

PREP IMPLEMENTATION  
PACK : SOUTH AFRICA  
2016-2017

THESE ARE  
THE GENERATION  
THAT WILL END  
HIV

I HAVE THE  
RIGHT DUTY  
TO LIVE HIV  
FREE  
I HAVE THE  
DUTY TO HELP STOP  
THE SPREAD OF  
HIV

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# INTRODUCTION

The National Department of Health rolled out oral pre-exposure prophylaxis (PrEP) to select clinics across South Africa in 2016. Implementation began on 1 June 2016 with 11 sites in 5 provinces; an additional site was added in November, to create a total of 12 implementing sites in 2016.

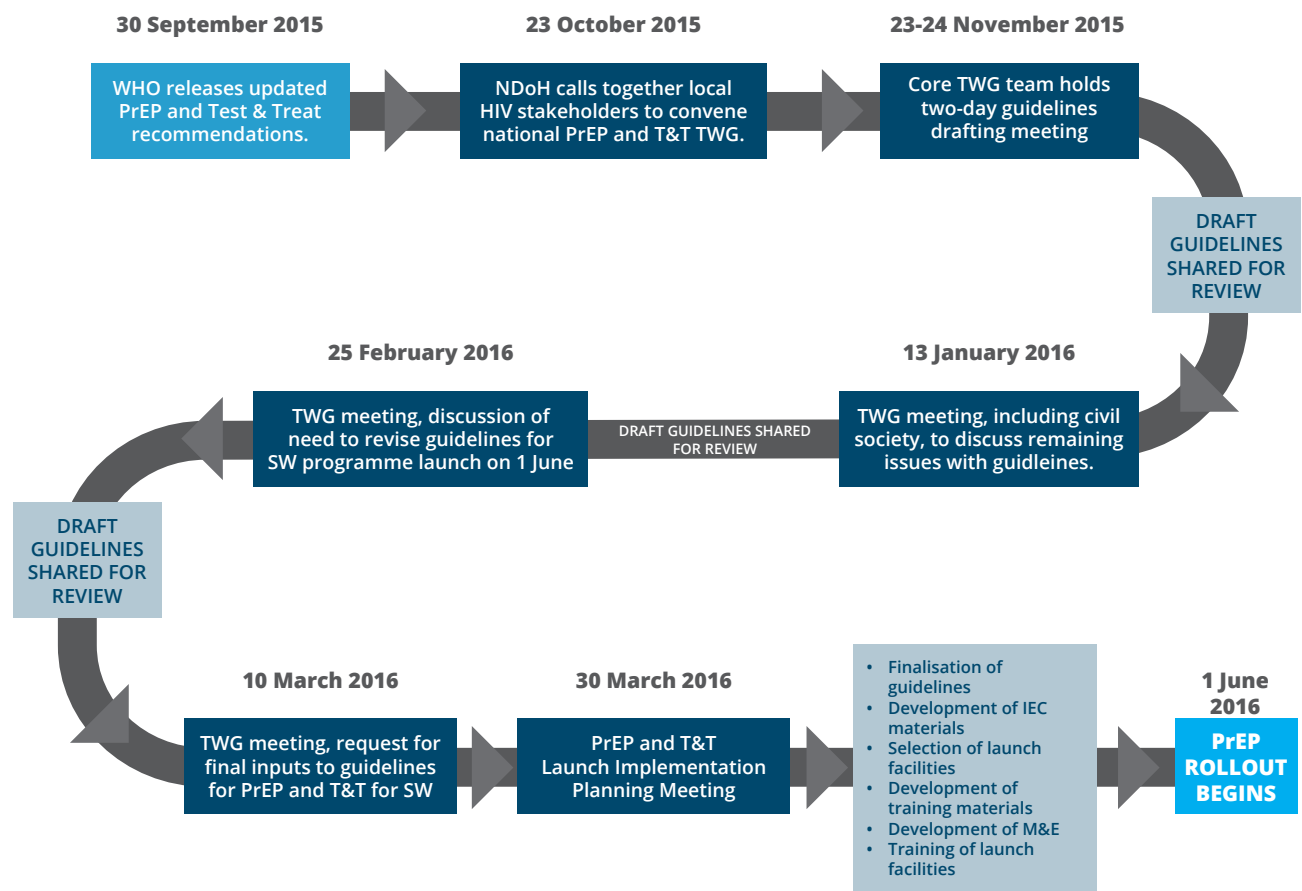
This Implementation Pack provides a comprehensive overview of this roll-out, from policy creation and site selection, to communications materials and M&E reporting processes. All materials used in the launch are included in this Pack. South Africa is the first country on the African continent to implement oral PrEP outside of studies and demonstration projects. This Pack is intended to provide insight into the NDoH's roll-out process. The Implementation Pack was created by the NDoH and its supporting partners responsible for South Africa's oral PrEP roll-out.

# SA TIMELINE

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# SA TIMELINE



# POLICY & GUIDELINES

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# WHO GUIDELINES

## CONSOLIDATED GUIDELINES ON THE USE OF ANTIRETROVIRAL DRUGS FOR TREATING AND PREVENTING HIV INFECTION - RECOMMENDATIONS FOR A PUBLIC HEALTH APPROACH **SECOND EDITION 2016**

This document contains content that was previously published in the following two documents:

- “Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV: Early Release”, published in September 2015.
- “Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: what’s new”, Policy brief, published in November 2015 and disseminated in December 2015.

**THE FULL GUIDELINE DOCUMENT IS AVAILABLE ON THE PrEP IMPLEMENTATION PACK MEMORY STICK**

# WHO GUIDELINES

## EXECUTIVE SUMMARY

These guidelines provide guidance on the diagnosis of human immunodeficiency virus (HIV) infection, the use of antiretroviral (ARV) drugs for treating and preventing HIV infection and the care of people living with HIV. They are structured along the continuum of HIV testing, prevention, treatment and care.

### Rationale

WHO first published guidelines on the use of antiretroviral therapy (ART) for HIV infection among adults and adolescents in 2002, and on the use of ARV drugs to prevent mother-to-child HIV transmission in 2004. The 2006 updates of the guidelines introduced the concept of a public health approach, with simplified and harmonized ART regimens. In 2013, for the first time, WHO revised and combined these and other ARV-related guidance documents into consolidated guidelines that address the use of ARV drugs for HIV treatment and prevention across all age groups and populations, based on the HIV service continuum. This edition updates the 2013 consolidated guidelines on the use of antiretroviral drugs following an extensive review of evidence and consultations in mid-2015, shared at the end of 2015, and now published in full in 2016.

Consolidated simplified guidance was developed in response to expressed needs of country programmes, to include all age groups and populations across both clinical and operational aspects of care. Continuing with this approach allows all guidelines impacting on the continuum of HIV care to be harmonized based on a public health approach.

Several significant developments have occurred in the HIV field since 2013. In treatment, strong evidence has emerged to show that using ART earlier results in better clinical outcomes for people living with HIV compared with delayed treatment. Further, safer and more efficacious ARV drugs are becoming available and a newer class of drugs – integrase inhibitors – is becoming more affordable for low- and middle-income countries. Most countries have moved or are moving to provide lifelong ART regardless of CD4 cell count to all pregnant and breastfeeding women, and many are moving to implement viral load testing as the preferred means of monitoring people who are taking ART. New point-of-care viral load testing technologies offer further potential to expand this approach.



In prevention, clinical trial results have strongly confirmed the efficacy of the ARV drug tenofovir disoproxil fumarate alone or in combination with emtricitabine for use as pre-exposure prophylaxis (PrEP) to prevent HIV acquisition in a wide variety of settings and populations. New innovative approaches to HIV testing are being implemented, including home testing, community-based testing and self-testing. The opportunity to use ARV drugs for treating and preventing HIV more effectively are growing rapidly.

Although countries are at different stages of ART coverage and implementation of the 2013 guidelines, there is a consistent trend towards initiating treatment earlier and expanding the use of ARV drugs for HIV prevention to achieve greater impact. This is accompanied by strong recognition that expanding access to HIV testing, treatment and prevention in settings with the highest burden of HIV infection and for the most vulnerable populations, along with greater efforts to address stigma and discrimination, are essential to ensure continued focus and to accelerate the response to the epidemic.

These guidelines present several new recommendations, including the recommendation to provide lifelong ART to all children, adolescents and adults, including all pregnant and breastfeeding women living with HIV, regardless of CD4 cell count. WHO has also expanded earlier recommendations to offer PrEP to selected people at substantial risk of acquiring HIV. Alternative first-line treatment regimens are recommended, including an integrase inhibitor as an option in resource-limited settings and reduced dosage of a key recommended first-line drug, efavirenz, to improve tolerability and reduce costs. Because of their anticipated public health impact, the new recommendations on when to start ART and the use of PrEP contained in these guidelines were released in September 2015.

