SOUTHERN AFRICAN DEVELOPMENT COMMUNITY
TOWARDS A COMMON FUTURE

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Regional Minimum Standards for Harmonised Approaches to the Prevention of Mother-to-Child Transmission of HIV in the SADC Region

ORIGINAL IN
ENGLISH

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Azido-Thymidine
CDC	Centres for Disease Control and Prevention (USA)
HAART	Highly-active antiretroviral therapy
HIV	Human immunodeficiency virus
HTC	HIV testing and counselling
NAC	National AIDS council
NGO	Nongovernmental organisation
PICT	Provider-initiated counselling and testing
PMTCT	Prevention of mother-to-child transmission of HIV
SADC	Southern African Development Community
STD	Sexually transmitted disease
STI	Sexually transmitted infection
TB	Tuberculosis
UN	United Nations
UNAIDS	United Nations Joint Programme on AIDS
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
VCT	Voluntary counselling and testing
WHO	World Health Organization

1. BACKGROUND

One of the main aims of the Southern African Development Community (SADC) is regional economic and political integration. As the region moves toward the achievement of this objective, however, it faces the challenge of the impact of AIDS on social, political and economic development. The region leads the world in terms of HIV infections, and the majority of Member States have national adult HIV prevalence levels exceeding 10%, while several have adult prevalence higher than 15%.

Eleven SADC Member States are among the 27 countries that are estimated to account for 80% of all children living with HIV worldwide. HIV infection in children is predominantly a result of mother-to-child transmission of the virus, and is an underlying factor in many infant and childhood illnesses and deaths in the region.

There are signs, however, that prevention of mother-to-child transmission of HIV (PMTCT) programmes are beginning to have a noticeable impact on the prevalence of HIV and AIDS in children. Uptake of PMTCT in Member States ranges between 2% and 91%, which indicates that Member States are at very different levels of programme implementation. According to the SADC HIV Epidemic Report (2008), the uptake of PMTCT is on the increase in the region, although it is generally below universal access targets. Nine Member States recorded an increase in the uptake of PMTCT in 2007, compared to 2005. Although Universal Access targets may seem ambitious for a number of Member States, several may be able to attain them if they maintain the pace of implementation. In four SADC Member States, at least 50% of HIV-positive pregnant women were receiving PMTCT services in 2007.

Recognising the devastating effects of the AIDS epidemic, SADC Heads of State and Government made a commitment in the Maseru Declaration (2003) to combat HIV and AIDS and other deadly and communicable diseases. They specifically emphasised the need for rapid scale-up of PMTCT programmes, and for ensuring that uptake is high enough to achieve the desired public health impact. The Maseru Declaration also reaffirmed earlier commitments, such as the United Nations General Assembly Special Session (UNGASS) on HIV and AIDS (2001), which, among other things, committed to halting the transmission of HIV from mothers to children. The UNGASS Declaration also committed to reducing by 20% (by 2005) and 50% (by 2010) the proportion of infants and children infected with HIV.

In line with the overall regional integration agenda and the control of communicable and other health problems, the SADC region has drafted the Protocol on Health (2004), which guides implementation of the regional health agenda. The Protocol calls for the harmonisation of regional approaches, and regional cooperation.

These regional minimum standards serve as a harmonisation framework for regional approaches to PMTCT, and therefore form part of the operationalisation of the various declarations to which Member States are signatories. They are also in line with the regional agenda of integration.

2. RATIONALE

The *Protocol on Health*, various sections of which address important aspects of facilitating regional cooperation and integration, informs these regional minimum standards. Article 9 on communicable diseases, for example, calls for the harmonisation of policies and the sharing of information in the region, while article 10 (which deals specifically with HIV and AIDS) mandates Member States to:

- Harmonise policies aimed at disease prevention and control, including cooperation and identification of mechanisms to reduce the transmission of sexually transmitted diseases (STDs) and HIV infection;
- Develop approaches for the prevention and management of HIV and AIDS and other STDS to be implemented in a coherent, comparable, harmonised, and standardised manner; and
- Develop regional policies and plans that recognise the inter-sectoral impact of HIV and AIDS and STDs, and the need for an inter-sectoral approach to these diseases.

The specific focus on PMTCT is adopted from the *Maseru Declaration*, which calls for “rapid scale up of programmes for prevention of mother-to-child transmission of HIV and ensuring that levels of uptake are sufficient to reach the desired public health impact”.

