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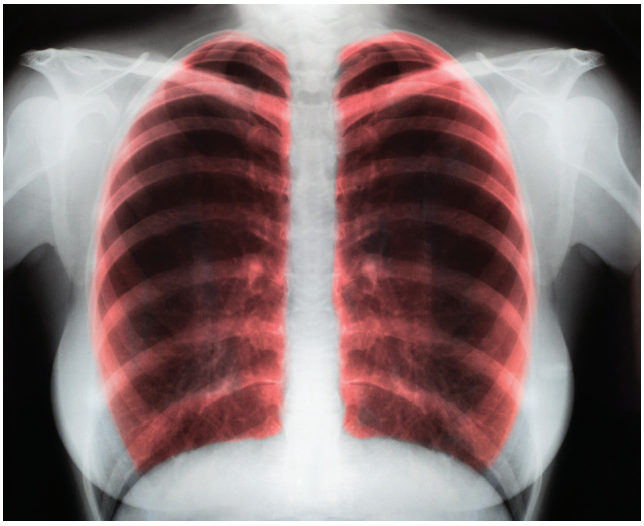

Harmonised Minimum Standards for the Prevention, Treatment and Management of Tuberculosis in the SADC Region

ORIGINAL IN
ENGLISH

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ACRONYMS & ABBREVIATIONS

AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral treatment
DOTS	Directly observed therapy, short-course
HIV	Human immunodeficiency virus
GFATM	Global Fund to fight AIDS, tuberculosis, and malaria
MDG	Millennium Development Goal
MDR-TB	Multidrug-resistant tuberculosis
NGO	Nongovernmental organisation
PLWHA	People living with HIV and AIDS
SADC	Southern African Development Community
SATCI	Southern African TB Control Initiative
TB	Tuberculosis
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis

1. BACKGROUND

The Southern African countries bear a large share of the global tuberculosis (TB) burden, which is mainly driven by HIV&AIDS and poor socio-economic conditions. Among the 15 Member States of the Southern African Development Community (SADC), eight have TB prevalence rates higher than the African average. The 15 countries of the SADC region also include five of the 22 global TB high-burden countries identified by the WHO. All the high-burden countries in Africa (except Ethiopia, Kenya and Nigeria) are in the SADC region. The SADC region has some of the highest national adult HIV prevalence rates in the world, and accounts for more than 37% of all people living with HIV.

There is considerable variation in prevalence rates between countries, with HIV infections levels exceeding 30% among pregnant women attending antenatal care in some countries (such as Swaziland), but less than 5% prevalence in others (such as Madagascar). Globally, every country with an estimated HIV prevalence in new TB cases of more than 50% is in the SADC region. Multidrug-resistant TB (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 Member States currently account for half of all MDR-TB cases in Africa.

Tuberculosis has increasingly become a cross-border issue in southern Africa. High rates of population mobility within the SADC region are among the key drivers in the resurgence of TB, along with HIV and AIDS. Mobile populations are frequently at a higher risk for communicable diseases, due to poor integration with host country health services, language and cultural barriers, and generally lower levels of income. 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 directly observed therapy, short-course (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.

As TB has resurged in recent years, SADC Member States have increased their efforts to combat the disease and scale up a coordinated response to TB, TB/HIV, and MDR-TB. Member States national TB programmes have conducted significant work to increase TB services, frequently in collaboration with other Member States, as well as with international partners and donor assistance agencies. In addressing the challenges of TB, Member States have demonstrated a steady commitment to the key global and regional protocols, including the Stop TB Strategy, the SADC Protocol on Health and the Strategic Framework for the Control of TB in the SADC Region.

2. LESSONS LEARNED FROM THE SADC TB ASSESSMENT REPORT

The SADC Secretariat conducted an assessment of the TB situation and responses in all Member States in 2009. The assessment 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 Member State. The assessment also reviewed the capacities (including infrastructure, technical, human and financial resources) available to implement the approved policies, strategies and protocols, and to identify critical gaps in the implementation of the policies and guidelines.

The assessment revealed that all Member States have made strong progress in developing their TB control systems – for example, a number of Member States have recorded high levels of DOTS coverage and most of the key TB policies are in place.