Implementing all the recommendations in these guidelines at the national and global levels will have important implications for programme priority-setting, funding and service delivery. As in 2013, operational guidance is included to help countries as they work to implement new approaches and strengthen the treatment cascade. These guidelines include 10 new recommendations to improve the quality and efficiency of services to people living with HIV. Implementation of the recommendation on universal eligibility for ART will mean that more people will start ART earlier. Importantly, in this guidance WHO emphasizes the need for differentiated approaches to care for people who are stable on ART, such as reducing the frequency of clinic visits and community ART distribution. Such efficiencies are essential if countries with a high burden of HIV infection are to manage their growing numbers of people receiving ART and reduce the burden on people receiving treatment and health facilities.

The second edition of the consolidated guidelines on the use of antiretroviral drugs is being published in a changing global context for HIV and for health more broadly. The goal of providing HIV treatment to 15 million people by the end of 2015 has been achieved. From 2016, countries need to further accelerate efforts to meet the ambitious Fast-Track target for 2020, including achieving major reductions in the number of people dying from HIV related causes and the 90-90-90 treatment target: ensuring that 90% of the people living with HIV know their HIV status; 90% of the people living with HIV who know their HIV status are accessing treatment; and 90% of people living with HIV who are receiving treatment have suppressed viral load. The clinical and operational recommendations in these guidelines together with two sets of consolidated guidelines on HIV testing services and strategic information published in 2015 should contribute strongly to achieving these goals in the coming years and to other health and development priorities in the Sustainable Development Goals. The forthcoming Global Health Sector Strategy on HIV 2016-2021 describes WHO's contribution to achieving the HIV- and health-related Sustainable Development Goals.

These guidelines present several new recommendations, including the recommendation to provide lifelong ART to all children, adolescents and adults, including all pregnant and breastfeeding women living with HIV, regardless of CD4 cell count.

## Process of guideline development

This edition of the guidelines was revised in accordance with procedures established by the WHO Guidelines Review Committee. New clinical and operational recommendations in the guidelines are based on the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to reviewing evidence. Modelling, expert consultations and country case studies have all strongly informed the guidelines. The process has also identified key gaps in knowledge that will help to guide the future HIV research agenda.

## Audience

The primary audience for these guidelines is national HIV programme managers in low- and middle-income countries. The guidelines will also be a useful resource for clinicians and should help to shape the priorities of policy-makers in development agencies, international organizations, nongovernmental organizations and other implementing partners during the next few years. The guidelines will also be of value to people living with HIV, communities and civil society organizations that will need to be engaged meaningfully to support their successful implementation.

The 2016 consolidated guidelines on the use of antiretroviral drugs represent an important step towards achieving the goal that the world set itself a decade ago, universal access to ARV drugs for treating and preventing HIV, and the ultimate goal of ending the HIV epidemic as a major public health threat by 2030.

# NDOH PrEP POLICY

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

**Final Draft - 5 May 2016**

**Updated - 8 December 2016**

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## 1. Introduction

South Africa has 6.8 million people (ages 15 to 49) living with HIV, representing 19 percent of the global HIV burden.<sup>1</sup> 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. With over 3.3 million people currently on ART, South Africa has the largest ART programme in the world.<sup>2</sup>

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

### 90-90-90 Targets

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

## 2. 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.

## 3. WHO Recommendations

This policy aims to address the need for an expanded and accelerated scale-up of HIV treatment and combination prevention, including immediate “test and treat” (T&T) and provision of pre-exposure 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 populations.<sup>3</sup> 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. The WHO defines substantial risk as a population group with an HIV incidence greater than 3 per 100 person-years in the absence of PrEP.<sup>4</sup>

On 30 September 2015, the WHO published an early-release to the new guidelines on the use of ART for the prevention and early treatment of HIV infection. These guidelines were then updated in June 2016.<sup>5</sup>

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.

4. Ibid.

5. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed. World Health Organization, June 2016.

The new guidelines recommend the following:

- 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.

## 4. 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 by targeting prioritized populations in phased approaches. For more detail, refer to the NDOH Guidelines for Expanding Combination Prevention and Treatment Options: 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 and 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

### 4.1 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) and are 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, antenatal care (ANC), sexual and reproductive health (SRH) services, contraception and fertility services, voluntary medical male circumcision (VMMC) services, sexually-transmitted infections (STIs) and TB screening, termination of pregnancy (ToP) services, post-rape care services, etc.) This will mitigate against stigmatisation when trying to obtain HTS and PrEP services.

## 4.2 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 adolescent girls and young women, men who have sex with men, transgender, sex workers, and serodiscordant 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 services, 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 exists 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

### 4.3 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 offering 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 public 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.

## 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, and 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 the 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.

## Monitoring and Evaluation

Systems should be in place to ensure that the PrEP and T&T policy is implemented effectively and efficiently. Opportunities need to be identified to incorporate PrEP and T&T 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 PrEP and T&T programmes. An M&E strategy, supported by partner institutions, will be developed to track and measure the implementation of the PrEP and T&T 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.

## 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.

# NDOH GUIDELINES

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

**8 February 2017**

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## Abbreviations and Acronyms

AGYW	Adolescent girls and young women
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
CHW	Community health worker
FTC	Emtricitabine
HBsAG	Hepatitis B surface antigen
HBV	Hepatitis B virus
HIV	Human immunodeficiency virus
HPTN	HIV Prevention Trials Network
HTS	HIV testing services
M&E	Monitoring and evaluation
MCC	Medicines Control Council
MDR-TB	Multidrug resistant - tuberculosis
MSM	Men who have sex with men
NDoH	National Department of Health
PEP	Post-exposure prophylaxis
PHC	Primary healthcare
PMTCT	Prevention of mother to child transmission
PrEP	Pre-exposure prophylaxis
SAHIVCS	South Africa HIV Clinicians Society
SAHMS-FSW	South Africa Health Monitoring Survey of Female Sex Workers
SRH	Sexual and reproductive health
STI	Sexually transmitted infection
SW	Sex worker
T&T	Test and treat
TAPS	Treatment and Prevention demonstration project
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
TDF/FTC	Tenofovir disoproxil fumarate/Emtricitabine
UNAIDS	The Joint United Nations Programme on HIV/AIDS
VMMC	Voluntary medical male circumcision
WHO	World Health Organization

## Definition of Key Terms

Term	Working definitions in these guidelines
Adolescent	Young person aged 15 to 19 years, inclusive
AGYW	Adolescent girls and young women aged 15 to 24 years
Adult	Person older than 19 years
ART	Antiretroviral therapy refers to the use of a combination of three ARV drugs to achieve viral suppression and is given for life
ARV	Antiretroviral drugs refer to the medicines active against HIV
Combination HIV prevention	A combination of behavioural, biomedical, and structural approaches to HIV prevention to achieve maximum impact on reducing HIV transmission and acquisition
Continuum of care	A comprehensive package of HIV prevention, diagnostics, treatment, care, and support services provided for people at risk of or living with HIV, and their families
Gender	"Gender" refers to the socially constructed roles, behaviours, activities, and attributes that a given society considers appropriate for men and women. Gender requires us to ensure that health policy, programmes, services, and delivery models are responsive to the needs of women, men, girls, and boys in all their diversity
Gender-based violence	Any act of physical, sexual, or psychological harm or suffering, including threats of such acts, coercion, or arbitrary deprivations of liberty in public or in private life
Healthcare provider	Anyone who renders healthcare; includes doctors, nurses, pharmacists, trained counsellors, and community health workers
Priority populations	Groups who are at increased risk and vulnerability to HIV due to specific high risk behaviours. Includes sex workers, MSM, incarcerated populations, people who use drugs or alcohol, transgender populations, and AGYW
PEP	The preventive ARV medical treatment started immediately after exposure to HIV in order to prevent infection
PrEP	The use of antiretroviral drugs by HIV-negative people before potential exposure to prevent the acquisition of HIV. Currently, PrEP refers to oral daily PrEP (tenofovir/emtricitabine or tenofovir alone) but may incorporate other formulations over time
Serodiscordant couples	Couples in an ongoing sexual relationship in which one partner is HIV-positive and the other is HIV-negative
Sex worker	Women, men, and transgendered people of all ages, who work with the primary intention of exchanging money for sex.
Substantial risk	Substantial risk of HIV infection is defined as a population group with an HIV incidence greater than 3 per 100 person-years in the absence of PrEP
Transgender population	Refers to people whose gender identity and expression are different to the social expectations of gender. They may see themselves as male, female, gender non-conformist, or one of many other gender-variant categories
Use of ARV drugs for HIV prevention	Refers to the HIV prevention benefits of using ARV drugs. This can include preventing mother-to-child transmission of HIV by treating the mother during pregnancy and breastfeeding, using ARV drugs to reduce the transmission of HIV among serodiscordant couples, using ARV drugs to prevent people from acquiring HIV when they are exposed to HIV (post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP)), and ART for HIV-positive individuals to reduce viral load.
Young women	Women aged 20 to 24 years, inclusive

# 1. Background and Rationale

## 1.1 WHO Recommendations

The World Health Organization (WHO) guidelines on the use of antiretroviral therapy (ART) have evolved since first published in 2002. 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 populations.<sup>1</sup> 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.