3. GUIDING PRINCIPLES

The regional minimum standards are informed by the WHO framework for a comprehensive approach to the prevention of HIV infections in infants and young children.

The standards are organised in accordance with the four main components of the comprehensive approach framework:

- Preventing HIV infection in women.
- Preventing unintended pregnancies in HIV-infected women.
- Preventing transmission from an HIV-infected woman to her infant.
- Providing care and support for HIV-infected women, their infants and their families.

4. PROCESS FOR DEVELOPMENT OF THE REGIONAL MINIMUM STANDARDS

The process for the development of this 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 the prevention of mother-to-child transmission of HIV (PMTCT) 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 15-16 December in Gaborone, Botswana. The team comprised Member States, Technical Partners, Civil society Organizations 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 25-27 May 2009, in Victoria Falls, Zimbabwe. The meeting recommended the draft reports for approval through the SADC structures subject to the incorporation of suggested changes.

Accordingly, the revised reports were reviewed by the SADC National AIDS Authorities in their meeting of 12-14 October 2009 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. Ministers approved the document at their meeting of 9-13 November 2009 at Ezulwini, Swaziland.

5. SADC REGIONAL MINIMUM STANDARDS FOR PMTCT

5.1 Minimum standards for prevention of HIV infection in women and couples

- Women and/or couples must be provided with health education and information on prevention and care including for sexually transmitted infections (STIs).
- Member States' HIV policies must promote HIV testing and counselling (HTC) for couples, index and partner, including support for disclosure, using both voluntary counselling and testing (VCT) and provider-initiated testing (PITC) and counselling.
- Member States' policies must make provisions for regular retesting for persons exposed to HIV.
- Member States must promote HIV counselling as part of routine health care.

5.2 Minimum standards for preventing unintended pregnancies in all women of reproductive age

- Family planning counselling and contraceptives must be provided at all opportunities, such as HIV care and treatment, VCT, preconception, antenatal, and postpartum services.

- PITC must be offered during family planning services and should be linked with counselling on reproductive choices and awareness of PMTCT.
- Member States' PMTCT policies and guidelines must include family planning and contraceptive options for pregnant HIV-positive women.
- HIV-positive women must be given access to all available options for family planning. There should be no forced sterilisation or other unwanted methods of family planning.
- Services for the prevention of unintended pregnancies must be promoted, including access to reproductive health commodities and contraceptives that are more youth-friendly.
- All women must be given information and care to assist them in remaining healthy during pregnancy (safe motherhood) – including safer sex, good nutrition, adequate rest, and the prevention and treatment of malaria, tuberculosis (TB), sexual and other infections, etc.

5.3 Minimum standards for preventing transmission of HIV from an infected woman to her infant

- Member States must provide routine quality antenatal and postpartum care for all women including information on PMTCT, and other sexual and reproductive health services.
- Safe obstetric practices for all women must emphasise:
  - Delivery by a skilled birth attendant;
  - Minimal invasive procedures during delivery;
  - Care for newborns must include minimum suctioning of nostrils; and
  - Newborns should immediately be given a bath, and a dose of Azido-Thymidine (AZT) as soon after birth as possible.
- Pregnant women must be given information about PMTCT of during antenatal information sessions.
- PITC must be promoted according to the status of the epidemic as follows:
  - In generalised epidemics, PITC should be available to all persons attending healthcare facilities, as a standard component of medical care, and in all antenatal, childbirth, postpartum, and paediatric care settings;
  - In low and concentrated epidemics, PITC may be considered for pregnant women identified as being at higher risk of HIV exposure, according to national or local criteria.
- Member States with generalised epidemics must provide routine retesting late in pregnancy, as well as syphilis screening.
- Pregnant women with HIV infection, who do not yet require antiretroviral therapy (ART), must be given ARV prophylactic regimens for PMTCT, in accordance with WHO recommendations.
- Member States must support infant feeding and counselling and follow WHO recommendations for infant feeding for children of HIV-infected mothers.

5.4 Minimum standards for providing care and support for HIV-infected women, their infants and families

5.4.1 Minimum standards for providing care and support for HIV-infected women

- Member States must endeavour to provide ART for all pregnant women who are eligible for treatment based on clinical staging or CD4 testing.
- ARV and other care must be extended to the father and other members of the family, according to need and the capacities of each Member State.
- Member States must work towards adhering to the WHO-recommended cut-off point of a 350 CD4 cell count for starting ART, according to the capacities and within the limits of the individual Member State.
- Cotrimoxazole prophylaxis must be provided where indicated (i.e. clinical stage 4 or CD4 <200 cells/mm3).

