

National Policy on HIV Pre-exposure Prophylaxis (PrEP) and Test and Treat (T&T)

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1. INTRODUCTION

South Africa has 6.8 million people (ages 15-49) living with HIV, representing 19% of the global HIV burden¹. Although the prevalence of HIV in South Africa remains high, it has been stable over the last decade, which can be attributed to the rapid scale-up and success of the antiretroviral treatment (ART) programme. Currently, with over 3.3 million people on ART, South Africa has the largest ART programme in the world².

The South African government has embarked on a deliberate effort to scale up HIV Testing Services (HTS) and strengthen HTS quality at all health facilities and non-health sites. In line with the ambitious targets for HIV reduction by 2030 as reflected in the National Development Plan, South Africa supports the UNAIDS Fast Track approach, the

90% of all people living with HIV knowing their HIV status, 90% of people who know their HIV-positive status having access to treatment, and 90% of people on treatment having suppressed viral loads

90-90-90 targets (see text box), and the prevention target of reducing the number of new HIV infections by 75% by 2020.

2. WHO RECOMMENDATIONS

This policy aims to address the need for an expanded and accelerated scale up of HIV treatment and combination prevention, including universal "test and treat" (T&T) and provision of preexposure prophylaxis (PrEP).

Since first published in 2002, the World Health Organization (WHO) guidelines on the use of ART have evolved. Over the years, additional evidence has emerged showing that earlier initiation of ART results in better long-term clinical outcomes for people living with HIV, resulting in a population impact on HIV transmission. Clinical trial results have also confirmed the efficacy of the drug tenofovir disoproxil fumarate (TDF), alone or in combination with emtricitabine (FTC), for use as PrEP to prevent people from acquiring HIV in a wide variety of settings and populations³. The use of PrEP to prevent people from acquiring HIV is an important new additional prevention option for populations who are at a substantial risk of acquiring HIV. WHO defines substantial risk as a population group with an HIV incidence greater than 3 per 100 person-years in the absence of PrEP⁴.

On 30 September 2015 WHO published an early-release to the new guidelines on the use of ART for the prevention and early treatment of HIV infection. These new guidelines recommend the following:

¹ Http://www.measuredhs.com/hivdata/

² tier.net, march 2013

³ Guidelines on When to Start Anti-Retroviral Therapy and on Pre-Exposure Prophylaxis for HIV. World Health Organization, Sept 2015.

- > ART should be initiated in everyone living with HIV regardless of their CD4 cell count.
- ➤ People with a substantial risk of HIV infection should be provided with daily PrEP as part of a combined HIV prevention strategy.

3. GOALS AND OBJECTIVES

The overall goal of the PrEP and T&T National Policy is to reduce the incidence of HIV infection in South Africa through the provision of expanded prevention and treatment options. In South Africa, this will be accomplished over time, targeting prioritized populations in phased approaches. For more detail, refer to:

 NDOH Guidelines for Expanding Combination Prevention and Treatment Options for Sex Workers: Oral Pre-Exposure Prophylaxis (PrEP) and Test and Treat (T&T)

OBJECTIVES OF THE PREP AND TEST & TREAT GUIDELINES

- **Expanded prevention options:** Offer and promote PrEP as an additional option in the context of combination prevention.
- ➤ Increase access to treatment: Provide T&T to those who test positive for HIV.
- ➤ Integration: Integrate PrEP and T&T into other HIV prevention programmes, policies, and services, as well as sexual and reproductive health, contraception and fertility planning services, and antenatal care.
- ➤ Quality of care: Provide PrEP and T&T within the broader framework of quality health service provision.
- ➤ Communication and community-based strategies: Implement appropriate, evidence-informed, communication and advocacy strategies to increase both healthcare provider and public awareness of PrEP and T&T within the context of HIV prevention, without stigmatising the intervention and its potential users, nor increasing risky sexual behaviour.

3.1. Expanded Prevention and Treatment Options

Testing and providing immediate treatment has the potential to cause a very steep reduction in HIV incidence, will reduce HIV-related morbidity and mortality, and will play a role in eliminating HIV as a public health problem.

PrEP should not displace or undermine the use of other effective and well-established HIV prevention interventions. While PrEP is a highly effective HIV prevention method, it has only been tested formally in the context of other combination HIV prevention tools and services, including regular HIV and STI testing, condom and condom compatible lubricant dissemination, STI treatment, and risk reduction counselling. As such, PrEP should be promoted as an additional prevention option among people for whom it is suitable and their communities, in conjunction with other appropriate prevention methods.

Some PrEP implementers may not have access to the full range of combination prevention services and may therefore need to establish effective referral pathways for these services. Prior to PrEP implementation, sites should confirm that these prevention services are in place

with adequate available resources (e.g. trained staff, medication, HIV tests, condoms, ART), accompanied by a plan to ensure ongoing commodity supplies. PrEP providers should also be supplied with job aids and tools, such as community education and literacy tools, to support healthcare providers who will provide PrEP services.

Ideally, PrEP and T&T should be fully integrated into the primary healthcare package at all the entry points of the public health system (primary healthcare (PHC) clinics, HTS, ANC, SRH services, contraception and fertility services, VMMC services, STI and TB screening, ToP services, post-rape care services, etc.) This will mitigate against stigmatisation when trying to obtain HTS and PrEP services.