In September 2015, the WHO released an early release to their new guidelines on when to start ART for early treatment of HIV infection and on the use of ART for HIV prevention.<sup>2</sup> These guidelines were then updated in June 2016.<sup>3</sup>

These new guidelines recommend the following:

- 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.

## 1.2 South Africa Context

South Africa has the largest HIV epidemic in the world, with 6.8 million people aged 15 to 49 living with HIV, representing 19 percent of the global HIV burden.<sup>4</sup> The South Africa HIV programme was launched in 2009. As of 2015, there are just over 3.3 million people on antiretroviral treatment (ART), creating the largest ART programme in the world.<sup>5</sup>

Despite this accelerated progress in initiating and treating HIV-positive people, there are still more than 3 million additional people that need treatment in line with the 2015 WHO ART guidelines.<sup>6</sup>

The epidemic has varied significantly across and within different provinces in South Africa. Even though the epidemic is generalised, it is also over-represented in some populations, specifically sex workers (SW) and men who have sex with men (MSM). It is also concentrated in the populations with very high vulnerability to HIV, such as adolescent girls and young women (AGYW).

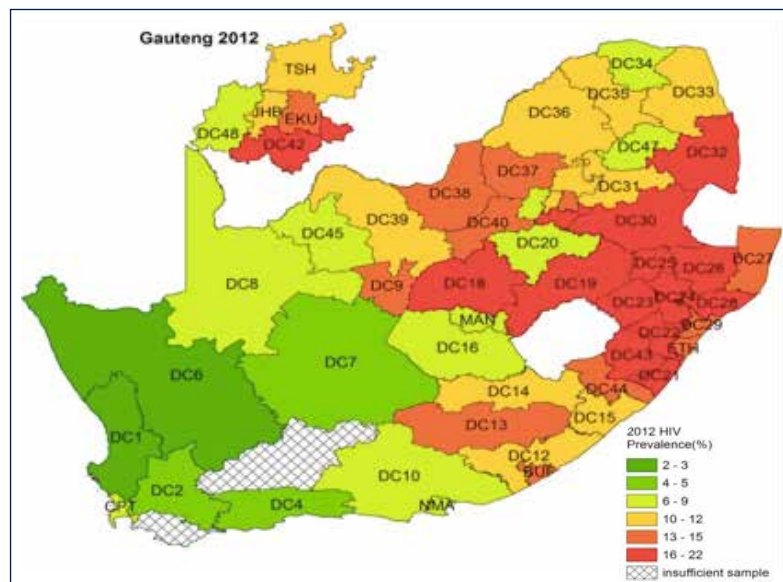


Figure 1. HIV Prevalence by District, South Africa 2012<sup>10</sup>

This contextual understanding of the HIV epidemic is critical to develop and implement effective HIV interventions. Differential vulnerability levels, social risk factors, high-risk sexual practices, and limited access to appropriate HIV interventions influence HIV incidence among these populations.<sup>7,8,9</sup>

In June 2016 the South African National Department of Health (NDoH) rolled out oral PrEP to select sex workers sites. At that time, the guidelines were specific for the sex worker rollout. These guidelines have now been updated to include additional target populations, including men who have sex with men, serodiscordant couples, and adolescent girls and young women. The inclusion of these additional target populations in the PrEP rollout will be at the direction of the NDoH, over time, targeting prioritized populations in phased approaches.

These guidelines focus on the provision of PrEP and universal test and treat (T&T) as part of a comprehensive combination prevention and expanded treatment policy, and should be read in conjunction with the National PrEP and T&T Policy, the South African National Sex Worker HIV Plan (2016 – 2019), the National Strategic Plan for HIV, TB and STIs (2012 – 2016), the National HIV Testing Services: Policy (2016), and the National Consolidated Guidelines for the Prevention of Mother-To-Child Transmission of HIV (PMTCT) and the Management of HIV in Children, Adolescents and Adults (2015).

### 1.2.1 Sex workers

In these guidelines, sex workers include: women, men, and transgendered populations, who sell sex regularly and occasionally, and those who may or may not self-identify as sex workers. Sex workers range in age and socio-economic status and are of diverse sexual orientation and gender identities.

The 2013 rapid population size estimate reported that there were around 153,000 sex workers in South Africa.<sup>11</sup> Sex workers have disproportionately higher risk for HIV acquisition because behavioural, legal, and social barriers increase their vulnerability.<sup>12</sup> An estimated 20 percent of the 350,000 people annually infected with HIV in South Africa are connected with sex work.<sup>13</sup>

Female sex workers carry an enormous burden of HIV: at least one-third have been infected with HIV by the age of 24; among those 25 and older, as many as 4 in 5 are HIV-positive.<sup>14</sup> HIV prevalence amongst female sex workers in South Africa is estimated to be 59.8 percent.<sup>15</sup> The SA Health Monitoring Survey of Female Sex Workers<sup>16</sup> estimates the prevalence of HIV among female sex workers at 71.8 percent in Johannesburg, 39.7 percent in Cape Town, and 53.5 percent in eThekweni. Fortunately, the vast majority have tested for HIV, and more than three-quarters of HIV-positive female sex workers are aware of their status.

The same report observed marked increases in HIV prevalence among female sex workers as they get older, comparing those 16 to 24 to those 25 and older (Johannesburg, 59.0 percent vs 78.8 percent; Durban 29.4 percent vs 71.2 percent). Young sex workers may be more vulnerable to HIV than their older counterparts because of less power to negotiate condom use, greater susceptibility to violence, and greater number of sexual partners due to exploitation and male age preferences.<sup>17</sup> These high rates confirm the urgency of focusing interventions on HIV-positive sex workers, as well as preventing acquisition in HIV-negative sex workers. By making PrEP and T&T available to sex workers, their HIV risk can be reduced.

The evidence for inclusion of PrEP for sex workers is strong and there are existing platforms for healthcare delivery specifically targeted to these high-risk, hard to reach populations. For these reasons, rollout of PrEP and T&T should be considered in this group first.<sup>18</sup> In this respect, sex workers in South Africa have been prioritized as a population at substantial risk due to lack of power to insist on condoms, high rates of gender based violence and rape, and lack of legal protection.

### 1.2.2 Men who have sex with men

Up to 1 percent of South Africa's adult population may be engaging in same sex practices. This implies there were approximately 1.4 million MSM between the ages of 15 and 49 years old in South Africa in 2014.<sup>19</sup> Young MSMs are even more vulnerable to HIV as they may engage in overlapping risk behaviours, such as injecting drugs and selling sex.<sup>20</sup> There are structural, social, and individual-level risk factors for HIV among MSM, which make the HIV epidemic among MSM fundamentally different from other groups at risk.<sup>21</sup> MSM HIV prevalence is between 1.89 to 4.65 times higher than non-MSM males of similar ages, where representative surveys have been conducted.<sup>22</sup> There is a need to scale up and improve sustained, comprehensive, and effective HIV prevention efforts targeting MSM. Offering PrEP to MSM, especially those that do not use condoms, showed the largest impact in the prevention of HIV infection.<sup>23</sup>

### 1.2.3 Serodiscordant couples

HIV-1 transmission occurs among HIV serodiscordant couples, where one of the partners is HIV-positive and the other is HIV-negative, with or without the knowledge of each other's status.<sup>24</sup> This results in repeated risk of HIV transmission over time. Knowledge of HIV status is still low among South Africans, with only 37.5 percent of males and 52.6 percent of females knowing their HIV status in 2012.<sup>25</sup> HIV discordant couples represent an important target population for HIV prevention. Couple-based HIV testing facilitates identification of HIV serodiscordant couples. Serodiscordant couples also often demonstrate minimal condom use and are therefore at considerable risk if the HIV-positive partner is not consistently virally suppressed. Provision of ART for the infected partner reduces sexual transmission by 96 percent and PrEP for the uninfected partner may reduce sexual transmission by as much as 75 percent.<sup>26</sup>

A study conducted in China showed that approximately 85 percent of serodiscordant couples were willing to use PrEP, whether to protect HIV-negative partners or for safer conception.<sup>27</sup> To effectively reduce HIV incidence among serodiscordant couples, it is recommended that the HIV-positive partner should be initiated on ART regardless of CD4 count while the HIV-negative partner uses PrEP.\*

\* PrEP use in the HIV-negative partner does not need to stop when the HIV-positive partner is virally suppressed. Personal choice and other potential risk factors should be considered by the clinician and client.