- Member States must promote and facilitate the active participation of people living with HIV, especially women, men, fathers and mothers living with HIV, in planning and delivering services, advocacy and community engagement.

- TB screening and treatment must be provided for women and their families living with HIV when indicated.

5.4.2 Minimum standards for providing care and support for HIV-infected children

- Member States must provide early HIV diagnostic testing and diagnosis of HIV-related conditions at six weeks, where virological tests are available.

- Where virological testing is not available, antibody testing must be done at 18 months.

- All HIV-exposed children born to mothers living with HIV must start cotrimoxazole preventive treatment at 4–6 weeks after birth and continue until HIV infection has been excluded and the infant is no longer at risk of acquiring HIV through breastfeeding.

- Provider-initiated, age-appropriate HIV testing must be offered for all infants and children where HIV is possible, suspected, or HIV exposure is recognised.

- All children suspected or known to have TB must be offered an HIV test.

- All HIV-exposed children must have a confirmatory HIV antibody test at or around 18 months.

- All infants below 12 months of age with confirmed HIV infection must be started on ART, irrespective of clinical or immunological stage.

- Where virological testing is not available, infants younger than 12 months of age with clinically diagnosed presumptively severe HIV must start ART. For children aged 12 months or older, clinical and immunological thresholds (<20% CD4 for 12-59 months, and <15 % CD4 for five years or over) should be used to identify those who need to start ART.

- The following treatment regimens are recommended for the region:

  - For HIV-infected infants with no exposure to maternal or infant non-nucleoside reverse transcriptase inhibitors, or whose exposure to maternal or infant antiretrovirals is unknown, standard nevirapine-containing triple therapy should be started;
  - For HIV-infected infants with a history of exposure to single dose nevirapine or non-nucleoside reverse transcriptase inhibitor containing maternal ART or preventive ARV regimens, a protease inhibitor-based triple ART regimen should be started. Where protease inhibitors are not available, affordable or feasible, nevirapine-based therapy should be used.

- All children receiving ART must be monitored.

- Ensure symptom management and palliative care if needed. This includes diagnosis and management of common childhood infections and conditions and Integrated Management of Childhood Illnesses.

5.5 Minimum standards for access to PMTCT in the SADC region

The recommendations on PMTCT made in the model law on HIV and AIDS in Southern Africa (2009) are endorsed:

- Member States must ensure that HIV testing is available to pregnant women and their families as part of antenatal care (ANC) services.

- Women living with HIV and their families must have access to counselling, information and services that can enable them to make informed and voluntary decisions in matters affecting their health and their reproductive choices.

- Member States must ensure that PMTCT programmes are available to all pregnant women living with HIV and must include their families. Such programmes shall include psychosocial support, follow-up services, and nutritional support for disadvantaged mothers and their families. Member States must also provide pregnant women and their families living with HIV with relevant and scientifically proven information regarding breastfeeding and alternatives to breastfeeding, with a view to reducing the risk of HIV transmission.

- When possible, and with the consent of the pregnant woman living with HIV, her partner or spouse must receive information and counselling on the implications of the PMTCT programme.

5.6 Minimum standards for integration of PMTCT into maternal and child health, and sexual and reproductive health services

PMTCT must be integrated into other sexual and reproductive health, as well as maternal and child health programmes.

6. Implementation Mechanisms for the Regional minimum standards

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

6.1 Stakeholder roles and responsibilities

The successful implementation of the regional Minimum Standards for the Prevention of the Mother to Child Programme requires the involvement of all key stakeholders at both national and regional levels. It is therefore important to provide an outline on their roles.

6.1.1 Member States

- The SADC Health Ministers will oversee and monitor the implementation of the minimum standards.

- Member States shall take a lead role in ensuring that the minimum standards are integrated to the annual work plans of their national PMTCT programmes.

- Member States shall ensure that national PMTCT programmes involve various departments in the Ministries of Health and key stakeholders in the public and private sectors (for example, donors, WHO, partners, community-based organisations, Private Sector 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.