As a framework for a heightened response to TB prevention control, the key policies in each Member State should reasonably include:

- TB treatment (including treatment of adult cases, paediatric cases, and pregnant mothers);
- TB/HIV integration and management of co infected patients;
- Infection prevention and control in TB and HIV settings; MDR-TB or XDR-TB;
- Public-private mix;
- TB in congregate settings;
- Financing; and
- Advocacy, communication, and social mobilisation.

While Member States have made strong progress towards developing these policies, there is a need to ensure that:

- Policies are updated to reflect current guidance and allow for new strategies and changes to treatment regimens;
- Policies currently in draft form are reviewed, finalised, adapted and adequately distributed; and
- Member States take measures to fill in the policy gaps, for example in relation to infection prevention & control, and to meet emerging policy requirements.

TB/HIV co-infection has been an area which has received significant attention. Member States have developed several successful strategies to improve collaboration between their national HIV and AIDS and TB programmes. In examining the extent to which national TB programmes have created effective links between TB activities and other government sectors, the assessment highlighted that strong commitment and leadership at the national level is an integral part of good coordination, as has been seen in Botswana.

Several countries (such as Malawi, Tanzania and Zambia) have shown that strong national commitment can also facilitate the coordination of donor-supported TB and HIV activities. The assessment in South Africa revealed that collaboration between TB and HIV programmes can effectively point the way towards tackling challenges in related areas, such as the need to further develop the national laboratory network and strengthen diagnostic capacities. TB control programmes are continuing to learn from the successes and failures of longstanding HIV efforts and endeavour to build off of achievements of HIV programmes. The assessment further revealed that MDR-TB is a growing problem for which few Member States are adequately prepared. The causes of MDR-TB are overlapping and relate to many of the broader implementation challenges faced by national TB programmes, as well as other areas of the health system.

These include adequacy of drug supply systems, collaboration between facility- and community-based care to support adherence to drug regimens, adequate and consistent application of infection prevention and control practices, coordinated long-term care for patients, especially those who are co-infected with HIV, and strengthening MDR-TB surveillance systems to give a complete picture of the current prevalence of MDR-TB in the region.

The potential severity of the impact of MDR-TB on achievements in TB control has led Member States to develop effective partnerships with international agencies and donors to tackle some of these issues and, for example, to expand the availability of second-line drugs.

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. National TB programmes 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 programmes at the facility levels. MDR-TB and XDR-TB, unfortunately, continue to increase in the region; unless forcefully addressed, they have the potential to reach epidemic proportions.

3. PURPOSE AND SCOPE OF THE MINIMUM STANDARDS FRAMEWORK

The purpose of this document is to propose minimum standards for the prevention and control of TB in the SADC Member States, with the aim of harmonising the management of TB in the region.

The minimum standards will integrate and reinforce the strong collaborations that have been forged among regional national TB programmes, and between the SADC Secretariat, the World Health Organization (WHO), and technical partners and donors at the country and sub-regional level, with the goal of improving case detection and TB treatment outcomes, reducing morbidity and mortality due to high TB-HIV co-infection rates, and preventing further spread of MDR-TB and XDR-TB.

The minimum standards address the key areas of TB control including diagnosis, case definition, treatment, paediatric TB, TB/HIV co-infection, and drug resistant TB. Minimum standards are also presented for several key cross-cutting issues relating to TB control, including laboratory services, cross-border control, and TB infection and prevention control.

4. PROCESS FOR DEVELOPMENT OF MINIMUM STANDARDS

The process for the development of the regional minimum standards was participatory including Member States, the SADC Secretariat and various stakeholders. The process was also informed by internationally-recognised best practices.

Firstly, a desk review of the current national, regional and global policies relevant to tuberculosis was conducted. This was followed by individual country assessments in each Member State, during which key informants within the respective programs, including development partners, civil society organizations and the private sector were consulted to provide information on the state of programmes and policies. The respondents also shed light on some challenges and best practices. Each visit culminated in a country level assessment report which was reviewed and validated by officials from Ministry of Health of each Member State.

The country reports were then compiled to inform a regional picture of the situation and response analysis. The draft regional assessment report was used as a basis for Regional Minimum Standards. Both the draft Regional assessment report and the draft regional minimum standards were then reviewed by a technical team for technical soundness on 8-9 February 2010 in Gaborone, Botswana. The team comprised Member States, Technical Partners, and the SADC Secretariat. The purpose of the review team was to strengthen the quality of the documents.