### 1.2.4 Adolescent girls and young women

UNAIDS and the WHO estimate there are about 380,000 new HIV infections among adolescent girls and young women (AGYW) aged 15 to 24 every year.<sup>28,29</sup> In 2013, almost 60 percent of all new HIV infections in this age group occurred among females.<sup>30</sup> In sub-Saharan Africa, women acquire HIV infection at least 5 to 7 years earlier than men.<sup>31</sup> Between 2005 and 2012, the global number of HIV-related deaths fell by 30 percent, but the corresponding number among adolescents increased by 50 percent.<sup>32</sup>

It is important to focus HIV prevention efforts on adolescents as they are at high risk of acquiring HIV and transmitting HIV to others.<sup>33</sup> Young girls with a mean age of 18 years are infected by men that are about 8 years older than themselves.<sup>34</sup> In their mid-20's, the same young women infect similar-age partners, who may then continue the cycle by engaging in sex with young uninfected girls.

Factors that make young women more vulnerable than men to acquiring HIV during sex include: biology; having sex with older men who are more likely to be infected;<sup>35</sup> multiple concurrent relationships;<sup>36</sup> low marriage rates;<sup>37</sup> transactional sex; low consistent condom use rates;<sup>38</sup> and limited skills in negotiating safer sex practice and sexual and gender-based violence (GBV). Despite this greater vulnerability, women have few options to reduce the acquisition of HIV.



### 1.3 Combination Prevention

Combination HIV prevention is an approach that seeks to achieve maximum impact on preventing new HIV infections by combining biomedical, socio-behavioural, and structural interventions that are human-rights-based and evidence-informed. The combination prevention package includes: condoms, lubricants, STI management, screening and management of intimate partner violence, sexual and reproductive health services, and HIV services, including counselling and testing, HIV management, ART, PEP, and PrEP.

#### BOX 1. WHAT IS A COMBINATION PREVENTION PROGRAMME?

Combination prevention programmes are: ...rights-based, evidence-informed, and community-owned programmes that use a mix of biomedical, behavioural, and structural interventions, prioritized to meet the current HIV prevention needs of particular individuals and communities, so as to have the greatest sustained impact on reducing new infections. Well-designed combination prevention programmes are carefully tailored to national and local needs and conditions; focus resources on the mix of programmatic and policy actions required to address both immediate risks and underlying vulnerability; and they are thoughtfully planned and managed to operate synergistically and consistently on multiple levels (e.g. individual, relationship, community, society) and over an adequate period of time. They mobilize community, private sector, government and global resources in a collective undertaking; require and benefit from enhanced partnership and coordination; and they incorporate mechanisms for learning, capacity building, and flexibility to permit continual improvement and adaptation to the changing environment.

*UNAIDS Prevention Reference Group*

### 1.4 Test and Treat All

Globally, around one-third of the 15 million individuals who are eligible for treatment are currently receiving ART.<sup>40</sup> For each person started on ART, at least two more individuals become newly infected with HIV. This causes a continuous increase in the number of HIV-positive people who will require ART in future. The WHO recommends that ART should be initiated among all adults and children with HIV regardless of WHO clinical stage and at any CD4 cell count, prioritising those with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and adults with CD4 count  $\leq 500$  cells/mm<sup>3</sup>. Earlier initiation of ART results in better long-term clinical outcomes for HIV-positive people and reduces an individual's viral load and, therefore, their infectiousness.

The HIV Prevention Trials Network (HPTN) 052 study showed that starting ART early reduced the overall risk of HIV sexual transmission to uninfected partners by 93 percent.<sup>41</sup> With approximately 6.8 million people infected with HIV in South Africa, and just over 3 million on ART, the unmet need is approximately 50 percent. T&T is proposed as a new, highly effective HIV prevention strategy. T&T interventions are built around two main components. First, HIV testing services are offered to all members of a defined high-risk population to identify those already infected with HIV but not yet linked to care, followed by regular and repeat HIV testing of those who test HIV-negative to identify new positives as early as possible after seroconversion. Second, the initiation of life-long ART immediately after HIV diagnosis, regardless of CD4 count.<sup>42,43,44</sup>

To test and treat all has the potential to cause a very steep reduction in HIV incidence, will reduce HIV-related morbidity and mortality, and could potentially eliminate HIV as a public health problem over a period of 15 to 20 years.<sup>45</sup> WHO recommends that all HIV infected individuals are started on ART regardless of their CD4 count.

As of September 2016, South Africa is implementing T&T for all. All HIV positive people will be offered immediate initiation on ART, regardless of CD4 count or clinical staging, in line with the National Consolidated Guidelines for the Prevention of Mother-To-Child

Transmission of HIV (PMTCT) and the Management of HIV in Children, Adolescents, and Adults (2015) and the National HIV Testing Services: Policy (2016).

## 1.5 Oral Pre-Exposure Prophylaxis

PrEP is defined by the WHO as the use of antiretroviral drugs by HIV-negative people before potential exposure to HIV to prevent HIV acquisition. Oral PrEP is an evidence-based HIV risk-reduction intervention to be offered to all people at substantial risk of acquiring HIV.<sup>46</sup> The WHO defines substantial risk as a population group with an HIV incidence greater than 3 per 100 person-years in the absence of PrEP.<sup>47</sup> Defining who should be offered PrEP requires a country to balance the risk of HIV exposure, the risk of adverse events, and available resources.

The WHO recommends that PrEP (containing tenofovir disoproxil fumarate (TDF)) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of a combination of prevention approaches that include: HTS, counselling, male and female condoms, lubricants, ART for HIV-positive partners in serodiscordant couples, and VMMC. Populations who would benefit most from PrEP are often underserved and likely to have low levels of HIV testing and high levels of undiagnosed HIV, and may need to be linked to other services.

PrEP has been shown to be safe with minimal side effects.<sup>48,49</sup> One of the main guiding principles for PrEP as an intervention is that it will enable and empower people to have an informed and additional choice of an HIV prevention method. The evidence and benefits of PrEP are summarized in Appendix 1.

## 1.6 Implementation of PrEP and T&T

To inform the implementation of PrEP and T&T, the evidence from several demonstration projects will be used. The demonstration projects will enable the country to scale up PrEP and T&T. The current platform of delivery for PrEP is through existing sex worker programmes and linkage to primary healthcare facilities, where appropriate, with the aim of integrating them into existing public health services. Additional delivery mechanisms and target populations will be incorporated in a phased approach with NDoH direction.

## 1.7 Oral PrEP Drugs: TDF and TDF/FTC

Tenofovir (TDF) and tenofovir/emtricitabine (TDF/FTC) in a single tablet fixed dose combination (FDC) are the oral antiretroviral agents used in oral PrEP studies to date. A systematic review and meta-analysis of PrEP trials containing TDF demonstrated that the level of protection from TDF versus TDF/FTC did not differ by age, gender, regimen, or mode of acquiring HIV (rectal, penile, or vaginal). In a May 2015 meta-analysis of all PrEP trials, daily oral TDF has comparable efficacy to TDF/FTC. However, the use of TDF monotherapy for HIV prevention has not been investigated in some key populations and on this basis, the Southern African HIV Clinicians Society (SAHIVCS) recommends the use of TDF/FTC in combination for oral PrEP.

Gilead's TDF/FTC combination pill, Truvada®, was approved for use as PrEP by the Medicine Control Council (MCC) in December 2015, in combination with safer sexual practices. Four additional TDF/FTC products have received approval for use as PrEP in South Africa as of July 2016: Aspen (Truvada and Tencitab), Cipla (Didivir), and Mylan (Tenemine).

