Number of countries mobilizing additional resources for prevention and control of TB
  - Number of member states with functional inter-country and cross-border initiatives
  - Number of countries with functional rapid response system for M/XDR TB
  - Number of countries implementing the regional TB referral/transfer form
  - Number of countries reporting core indicators to the SADC Secretariat

---

\(^{i}\) A Database for HIV/AIDS Researches in the SADC Region, [http://www.sadc.int/sadcaidsinfo/index.cfm](http://www.sadc.int/sadcaidsinfo/index.cfm)


\(^{iii}\) Ibid, p 12


\(^{v}\) SADC “Regional Indicative Strategic Development Plan,”