Following the technical review and the incorporation of the comments, the documents were then presented to a regional workshop for validation of the situation and response analysis report and consensus building on the proposed regional minimum standards. All Member States and major stakeholders including regional partners and civil society organisations were invited to the validation and consensus building workshop. The workshop was held on 29-30 March 2010 in Gaborone, Botswana. The meeting recommended the draft reports for approval through the SADC structures subject to the incorporation of suggested changes.

The report was also reviewed by the CD Project Steering Committee at their meeting of March 2010 for technical soundness and recommendation for approval by Ministers. Finally, the document was reviewed by Senior Officials in Ministries of Health and those responsible for HIV and AIDS before being submitted for approval by the joint ministerial committee of Ministers of Health and those responsible for HIV and AIDS. The document was approved by the joint Ministerial Meeting in April 2010 in Seychelles.

5. FOUNDATION FOR DEVELOPING 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 relate to communicable diseases, call on Member States to work together and assist one another, which requires the harmonisation of policies and information sharing across the region.

In 2006, in response to the Maputo Declaration, a Regional Emergency Response Plan was drafted. It 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-centred 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-TB and 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.

The harmonised policies and minimum standards for TB, MDR-TB and TB/HIV will be guided 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”.Among the guiding principles for harmonising the policy framework in the SADC region includes the SADC Protocol on Health Article 12, which stipulates that Member States “co-operate and assist one another: a) to develop strategies for the sustained control of tuberculosis, including the efficient supply and delivery of drugs; and b) to ensure, where appropriate, the harmonisation of tuberculosis control activities and HIV and AIDS programmes”.

The Strategic Framework for the Control of TB in the SADC Region, 2007-2015 further 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 harmonised policies and minimum standards in the SADC region will ensure that Member States contribute separately and collectively to the achievement of the MDG goals.

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

6.1 Minimum standards for diagnosis

Member states shall ensure that:

- All persons with unexplained productive cough of two weeks or more are investigated for TB.
- All persons suspected of having TB provide sputum specimens for microscopic investigation of AFB according to WHO guidelines. It is recommended that two specimens are collected from each suspect, one of the sputa should be an early morning one and the other should be taken “on spot”.
- For all persons suspected of having extra-pulmonary TB, appropriate specimens from the suspected site of involvement are obtained for microscopy, and where possible for culture and histopathological examination.
- All persons with at least two negative smear results, but where TB is still suspected, shall have a chest X-ray done.
- In situations where the chest X-ray is done first and findings are suggestive of TB, sputum specimens are submitted for Acid Fast Bacilli (AFB) examination.
- All previously treated TB cases shall have a culture and drug sensitivity test taken at the point of diagnosis, at end of intensive phase and at end of treatment.
- All TB patients failing to convert from smear positive to negative have a culture and drug sensitivity test done to exclude drug-resistant TB.

6.2 Minimum standards for case definitions

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

Site of disease (pulmonary or extra-pulmonary)

- A patient should be diagnosed as pulmonary TB if the disease involves the lung parenchyma.
- A patient should be diagnosed as extra-pulmonary TB if the TB involves organs other than the lungs.
- A patient diagnosed with both pulmonary TB and extra-pulmonary TB should be defined as a PTB case.

Bacteriology (sputum smear and culture results)

- A single positive smear result is a confirmation of smear positive TB case.
- Two negative smear results with chest X-ray abnormalities consistent with TB is defined as smear-negative TB. A culture should be done on such cases.
- Two negative smear results with a positive culture is a confirmation of smear-negative TB.
- 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.
- 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, amykacin, capreomycin.

History of previous TB treatment

- 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 four weeks.

- Previously treated cases are defined as cases of TB who have taken anti-TB drugs before for four weeks or more and either relapsed, defaulted or had treatment failure.
- Patients with smear-positive sputum at the end of a second or subsequent course of treatment are defined as relapsed, defaulted or failed.