TDF alone has not yet been approved for use as PrEP by the MCC and no applications have been made to the MCC for registration of TDF for PrEP use to date.

### 1.7.1 Daily PrEP vs non-daily PrEP

The WHO does not currently recommend intermittent use of PrEP. The ADAPT study (HPTN 067) conducted among women in Cape Town evaluated the feasibility of non-daily oral PrEP using Truvada.<sup>50</sup> The study showed better adherence and coverage of potential sexual exposure when PrEP is taken daily. Daily adherence is more forgiving in the case of missed doses and results in more sustained use during periods of HIV acquisition risk, as opposed to intermittent use.<sup>51</sup>

## 1.8 Adherence

Adherence is important in both PrEP use and HIV treatment and will form an integral part of the combination prevention and T&T programme. Adherence is a significant modifier of PrEP effectiveness. PrEP can be started and stopped as a person moves through “seasons of risk,” whereas ART is lifelong.

### Box 2. Effective Use

Effective use of PrEP requires daily usage. It should be taken for a specified period, initially for attainment of full protection, followed by daily use for the duration of possible exposure to HIV infection, followed by a continuous use for one month after the cessation of exposure. Good quality counselling fosters adherence and supports a comprehensive plan for sexual and reproductive health.

It is important to offer a combination prevention package of services for PrEP users to further decrease risk of HIV infection. These include: VMMC, consistent and correct use of condoms, use of lubricants, and risk assessment and reduction.

## 1.9 HIV drug resistance

The risk of HIV drug resistance to either TDF or FTC is low, occurring in approximately 1 in 1,000 PrEP users in clinical trials, and was mainly seen in those with acute undetected HIV infection at the time of initiating PrEP. Various trials have shown that the overall implementation of PrEP is expected to decrease the public health burden of HIV drug resistance.<sup>52,53,54</sup> Had the averted infections occurred in the absence of PrEP, more resistance would be expected to occur during the treatment of these infections than occurred due to PrEP use.

## 1.10 Pregnancy And Breastfeeding

Oral PrEP is contraindicated for use in pregnancy and breastfeeding by the South Africa MCC. Therefore, the stance of the NDOH is that PrEP shall not be offered to pregnant or breastfeeding women without further guidance from the MCC.

The WHO is doing additional research on the benefits and risks of PrEP in pregnancy and has recently released the following statement:

*Although additional surveillance is important, at the present time, given the available safety data, there does not appear to be a safety-related rationale for discontinuing PrEP during pregnancy and breastfeeding for HIV-uninfected women receiving PrEP who become pregnant and remain at continuing risk of HIV acquisition.<sup>55</sup>*

Pregnancy itself is associated with an increased risk of becoming infected with HIV.<sup>56</sup> The use of PrEP around the time of conception and during pregnancy offers a means of protection to the uninfected partner. HIV-negative women in serodiscordant relationships are at risk of acquiring HIV infection whilst trying to conceive through unprotected sex.

PrEP trials involving heterosexual women excluded pregnant women from enrolment; those who fell pregnant during the conduct of the study were discontinued from PrEP. One study of 46 uninfected women in serodiscordant relationships demonstrated no adverse effects on the pregnancy or cases of HIV transmission when TDF was used around the time of conception. There are several ongoing demonstration projects that will allow women to continue PrEP if they fall pregnant, which will provide additional data to inform future recommendations. In addition, the Antiretroviral Pregnancy Registry shows no evidence of adverse outcomes amongst infants exposed to these medications when used as ART in utero.

## 2. Guiding Principles

PrEP and T&T will contribute to the country's targets for HIV reduction by 2030, as reflected in the National Development Plan. South Africa supports the UNAIDS Fast Track approach, the 90-90-90 targets, and the prevention target of reducing the number of new HIV infections by 75 percent by 2020. To achieve these goals, there is a need for an expanded and accelerated scale up of HIV treatment and combination prevention, including PrEP.

These new guidelines will assist in providing the necessary guidance towards improved management of HIV prevention across different populations.

### Box 3. Objectives of the PrEP and Test & Treat Guidelines

- **Expanded prevention options:** Offer and promote PrEP in the context of combination prevention
- **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 ANC services
- **Quality of care:** Provide PrEP within the broader framework of quality health service provision
- **Communication and community-based strategies:** Implement appropriate, evidence-informed, communication and advocacy strategies to increase healthcare provider and public awareness of PrEP and T&T within the context of HIV prevention without stigmatising the intervention and potential users, nor increasing risky sexual behaviour
- **Monitoring and evaluation:** M&E systems are in place to monitor and evaluate provision, quality of care, outcomes, and impact

*From the National PrEP and T&T Policy*

### 2.1 Enabling and Empowering Individuals to Have an Informed Choice of HIV Prevention

These guidelines are underpinned by a rights-based approach, whereby individuals are provided with information that will enable them to make decisions on options for HIV prevention. A rights-based approach also includes confidentiality and equal access to non-discriminatory healthcare, privacy, prevention choice, informed decision-making, and shared responsibility.

## 2.2 Increased Effectiveness and Efficiency for the HIV Programme

Two important objectives of the HIV programme are to avert new HIV infections and improve access to ART. Both PrEP and T&T will contribute to increased effectiveness of the HIV programme. Averted HIV infections translates to a reduced burden on the national health system and each newly identified HIV-positive person treated reduces the burden on the clients and their families and communities.

## 2.3 Integration of PrEP and Test & Treat across Various Entry Points

PrEP and T&T will be integrated into 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, termination of pregnancy services, post-rape care services, etc.). This will mitigate stigmatisation when trying to obtain HTS and PrEP services.

# 3. PrEP Clinical Guidelines

The implementation of PrEP will increase the use of HTS, which will assist in getting people to know their HIV status. Those that test HIV-positive during screening should immediately be referred for HIV treatment and care. It is therefore important to establish a seamless transition between PrEP and HIV treatment programmes.

PrEP should not displace or undermine the use of other effective and well-established HIV combination prevention interventions. PrEP should be promoted as an additional prevention choice among sex workers in conjunction with other appropriate prevention methods.

For those that test HIV positive during HTS, please refer to the National Consolidated Guidelines for the Prevention of Mother-To-Child Transmission of HIV (PMTCT) and the Management of HIV in Children, Adolescents, and Adults (2015) and the National HIV Testing Services: Policy (2016) for the appropriate treatment options.

## 3.1 Enrolment for PrEP

Following HIV testing, if client is HIV-positive, immediately refer for ART initiation. If client is HIV-negative, PrEP should be offered after screening as part of a combination prevention package (refer to algorithm on page 16).

Some individuals requesting PrEP are likely to be at ongoing or substantial risk for HIV and might always fall into a window period when trying to confirm HIV status (e.g. a sex worker with recurrent daily exposures). These individuals should not be excluded from accessing PrEP, as they potentially have the most to gain from the intervention.

Risk assessment questions can be used as part of combination prevention to explore risk and risk reduction and prevention strategies.

#### Box 4. Risk Reduction Counselling

Explore the following topics, as appropriate:

- Avoiding unprotected sex
- Consistent and correct use of condoms
- Knowing your HIV status and your partner's HIV status
- Are you or your partner on ART?
- Use of recreational or injection drugs for you or your client or partner
- Sex under the influence of alcohol and/or drugs
- Experience of intimate partner violence/sexual violence
- Use of ARVs to prevent HIV following unprotected sex (PEP)

### 3.2 Contraindications for PrEP

The following are contraindications for PrEP use:

- Pre-existing HIV infection
- Creatinine clearance of less than 60mL/min
- Adolescents <35kg or <15 years of age who are not Tanner stage 3 (sexual maturity rating) or greater
- Unwilling/unable to adhere to daily PrEP
- Pregnancy (as per Truvada package insert) \*refer to section 1.10

Other important considerations include:

- TDF/FTC is active against Hepatitis B infection. Discontinuation of TDF/FTC requires close monitoring in those infected with Hepatitis B due to the concern for rebound viraemia.
- Persons with osteopenia/osteomalacia/osteoporosis may be at risk of bone loss associated with TDF.
- Women who want to conceive and are eligible for PrEP must be monitored.
- TDF should not be co-administered with other nephrotoxic drugs, e.g. aminoglycosides.
- Standard TB medication does not interact with PrEP drugs and there is no need for dose adjustments.
- Clients on MDR-TB medications may have increased risk of renal side effects. PrEP should therefore be avoided. Other prevention methods should be recommended and PrEP screening should be delayed until the end of MDR-TB treatment.
- Standard hormonal contraception does not affect PrEP effectiveness, nor does PrEP affect contraceptive effectiveness.<sup>57</sup>
- There are currently no published studies on the use of PrEP for individuals under 18.
- Offer immediate treatment if the PrEP user seroconverts.