3.2. Quality of Care

Healthcare providers, including clinical staff, counsellors, and ward-based outreach teams (WBOTS), should be provided with the competencies to provide quality PrEP and T&T services, across levels of care. In-service training on clinical guidelines, counselling, and attitudes are important to promote uptake and retention in care by creating a non-stigmatising and supportive environment for priority populations. Provision of priority population sensitivity training to all healthcare providers prior to implementation is important to promote quality of care and trust between clients and service providers.

Training should include the following:

- Clinical guidelines
- Counselling
- Sensitivity to priority populations to create a non-stigmatising and supportive environment, with particular focus on special considerations for MSM, transgender, SW, and serodiscodant couples
- A detailed overview of the nature and purpose of PrEP and why it should be prescribed for priority populations at substantial risk of HIV infection
- Strategies for providing PrEP education to a multitude of clients with varying risk profiles
- Sensitisation to the realities of prescribing PrEP in a high-risk population
- The importance of adherence
- Guidance on how best to integrate with other combination HIV prevention service, including T&T

In addition to sensitivity and competency training on priority populations, all staff affiliated with PrEP and T&T service delivery should complete a PrEP and T&T implementation training programme. Specifically, training should provide staff with a detailed overview of the nature and purpose of PrEP and why it should be prescribed for priority populations at substantial risk of HIV infection. The training should provide strategies for providing PrEP education to a multitude of clients with varying risk profiles. The training should sensitise healthcare providers to the realities of prescribing PrEP in a high-risk population, the importance of adherence, and how best to integrate this with other combination HIV prevention services. The T&T

component will build on what is already existing, and will include special considerations for priority populations.

Implementing sites should schedule regular follow up training for all staff in order to maintain the quality of service over time and to address any identified trends in performance. These trainings will also serve to support healthcare workers to promote the needs of their clients.

QUALITY PREP AND T&T SERVICE PROVISION

- Functioning supply chain, including drugs and commodities for HTS and monitoring
- > Adequate supply of prevention commodities
- Efficient HTS
- Access and training on operational and clinical guidelines
- Rights-based provision

3.3. Communication and Community Based Strategies

As PrEP is just becoming available in South Africa, community awareness of its benefits is limited. Clinics and other service providers providing PrEP and T&T have the opportunity to improve overall awareness in their communities and among their clients. Particularly for priority populations, information dissemination between peers and within social networks is useful, as well as the involvement of community liaison groups in the service delivery decision making processes.

Appropriate, evidence-informed demand creation and advocacy strategies should be implemented to increase the public's awareness of T&T and PrEP, within the context of HIV prevention, without stigmatising the intervention or its potential users, or increasing risky sexual behaviour. Healthcare providers must understand the importance of HIV prevention and be able to provide PrEP and T&T information, and counselling to ensure safe, effective use of PrEP and ART.

Clients should have access to multilingual information, education, and communication materials about PrEP and T&T. The community should be engaged to address socio-cultural barriers that may impede uptake of and adherence to PrEP and initiation on ART.

4. TARGET AUDIENCE

This policy document, and the associated guidelines, are intended for clinical and non-clinical service providers in HTS, contraception and fertility planning, sexual and reproductive health, and maternal, child, and neonatal services, as well as those implementing programmes for high risk populations. The guidelines apply to national, provincial, and district health facility managers and healthcare providers in the private and public health sectors; healthcare providers engaged by community- and faith-based organisations (CBOs/FBOs), non-

governmental organisations (NGOs), the private sector, educational institutions, and other service providers.

5. ETHICAL AND LEGAL CONSIDERATIONS

Provision should be framed by a human rights-based approach, and should uphold the rights of all clients. T&T and PrEP must be offered in a way that upholds the rights described in the Constitution of South Africa. Four important human rights are described below.

5.1. Right to Dignity and Non-Discrimination

Every person has inherent dignity and the right to have their dignity respected and protected. No actions should be taken against any individuals solely on the basis of their HIV status, gender, sexual status, or job, as this will constitute stigma and discrimination.

5.2. Right to Privacy and Confidentiality

All personal information concerning a client, their health status, treatment or stay in a health establishment, must be kept confidential, unless ordered by the court of law or done so for the advancement of client's care and treatment after following the necessary procedure.

5.3. Requirements of Informed Consent

Informed consent refers to a person being given relevant and appropriate information about an HIV test, and based on that information, given an opportunity to either accept or refuse to do the HIV test. Informed consent should always be in written form and signed by only the client and the healthcare provider to avoid unintended disclosure of results.

5.4. Right to Services

Clients who do not meet the target population criteria but who "self-select" and request PrEP and T&T services should not be turned away. If a client feels they are at substantial risk for HIV infection, proceed with service provision and eligibility testing for PrEP.

6. Monitoring and Evaluation

Systems should be in place to ensure that the T&T and PrEP policy is implemented effectively and efficiently. Opportunities need to be identified to incorporate T&T and PrEP services into existing systems and structures.

Appropriate monitoring and evaluation (M&E) systems need to be in place to monitor and evaluate provision, quality of care, and impact of the T&T and PrEP programmes. An M&E

strategy, supported by partner institutions, will be developed to track and measure the implementation of the T&T and PrEP policy, and to assess progress against indicators.

The provision of PrEP and T&T must be evidence-guided, and data from M&E and additional research will inform additional policy formulation, programme planning, future recommendations, and implementation.

7. COSTING AND FINANCING THE PREP AND T&T POLICY

Costing models must establish the cost of implementation of these plans at national and provincial levels, to be completed in conjunction with the recommended interdepartmental mechanism. Donor funding will provide an important source for numerous interventions described here.