6.3 Minimum standards for treatment

Member States shall ensure that:

- All anti-TB drugs purchased by Member States should conform to WHO prequalification standards.
- Fixed-dose combination drugs are the mainstay of TB treatment over single drugs.
- The dose of anti-TB drugs conforms to international standards.
- All new patients receive first-line treatment, based on the WHO 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.
- 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.
- All patients who have been treated previously with anti-TB drugs for more than four weeks receive treatment which consists 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.
- All patients are monitored for response to therapy by sputum microscopy. In new pulmonary TB cases, two specimens should be collected at completion of initial phase of treatment (two months), thereafter at five months and at end of treatment for new cases. In previously treated pulmonary TB cases at the end of three months, then at the end of seven months.
- All patients who fail to convert at end of intensive phase are further investigated by culture and drug sensitivity tests.
- A patient-centred approach is used to promote adherence to the treatment. A written record of all medications given, bacteriological response and adverse reactions should be maintained for all patients.
- A mechanism of identifying patients who default from treatment early and a system of tracing them is established.
- TB drugs are included in the Essential Drug list, and ensure that an effective drug management system is established.
- A mechanism is established for contact tracing once an infectious case of TB has been diagnosed.

6.4 Minimum standards for TB/HIV collaboration

Member States shall ensure that:

- A TB/HIV collaboration body for TB/HIV activities is established at the national level. Similar bodies should also be established at lower levels, including health facilities.
- HIV counselling and testing is provided to all TB patients as part of routine management.
- TB screening is provided to all HIV-positive clients as part of routine management.
- All co-infected patients receive cotrimoxazole prophylaxis.
- All co-infected patients are evaluated (WHO staging, clinical examination) to determine whether antiretroviral therapy (ART) is indicated during the course of treatment for TB.
- The choice of antiretroviral (ARV) drugs for co-infected patients is according to WHO guidelines.
- All eligible HIV-positive clients where active TB has been excluded are provided with isoniazid prophylaxis.

6.5 Minimum standards for paediatric care

Member States shall ensure that:

- Specific TB paediatrics guidelines are adapted based on the latest 2009 WHO recommendations for paediatric management of TB.
- All children under five and those that are HIV infected (irrespective of age) with a positive Tuberculin skin test are screened for TB disease.
- All children under five years of age in close contact with an infectious case of TB who are asymptomatic for TB receive isoniazid to prevent the development of TB disease.
- A child presenting with a history of exposure to an infectious TB case or with confirmed infection (positive Tuberculin skin test) is regarded as a TB case if there are symptoms of TB and an abnormal chest X-ray suggestive of TB.
- 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 Tuberculin skin test) and an abnormal chest X-ray suggestive of TB.
- Where possible, diagnosis is confirmed by collecting a gastric aspirate or sputum for smear and culture.
- 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 Tuberculin skin test.
- All case definitions presented in section 6.2 (above) also apply to children in terms of site of disease, bacteriology, severity and history of previous treatment.
- When a child is diagnosed with any form of TB, the parents, household and community contacts (if not already on TB treatment) are carefully evaluated to make sure one of them is not the source case.
- All children diagnosed with TB are provided with nutritional support.
- Children are treated using the same principles as adults.

6.6 Minimum standards for drug-resistant TB

Member States shall ensure that:

- MDR-TB management is part of national TB control programmes.
- Specific guidelines for the “Management of Drug-Resistant Tuberculosis”, according to WHO guidelines, are developed.
- Adequate capacity is present to diagnose MDR-TB (facility with culture and drug sensitivity testing capacity).
- A “needs assessment” is conducted to establish the capacity of each Member State to diagnose drug-resistant TB, for example, the 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.
- Investments are made to introduce new WHO approved diagnostic tools for MDR-TB, for example, line probe assays.
- Confirmed cases of MDR-TB have access to culture and drug sensitivity testing to monitor response to treatment.
- Second-line drugs are procured and are available to those who require them.
- Drugs are procured from WHO pre-qualified companies.
- Studies are conducted on the prevalence of TB drug resistance to guide management and response as a nation.
- A guide for continuum of care for MDR- and XDR-TB is developed to ensure that patients have access to care and treatment.
- Formal linkages are established with supranational laboratories in the region or outside of the region to ensure that there is access to diagnose XDR-TB.
- Once a case of MDR-TB has been confirmed, active case finding amongst close contacts is conducted.

- Where there is limited funding, Member States should explore the possibilities of accessing drugs from the Global Drug Facility and from the Green Light Committee to access second-line drugs.

- National TB programmes develop strategies to address the management of mono- and poly-resistant TB. These will include access to laboratories for drug susceptibility testing and appropriate treatment regimens.

6.7 Minimum standards for cross-cutting issues

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

6.7.1 Advocacy, communication and social mobilisation

- Specific guidelines for advocacy, communication and social mobilisation are developed.