### 3.3 Eligibility for PrEP Use

Providers should educate and counsel potential PrEP users about PrEP, which should always be provided as part of a combination prevention package.

#### Box 5. Eligibility Criteria for PrEP Use

- No contraindications to TDF or FTC
- HIV-negative
- No suspicion of acute HIV infection (refer to Table 1, below)
- Willing and able to adhere to PrEP

**Table 1. Acute Viral Symptoms of HIV Seroconversion<sup>58,59</sup>**

Symptom	Sign
Malaise, anorexia, myalgia, headache, sore throat, sore glands, rash	Fever, sweating, viral meningitis, generalised lymphadenopathy, hepatosplenomegaly, pharyngitis, truncal rash, orogenital herpetic ulceration, oral/oesophageal candidiasis, cervical adenopathy

If the client has symptoms or signs of acute HIV infection, PrEP should be postponed until symptoms subside and a repeat rapid HIV test after 4 weeks remains negative.

### 3.4 Baseline Investigations

**Table 2. Clinical Screening Investigations**

Investigation	Purpose
HIV test (using algorithm in the HTS guidelines)	Assessment of HIV status
Creatinine clearance	To identify pre-existing renal disease
Hepatitis B surface antigen (HBsAg)*	To identify undiagnosed hepatitis B infection To identify those eligible for vaccination against hepatitis B
ALT if HBsAg positive	To determine if vaccination against HBV infection or treatment of HBV is required
Urine pregnancy test	To identify if client is pregnant
Syphilis rapid plasma reagin (RPR)	To diagnose syphilis infection for treatment
Syndromic STI screening	To diagnose and treat STI
<ul style="list-style-type: none"> <li>• Clients with acute or chronic hepatitis B infection can be safely initiated onto PrEP but require liver function monitoring.<sup>60</sup></li> <li>• Bone density measurements are not needed</li> </ul>	

Clients with abnormal renal function (estimated creatinine clearance <60 mL/min) should be informed to stop taking PrEP and the test must be repeated after two weeks. If renal function returns to normal and other PrEP criteria are met, PrEP may be re-started.

## 3.5 Prescription of PrEP drugs

The recommended regimen, which can be used in all populations is:

- TDF/FTC 1 tablet by mouth (PO) daily – Brand: Truvada (Gilead), Tenemine (Mylan), Didivir (Cypla), Emtevir (Adcock), Tencitab (Aspen)

Prescription intervals:

- At initiation – provide 1-month supply
- At 1 month – repeat HIV test and provide 3-month prescription (for collection every month)
- Every 3 months – repeat HIV test and provide 3-month prescription (for collection every month)

Other HIV prevention methods should be discussed and provided at all visits. Users should be advised that a negative HIV test is required before PrEP drugs can be prescribed at initiation and with every prescription refill, as well as when restarting after a discontinuation. It should be made clear that PrEP is not treatment for HIV, despite using the same medicines, and therefore it should not be shared with people who have not tested HIV negative.

### Box 6. Reaching Full Protection

Clients initiating PrEP need 20 days of daily dosing to reach adequate tissue levels of PrEP drugs. During this period, other protective precautions should be used, such as abstinence or condoms.

## 3.6 Side Effects

The major toxicities associated with TDF/FTC are rare in PrEP exposure to date. Minor side effects are relatively common but are mild and self-limiting if they do occur (approximately 1 in 10 individuals in the first 1 to 2 months), and do not require discontinuation of PrEP.

### Box 7. Potential Side Effects

**Major side effects:** renal toxicity and metabolic complications (decreased bone mineral density, which is reversible in adults upon stopping PrEP), extremely small risk of lactic acidosis and hepatic steatosis or steatohepatitis

**Minor side effects:** gastrointestinal symptoms (diarrhoea, nausea, vomiting and flatulence), which are self-limiting and typically end within first month of use; unintentional weight loss

**Less predictable side effects:** hypersensitivity reactions and flares of hepatitis B in those who are chronic carriers if they stop TDF/FTC

## 3.7 PrEP Clients Who Test HIV-Positive

### 3.7.1 HIV-positive prior to initiation of PrEP

Clients who test HIV-positive must be offered ART as soon as possible, regardless of CD4 count. They must be linked to HIV care, treatment, and support. Where possible, their partners should be encouraged to test for HIV.



### 3.7.2 HIV-positive after initiation of PrEP

HIV seroconversion after initiating PrEP can occur, and may be due to non-adherence or being in the window period at the time of testing. As soon as an HIV-positive test has been confirmed, ART should be immediately initiated using first-line regimens, and the client must be linked to HIV care and treatment. Resistance testing, or use of second-line regimens, is not recommended, as only about 3 percent of seroconverters who have received PrEP may have resistance to FTC or TDF.

## 3.8 PrEP Follow-Up and Monitoring

**Table 3. PrEP Follow-Up and Monitoring**

Activity	Following PrEP Initiation
Confirmation of HIV-negative status	At 1 month, then every 3 months
Address side effects	Every visit
Adherence counselling	Every visit
Creatinine clearance test	At 1 month, then every 3 months for the first year, then annually*
STI screening and treatment	Every visit
PrEP medication issuance	1 month supply, then 3 monthly prescription for monthly supply
Behavioural sexual risk reduction counselling	Every visit

\* The TAPS program will implement creatinine testing every 6 months. This additional data may provide evidence, which will allow for guideline updates in the future.

## 3.9 Risk Reduction Counselling

Risk-reduction counselling is a behavioural intervention that attempts to decrease an individual's chances of acquiring HIV and other STIs, and should be implemented together with HIV prevention counselling and sexual reproductive health and contraceptive counselling at all follow-up visits for PrEP users.<sup>61</sup>

The main objective of risk-reduction counselling is for clients to assess individual risk and set realistic goals for behaviour change that could reduce their risk of contracting HIV and other STIs, as well as reduce unwanted pregnancies. This is most effective when it is non-prejudicial and user-centred. Risk reduction counselling can be provided by any trained healthcare provider and should address the following points:

- Explore the context of the client's specific sexual practices and psychosocial status, and assist client to recognise which of their behaviours are associated with higher risks for HIV infection. Healthcare providers should also be aware that clients might not always perceive their own risk, or be in denial about it.
- Identify the sexual health protection needs of the potential PrEP user and reflect on what their main concerns appear to be.
- Strategize with the client on how they can manage these concerns or needs.
- Agree on which strategies the client is willing to explore and guide them to decide on how to implement the strategy.

### 3.10 Discontinuation of PrEP

PrEP should be stopped if the client:

- Tests HIV-positive
- Develops renal disease
- Is non-adherent to PrEP
- Does not need or want PrEP
- No longer meets eligibility criteria
- If there are safety concerns where the risks of PrEP use outweigh potential benefits

The duration of PrEP use may vary and individuals are likely to start and stop PrEP depending on their risk assessment at different periods in their lives. Because PrEP is user-driven, users should be given information on the correct way to stop PrEP to ensure effectiveness. Users who want to stop PrEP should do so after consultation with the healthcare provider. PrEP medication should be continued for 28 days after the last potential HIV exposure to ensure coverage and protection.

### 3.11 Reducing the Risk of Antiretroviral Resistance

To minimise the risks of developing ARV resistance, HIV testing must be done every three months with a symptom screen and a targeted examination to exclude acute HIV infection. HIV testing should also be repeated whenever symptoms of a viral illness are present.

#### Box 8. Resistance Risk Reduction

- Feasibly exclude acute HIV infection before initiating PrEP by:
  - HIV testing before commencing or re-prescribing PrEP
  - Conducting a clinical screen to detect signs and symptoms of acute HIV infection
  - Delaying PrEP and investigating if there are suspicions of acute HIV infection
- Assess adherence with every visit - enquire about pill taking patterns and missed doses
- Support the client to maximise adherence
- Provide adequate supply of drugs and give consideration to the individual needs
- Revisit eligibility criteria every time the client re-starts PrEP; this must be done by the healthcare provider, not by the client
- Discontinue when client's risk profile has changed and client is no longer at substantial risk

### 3.12 Hepatitis B Management

TDF and FTC both have hepatitis B antiviral activity. The potential risk exists that exposure to these antivirals may treat unidentified chronic hepatitis B infection with a consequent viral flare (rebound) upon drug withdrawal that can result in a liver injury.<sup>62</sup> To avoid this risk, screening for hepatitis B surface antigen and antibodies occurs prior to PrEP commencement.