6.1.2 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 PMTCT programmes in the region in relation to the commitments made by Member States (such as the SADC Protocol on Health, and the Maseru Declaration on HIV and AIDS);

- Facilitating the harmonisation of policy guidelines and protocols for the prevention of mother to child transmission of HIV;

- 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 resource mobilisation and technical support in the region; and

- Coordinating regional training programmes on the prevention of mother to child transmission of HIV.

6.1.3 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 Minimum Standards.

UN Agencies and other development partners

Their roles will vary but will include:

- 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 PMTCT activities.
- Assisting with inputs in harmonising the management protocols to support implementation, including routine reporting and recording PMTCT data.

Local and international donors and NGOs shall:

- Assist in implementation of agreed on minimum standards.
- Advocate for strengthening of PMTCT.
- 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 PMTCT in the overall primary health care services.
- Provide feedback to MS on the progress or otherwise in the implementation of the minimum standards.

6.2 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 the PMTCT 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.
- National PMTCT programmes receive endorsement from their Ministries of Health where additional finances are required.

6.3 Monitoring and evaluation

6.3.1 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 them. 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 PMTCT 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 PMTCT.

6.3.2 Monitoring and Evaluation at MS Level

There are broad areas that are articulated in the Minimum Standards for PMTCT that if fully implemented will lead to realization of PMTCT commitments and harmonisation of PMTCT 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:

- Prevention of HIV infection in women and couples;
- Prevention of unintended pregnancies in all women of reproductive age;
- Prevention of transmission of HIV from an infected women to her infant;
- Provision of care and support for HIV-infected women, their infants and families;
- Access to PMTCT;
- Integration of PMTCT into maternal and child health, and sexual and reproductive health services;
- Development and implementation of plans to strengthen human capacity to implement minimum standards; and
- Domestication of Minimum Standards into national M&E systems.

Member States will collect information on the broad areas above on an annual basis and prepare an annual report. The detailed variables on which information will be collected are in a separate document “Framework for monitoring progress in implementing Regional Policies and Frameworks”.

6.3.3 Monitoring and Evaluation at the SADC Regional Level

At the SADC regional level, tracking implementation progress for the minimum standards for PMTCT will focus on issues relevant at that level. It should be noted that the aspects of PMTCT monitored are exactly the same with those monitored at the MS level. The difference is that at the regional level, interest will be to know the number of MS that are implementing each of the aspects of PMTCT that are articulated in the Minimum Standards. Thus, more specifically, at the regional level monitoring will focus on the number of MS implementing the following:

- Prevention of HIV infection in women and couples;
- Prevention of unintended pregnancies in all women of reproductive age;
- Prevention of transmission of HIV from an infected women to her infant;
- Provision of care and support for HIV-infected women, their infants and families;
- Access to PMTCT;
- Integration of PMTCT into maternal and child health, and sexual and reproductive health services; and
- Development and implementation of plans to strengthen human capacity to implement minimum standards;

Specific details on the information to be collected are contained in the “Framework for monitoring progress in implementing regional Policies and Frameworks” document.

6.3.4 Reporting Mechanisms

Member States will prepare national reports on the implementation of PMTCT 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 PMTCT. On the basis of MS reports, the SADC Secretariat will compile an annual regional report detailing progress in the implementation of minimum standards for PMTCT. This report will be a section in the annual regional HIV and AIDS Epidemic Report. Thus, the submission timelines of MS reports on the implementation of minimum standards for PMTCT will be in line with submission of national HIV and AIDS Epidemic Reports as detailed in the "SADC Harmonised Surveillance Framework for HIV and AIDS, TB and Malaria".

The SADC Secretariat will share the report with HIV and AIDS Managers, PMTCT Programme Managers from MS and PMTCT Experts from partner organisations for their review and comments in mid-June every year. MS PMTCT Managers at MS levels will compile comments from stakeholders in their country and share them with the SADC Secretariat by mid-July. The SADC Secretariat will incorporate the comments and present the Draft Regional Report as a section in the SADC HIV and AIDS Epidemic Report to Senior Officials from the Ministries of Health and Ministries responsible for HIV and AIDS for comments and recommendations to Ministers of Health and Ministers responsible for HIV and AIDS for final review, comments and approval at their annual meeting.

The PMTCT component of the SADC HIV and AIDS Epidemic Report will be analysed to identify implementation challenges and recommend concrete solutions to the identified bottlenecks. Thus, the PMTC report will be used for decision making and policy reviews at both the national and regional levels.

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