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

- Advocacy, communication and social mobilisation guidelines are accompanied by an implementation plan defining the roles and responsibilities of all stakeholders.

- National TB programmes play a leading role in the coordination of advocacy, communication and social mobilisation 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 advocacy, communication and social mobilisation activities.

- National TB programmes harness and coordinate community involvement in TB control activities through the inclusion of patients, community based organisations, faith-based organisations, donors and other relevant stakeholders.

- National TB programmes, along with other stakeholders, undertake behaviour change activities among providers to ensure compliance with the WHO advocacy, communication and social mobilisation guidelines.

- National TB programmes, along with other stakeholders (national and local media), undertake public education and awareness campaigns to increase case detection, screening of contacts, and to improve TB infection prevention and control in the health facilities and communities.

- National TB programmes, along with other stakeholders, undertake patient education campaigns to increase patient and care giver adherence with treatment regimens.

6.7.2 Laboratory services

- Internal and external quality assurance systems are institutionalised.

- There is an external quality assurance system with blinded re-checking, panel testing and supervision.

- Laboratories develop a specific TB infection control standard operating procedures for the protection of laboratory staff.

- Funding is secured for the purchase of all laboratory supplies (reagents and consumables).

- They meet the minimum WHO requirement of at least one microscopy laboratory per 100 000 population.

6.7.3 Infection prevention and control

- A specific TB infection, prevention and control guideline is developed addressing all components of infection control (administrative, environmental and personal protection).

- All health care facilities develop an infection control plan.

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

- All health care facilities promote an “open window policy,” cough etiquette and triaging of patients.

- There is adequate availability of respirators for all health care workers and visitors who come in contact with suspects and confirmed MDR- or XDR-TB cases.

- A medical surveillance system for TB among health care workers is established.

- Healthy hygiene practices and cough etiquette are promoted in general public areas in the community (for example, public transport areas, shopping malls, entertainment areas airport).

- Guidelines for TB control in congregate settings according to WHO recommendations are developed.

- Indicators are developed to monitor all elements of infection control in relation to the three broad infection control categories.

- Infection control practices are promoted in work place programmes.

6.7.4 Public-private mix

- Guidelines are developed for public private mix according to the WHO recommendations.

- National TB programmes develop memoranda of understanding with the private sector to address specific areas that the private sector manages in terms of TB control.

- Specific indicators are set to monitor public-private mix DOTS, based on the service provided by the private sector.

- National TB programmes establish linkages with training institutions including Universities.

6.7.5 Cross-border issues

- A standardised referral form is developed and implemented for TB and MDR- or XDR-TB patients who move across borders including feedback mechanisms.

- Formal agreements are established in terms of referral and transfer of patients among Member States that share borders.

- A system is developed for determining the proportion of patients with TB who travel outside their country borders.

6.7.6 Donor coordination

- A donor coordinating committee is established.

- National TB programmes identify gaps in the TB control programmes, which can be funded by donors.

6.7.7 Policies and guidelines

- National TB programmes develop and update guidelines as new information becomes available, according to international standards.

- Plans are developed for the dissemination of guidelines to all levels of health service delivery including other sectors that manage TB, for example, the private sector.

- A training and monitoring plan is established for staff after the dissemination of guidelines to support implementation.

- TB/HIV coordinating bodies are used to identify areas of common inter departmental activities within the guidelines in order to improve and harmonise implementation (for example, TB programme and HIV and AIDS departments).

6.7.8 Human resources to manage TB control

- A TB staffing policy is developed, based on the “Recruit, Train & Retain strategy”.

- In-service training and refresher courses are developed for all cadres, including staff from the laboratories and pharmacy.

- Both short- and long-term training programmes are developed to accommodate the high turn around and rotation of staff.

- National TB programmes are staffed and all key activities related to TB control have staff to manage them. Examples of key programmes under the national TB programmes manager would be the following: TB/HIV, monitoring and evaluation, MDR-TB, advocacy, communication and social mobilisation, laboratories, drug supply, research coordination, training and public-private mix.

- Staff that manage the different activities are capacitated in the different areas of discipline.
- National TB programme managers are provided with opportunities to attend courses that are available in the region/globally to improve their skills and knowledge, particularly in programmes management and data analysis.
- Where there are financial constraints, donors are encouraged to fill in the gaps in terms of appointment of additional staff.
- A needs assessment is conducted in terms of staffing to manage TB, TB/HIV and MDR-TB at all levels of health service delivery.