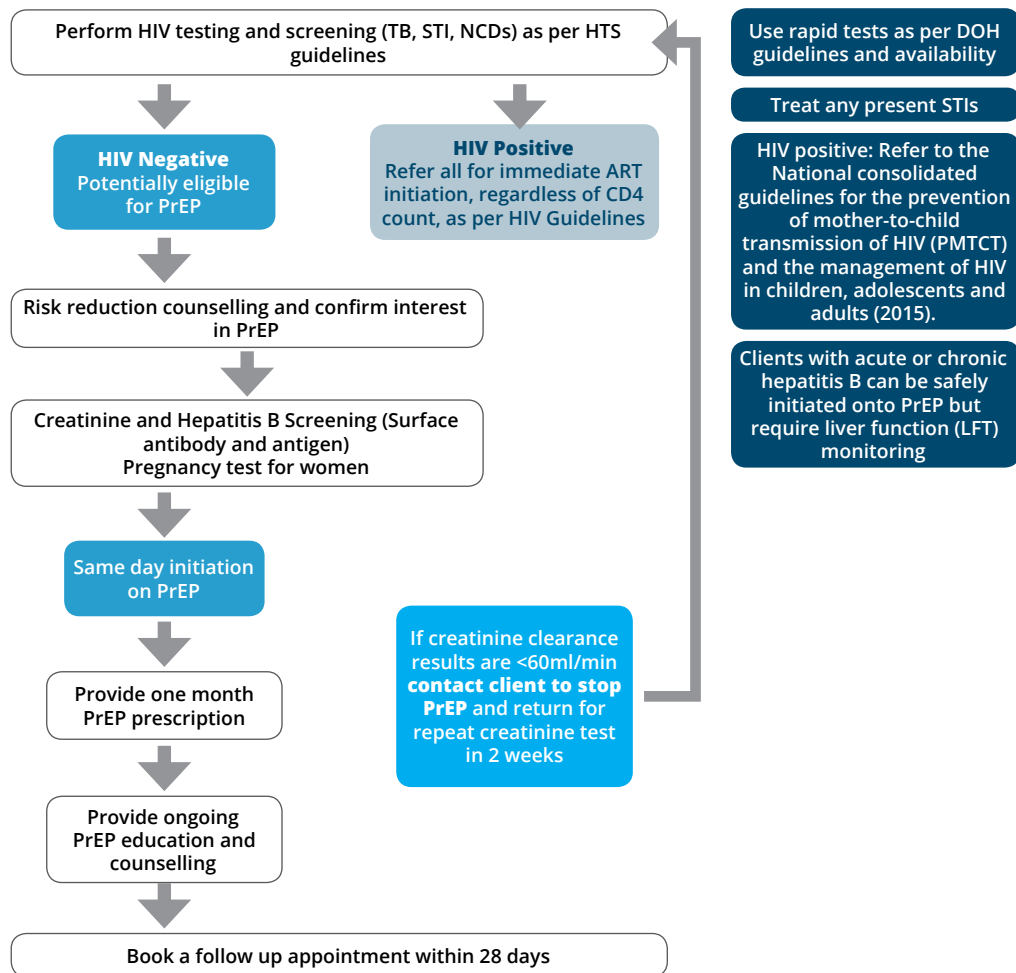
If hepatitis B surface antigen (HBsAg) is positive, the user should be investigated prior to commencement of short-term PrEP. PrEP is not contraindicated in those with HBV but liver function monitoring should be performed. PrEP users with persistently elevated or abnormal liver function tests should be referred for assessment. Liver function tests should be checked after stopping PrEP in those with chronic hepatitis B infection. People with chronic hepatitis B infection may choose to continue using tenofovir to control their hepatitis, even if they do not require these drugs any longer for the indication of PrEP.

Users with a history of injecting drug use should be screened for hepatitis C and, if positive, referred for further care.

Table 4. Hepatitis B Immune Status and Prep Eligibility

Hepatitis B surface antigen (HBsAg)	Hepatitis B surface antibody (HBsAb)	Action
Negative (-)	Negative (-)	Start PrEP, vaccinate concurrently if available
Negative (-)	Positive (+)	Start PrEP, no vaccine needed
Positive (+)	N/A	Refer for evaluation

Figure 2. PrEP and T&T Screening and Initiation Algorithm



## 4. Service Delivery Guidance

### 4.1 Capacity Building of Healthcare Providers

The National Department of Health Operational Guidelines for HIV, STI, and TB Programmes for Key Populations in South Africa acknowledges the need for healthcare provider sensitisation training in order to better support public healthcare services and adolescent friendly services for priority populations.<sup>63</sup>

In the context of PrEP and T&T sex worker programmes, healthcare provider sensitisation training may promote stronger uptake and retention in care by creating a non-stigmatising and supportive space for delivery of PrEP and T&T in the sex worker population. All healthcare providers involved in the provision of PrEP and ART services should be involved in such training, including doctors, clinical nurse practitioners, staff nurses, counsellors, pharmacists, pharmacy assistants, outreach workers, other healthcare providers, and peer supporters.

In addition to sensitivity and competency training for sex workers, all healthcare providers affiliated with PrEP and ART service delivery should complete a PrEP and T&T implementation training programme, including clinical management, adherence, combination prevention, and risk reduction counselling.

### 4.2 Follow-Up and Retention in PrEP

After clients have initiated PrEP, the core focus of the service provider should be to support retention and maintain adherence among those using PrEP. For populations at substantial risk, there are important considerations that can affect their ability to be retained. Strategies for supporting follow-up and retention are discussed in Box 6 below.

#### 4.2.1 Provide ongoing counselling and education

At each follow-up visit, providers should assess if the use of PrEP has changed for their client and the effect this may have on the effectiveness of PrEP. Providers should support the client to identify strategies for improving adherence, which take into consideration the client's individual barriers and facilitators. Adherence counselling should be client-centred. Barriers and facilitators to adherence should be identified by the client and not prescribed by the provider. Ongoing education and counselling should then be provided to the client at each PrEP-related visit.

#### **Box 9. Strategies for Supporting PrEP Adherence**

- Use alternative methods of communication: SMS, social networking, mobile applications, etc.
- Integrate mobile services and outreach into existing services
- Enhance peer support strategies, such as the use of clubs
- Provide alternative clinic hours, if possible
- Collect additional contact information for each client
- Provide clients with referral partners in the event that they migrate, or provide with additional stock/prescription

#### 4.2.2 Promote client retention and follow-up

Individuals may face challenges in attending regular follow-up visits required for PrEP services. Strategies should be used to address the specific challenges faced by individuals to support retention in PrEP services and adherence. For example, sex worker populations may be highly mobile, may not consistently visit the same clinic or service provider over an extended period of time, and may find it difficult to attend clinic services during regular office hours.

#### **Box 10. Strategies for Supporting Retention and Communication**

- Schedule medication taking time to correspond with the user's daily routine activities
- Use reminders, e.g. cell phone, alarms, beepers, calendars
- Use pillboxes
- Review disclosure issues to identify those who can support the user's intentions to adhere or barriers to adherence due to lack of disclosure/privacy at home
- Join an on-line support group, e.g. Facebook: PrEP Rethinking HIV Prevention or #wethebrave

#### 4.3 Monitoring and Evaluation of Clinical PrEP Provision

Initial PrEP programmes should be accompanied by significant monitoring and evaluation (M&E) plans to measure programme rollout and the success of various implementation approaches, and also to capture lessons learned on the many unanswered questions regarding the best methods for screening and initiating clients and client monitoring (refer to the PrEP and T&T Implementation Plan).

### 5. About the Development of the PrEP and Test & Treat Guidelines

On 23 October 2015, a meeting was held at the National Department of Health to discuss the programmatic implications for adopting and implementing the new WHO guidelines for Test and Treat (T&T) and HIV Pre-Exposure Prophylaxis (PrEP). During that meeting it was decided that a core group of experts would convene to review evidence, programmatic implications, and develop national guidelines for PrEP.

The core group met on 23-24 November 2015 to prepare the draft PrEP guidelines. The Southern Africa HIV Clinicians Society's PrEP guidelines were used as the basis of the clinical section. The draft guidelines were shared with the expert community on 15 December 2015. Comments were incorporated and a revised version was shared with Dr. Yogan Pillay. Upon receipt of comments from Dr. Pillay, and recognising a number of outstanding issues still needed to be addressed, a third meeting with a larger group of experts and representatives from the South Africa HIV programme community was held on 13 January 2016 at the National Department of Health.