6.7.9 Monitoring and evaluation

- National TB programmes prioritise strengthening of data collection systems to ensure completeness, integrity, timeliness and consistency of TB data, with an emphasis on integrating data related to MDR- and XDR-TB, and TB/HIV.
- Established standard indicators and reporting schedules for TB, TB/HIV and MDR- and XDR-TB data.
- National TB programmes lead the standardisation of monitoring and evaluation indicators, tools, and reporting schedules among TB stakeholders.
- Capacities are improved at all levels to capture, record, and analyse TB and TB/HIV data.
- Guidelines are developed for providing feedback at all levels on TB data to improve accountability.

7. IMPLEMENTATION MECHANISMS FOR THE FRAMEWORK

The implementation mechanism defines the key stakeholders and their roles in the implementation of the Framework. Furthermore, it provides guidance on how the framework will be financed. Lastly, it identifies the critical indicators to be monitored to ensure that the framework is fully integrated in the work of the Member States. To this end, this section is intended to map out the road map on the domestication of the framework, including how it will be financed and monitored.

7.1 Stakeholder roles and responsibilities

The successful implementation of the regional Minimum Standards for TB requires the involvement of all key stakeholders at both national and regional levels. To this end, it is important to provide an outline on their roles.

7.1.1 Member States

- The SADC Health Ministers will oversee and monitor the implementation of this Framework.
- Member States shall take a lead role in ensuring that the minimum standards are integrated to the annual work plans of their national TB programmes.
- Member States shall ensure that national TB programmes involve various departments in the Ministries of Health (for example, laboratories, HIV and AIDS, pharmacy) and key stakeholders in the public and private sectors (for example, donors, WHO, partners, community-based organisations, and training institutions) to identify their roles in the implementation of the various activities articulated in the minimum standards.
- Member States shall identify challenges to implementation of each standard, identify the specific shortcomings that prevent the standards from being met, and identify the barriers and opportunities for each standard.
- Member States shall develop a detailed financial plan and avail resources for supporting the implementation of the harmonised minimum standard.

7.1.2 SADC Secretariat

The SADC Secretariat will coordinate the overall implementation and monitoring of these minimum standards on behalf of the Ministers of Health. Specific responsibilities will include:

- Advocating for implementation of effective TB prevention and control programmes in the region in relation to the commitments made by Member States (such as the SADC Protocol on Health, and the Maputo Declaration);
- Facilitating the harmonisation of policy guidelines and protocols for the prevention and control of TB, TB/HIV and MDR- and XDR-TB;

- Facilitating skills transfer and sharing of good/innovative practices, benchmarking of Member States among each other and provide a platform of sharing of good practices;
- Coordinating partners for resources mobilisation and technical support in the region;
- Facilitating the establishment of rapid response system for MDR-TB epidemic and in dealing with TB and TB/HIV hot zones in the region;
- Facilitating inter-country and cross-border TB prevention and control; and
- Coordinating regional training programmes on TB, TB/HIV and MDR- and XDR-TB.

7.1.3 Other stakeholders

Other stakeholders include UN Agencies, bilateral donors and development partners, local and international NGOs, community-based organisations and communities, the private sector and research and training institutions. All are essential for the successful implementation of the Framework.

UN Agencies and other development partners
Their roles will vary but will include:

- Identifying the TB burden in each Member State, through mechanisms such as modelling.
- Assisting in updating and developing new programmatic/clinical guidelines.
- Linking Member States with new technologies and tools for diagnostics.
- Supporting resource mobilisation to assist in implementing TB control activities.
- Assisting with inputs in harmonising the management protocols to support implantation, including routine reporting and recording of TB, TB/HIV, and MDR- and XDR-TB data.
- Assisting Member States and the Secretariat to coordinate TB cross-border issues.
- Assisting in ensuring access to TB services for mobile populations, women and other vulnerable populations.

Local and international donors and NGOs shall:

- 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 to MS on the progress or otherwise in the implementation of the minimum standards.

7.2 Financing mechanisms

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

Member States shall ensure that:

- Areas that need additional financial resources are identified, with the participation of all relevant stakeholders, including UN agencies, donors, development partners, and NGOs.
- Each area that needs improvement is costed. Examples could include the costing of implementing the advocacy, communications and social mobilisation strategy, expansion of the laboratory network, procurement of second-line drugs to manage drug-resistant TB.
- National TB programmes receive endorsement from their Ministries of Health where additional finances are required.

7.3 Monitoring and evaluation

7.3.1 Role of Monitoring and Evaluation in Implementation of Minimum Standards

These minimum standards need to be monitored in order to enable both Member States and the SADC Secretariat to objectively assess progress in implementing the regionally agreed Minimum Standards for the prevention, treatment and management of TB. Monitoring is an important management tool that helps to indentify implementation progress, challenges and bottlenecks that should be addressed for enhanced impacts. Effective monitoring shows programme managers the extent to which they are making progress in institutionalising the minimum standards into the national health programme. Furthermore, results from monitoring implementation of the minimum standards will inform management decisions aimed at fine-tuning the response to TB at the MS level. At the same time, results from monitoring will show progress that the region is making in the implementation of the SADC Protocol on Health as it relates to prevention, treatment and management of TB.

7.3.2 Monitoring and Evaluation at MS Level

There are broad areas that are articulated in the Minimum Standards for the Prevention, Treatment and Management of TB that when fully implemented will lead to realization of TB commitments and harmonisation of TB response across MS. These are the areas that MS are expected to collect data on as a way of systematically assessing progress in each of the areas articulated in the minimum standards. Member States will collect information to track progress on the following areas:

- Adherence to diagnosis procedures for TB;
- Adherence to TB treatment;
- Integration of TB/HIV collaborative activities in the general TB response;
- Adherence to pediatric care in line with procedures articulated in the minimum standards;
- Drug resistant TB;
- Development of policies and guidelines, for example, updating guidelines in line with international standards;
- Human resource capacity development;
- Development and implementation of infection prevention and control;
- Developing and implementation of quality control mechanisms for laboratory services;
- Develop and institute mechanisms for donor coordination;
- Allocation of financial resources; and
- Information Management Systems

Member States will collect this information on an annual basis and prepare an annual report. The detailed variables on the information that will be collected are in a separate document “Framework for monitoring implementation of Regional Policies and Frameworks”.

7.3.3 Monitoring and Evaluation at the SADC Regional Level

At the SADC regional level, tracking implementation progress for the minimum standards for prevention, treatment and management of TB will focus on issues relevant at that level. The interest at this level will be to establish the number of MS that have implemented each of the areas listed below. Thus, more specifically, at the regional level monitoring will focus on the following areas:

- Adherence to TB diagnosis and treatment guidelines;
- Integration of TB/HIV collaborative activities into national TB programmes;
- Adherence to treatment and management of drug resistant TB;
- Development of TB policies and guidelines in line with international standards;
- Development and implementation of plans to strengthen human capacity to implement minimum standards; and
- Domestication of Minimum Standards into national M&E systems.

Specific details on the information to be collected are contained in the “Framework for monitoring implementation of regional policies and frameworks” document.

7.4 Reporting Mechanisms

Member States will prepare national reports on the implementation of TB Minimum Standards based on the information on the areas to be monitored at the MS level. These national reports will be submitted to the SADC Secretariat annually by 30 April.

The reports that will be submitted by MS will also describe challenges that MS are experiencing in the implementation of Minimum Standards for prevention, treatment and management of TB. On the basis of MS reports, the SADC Secretariat will compile an annual regional report detailing progress in the implementation of minimum standards for the prevention, treatment and management of TB.

This report will be a section in the annual regional TB report. Thus, the submission timelines of MS reports on the implementation of minimum standards for prevention, treatment and management of TB will be in line with submission of national TB annual reports as detailed in the “SADC Harmonised Surveillance Framework for HIV and AIDS, TB and Malaria”.

The SADC Secretariat will share the report with TB Managers and the laboratory Experts from SADC MS for their review and comments by end of June every year. MS will share their comments with the SADC Secretariat by mid-July every year after which the report will be presented to senior officials from Ministries of Health and Ministries of HIV and AIDS for review and recommendation to Ministers. Finally, the draft report will be presented at the annual joint Ministerial meeting of SADC Ministers of Health and Ministers responsible for HIV and AIDS for further review and approval.

The TB report will be analysed to identify implementation challenges and recommend concrete solutions to the identified bottlenecks. Thus, the TB report will be used for decision making and policy reviews at both the national and regional levels.

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