Based on the outcome of the January meeting, a revised version of guidelines, as well as a draft policy, was shared with the larger group for comment in early February. Feedback was incorporated and the revised guidelines and policy were discussed with the larger technical working group members in a meeting on 25 February 2016.

In coordination with the launching of the South African National Sex Worker HIV Plan on 11 March 2016, a revised version of the PrEP and Test & Treat guidelines were developed, which focused on the provision of PrEP and T&T services, in the context of combination prevention and expanded treatment, for the sex worker population. The new, focused guidelines were shared with the expert group and discussed at an NDoH meeting, chaired by Dr. Pillay, on 10 March 2016.

In preparation for the inclusion of other target populations in the national PrEP rollout, the guidelines were updated in December 2016, with additional minor updates to this current version in February 2017.

## 6. Appendixes

Appendix 1. Evidence and Benefits of PrEP

Appendix 2. Costing and Implementation

Appendix 3. Organisations and Stakeholders Involved in the Drafting of the PrEP Guidelines

Appendix 4. Ongoing and Planned PrEP Trials and Demonstration Projects

## 7. References

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# FACILITY AUDIT TOOL

# PrEP FACILITY AUDIT TOOL

The facility audit tool is an online tool created to measure a facility's readiness to implement oral PrEP according to South African standards. It broadly covers key components of PrEP provision such as clinical services currently offered, staffing and human resources, availability and turnaround time for labs, drug storage capabilities, volume and regularity of clientele, data management, funding, and facility operations.

Please complete the following survey based on the latest information available for your facility.

**\* Required**

## General Information

1. Please provide the name of your facility. \*

---

2. Please provide contact information for key individuals at this facility. \*

---

## Services

3. Please confirm what services are currently offered at your facility. \*

Check all that apply.

- HTS (HCT)
- On site ART/STI
- Counselling
- Treatment adherence/support
- Opportunistic infection management
- TB testing and treatment
- Condoms
- PEP
- Emergency services - gender-based violence
- Emergency services - rape

Other: \_\_\_\_\_

4. Please please describe any other services offered at your facility. \*

---

## Human Resources

### **Clinical Team**

5. What is the total team size? \*

---

### **Clinical Team Medical Practitioners**

6. What is the total number of onsite fulltime medical practitioners? \*

---

7. What is the total number of onsite parttime medical practitioners? \*

---

8. What is the total number of medical practitioners who provide telephonic support only? \*

---

9. What is the total number of medical practitioners who only provide mentorship to NIMART trained nurses? \*

---

### **Clinical Team Nurses**

10. What is the total number of NIMART trained nurses? \*

---

11. What is the total number of professional nurses? \*

---

12. What is the total number of professional nurses with a dispensing license? \*

---

13. What is the total number of enrolled/staff nurses? \*

---

14. What is the total number of nursing auxiliaries/assistant nurses? \*

---

### **Outreach Team**

15. What is the total number of peer educators? \*

---

16. What is the total number of lay counselors? \*

---

17. What is the total number of community health workers? \*

---

18. What is the total number of peer educator supervisors/facilitators? \*

---

19. What other outreach staff, if any, does your site have? \*

---

### **Administrative Staff**

20. What is the total number of site managers/supervisors? \*

---

21. What is the total number of receptionists? \*

---

22. What is the total number of clerks? \*

---

23. What is the total number of data/M&E managers? \*

---

24. What is the total number of data capturers? \*

---

**Pharmacy Staff**

25. What is the total number of onsite fulltime pharmacists? \*

---

26. What is the total number of onsite parttime pharmacists? \*

---

27. What is the total number of pharmacists who provide only periodic support/supervision? \*

---

28. What is the total number of postbasic pharmacy assistants? \*

---

29. What is the total number of basic pharmacy assistants? \*

---

**Other Staff**

30. Please describe other staff, including total numbers, at your facility. \*

---

## Patient Information

### Patient Information General

31. What is the total number uniquely identified clients that have been served at your facility since inception of service? \*

---

32. On average, what number of your clients served are daily repeats? \*

---

33. On average, what number of your clients served are weekly repeats? \*

---

34. On average, what number of your clients served are monthly repeats? \*

---

35. On average, what number of your clients served are three monthly repeats? \*

---

36. On average, what number of your clients served are annual repeats? \*

---

37. On average, what number of your clients served are oneoffs? \*

---

38. How many new clients do you see in a month? \*

---

39. How many new HTS do you provide in a month? \*

---

40. How many repeat HTS do you provide in a year? \*

---

41. How many of your regular clients receive HTS every three months? \*

---



### Patient Information Targets

42. Do you have HTS targets? \*

*Mark only one oval.*

Yes

No

43. If you have HTS targets, what are they for 2016? If you do not have targets, please enter 0. \*

---

44. If you have HTS targets, what are they for 2017? If you do not have targets, please enter 0. \*

---

45. Do you have PrEP targets? \*

*Mark only one oval.*

Yes

No

46. If you have PrEP targets, what are they for 2016? If you do not have targets, please enter 0. \*

---

47. If you have PrEP targets, what are they for 2017? If you do not have targets, please enter 0. \*

---

48. Do you have ART targets? \*

*Mark only one oval.*

Yes

No

49. If you have ART targets, what are they for 2016? If you do not have targets, please enter 0. \*

---

50. If you have ART targets, what are they for 2017? If you do not have targets, please enter 0. \*

---

### Patient Information Documentation and Reordering Systems

51. Do you have a paperbased or electronic recording system for maintaining individual client records? \*

*Check all that apply.*

Paperbased

Electronic

Other: \_\_\_\_\_

52. Please describe your system in detail. \*

\_\_\_\_\_

53. Please describe how you manage client confidentiality. \*

\_\_\_\_\_

54. Do you have a unique identification system for each client seen? \*

*Mark only one oval.*

Yes

No

Other: \_\_\_\_\_

55. If you have a unique identification system for each client seen, please describe. \*

\_\_\_\_\_

56. Is your documentation compliant with legal requirements? \*

*Mark only one oval.*

Yes

No

Other: \_\_\_\_\_

57. Do clients have to formally consent for any service and/or procedure? \*

*Mark only one oval.*

- Yes
- No
- Other: \_\_\_\_\_

58. If clients have to formally consent for any service and/or procedure, please describe the process followed and how this is documented. \*

\_\_\_\_\_

### **Patient Information Referral Systems**

59. Do you need to refer patients for ART or PrEP? \*

*Mark only one oval.*

- Yes
- No
- Other: \_\_\_\_\_

60. If so, where do you need to refer patients for ART or PrEP? \*

\_\_\_\_\_

61. How do you confirm a referral has been successful? \*

\_\_\_\_\_

62. Do you have agreements in place with provincial or municipal DoH? \*

\_\_\_\_\_

## Adherence

### Adherence

63. Do you have treatment adherence support services in place? \*

*Mark only one oval.*

Yes

No

Other: \_\_\_\_\_

64. What adherence services do you have in place? \*

*Check all that apply.*

Counselling support

Peer support groups

SMS notifications

Other:

Drugs

Drugs

65. Is your site accredited to keep, store, and issue medicines on site? \*

*Mark only one oval.*

Yes

No

Other: \_\_\_\_\_

66. Are your drugs kept in a centralised store room at the facility? \*

*Mark only one oval.*

Yes

No

Other: \_\_\_\_\_

67. Are your drugs kept in a locked steel cabinet in the dispensing nurse's consulting room? \*

*Mark only one oval.*

- Yes  
 No  
 Other: \_\_\_\_\_

68. Do you have a stock control system? \*

*Mark only one oval.*

- Yes  
 No  
 Other: \_\_\_\_\_

69. Do you have temperature control in your drug storage space? \*

*Mark only one oval.*

- Yes  
 No  
 Other: \_\_\_\_\_

70. Do you keep emergency drugs on site? \*

*Mark only one oval.*

- Yes  
 No  
 Other: \_\_\_\_\_

71. Do you have a person responsible for managing the drug stock? \*

*Mark only one oval.*

- Yes  
 No  
 Other: \_\_\_\_\_

72. Provide a list of drugs that are kept at your facility. \*

---

73. Who supplies you with medical supplies (syringes, needles, cotton swabs, sterile equipment, etc.)? \*

---

74. If you keep ARVs on site, who supplies you with these? \*

*Check all that apply.*

NDoH

Donation

Order directly from supplier

Other: \_\_\_\_\_

75. If you provide PrEP on site, who supplies you with these? \*

*Check all that apply.*

NDoH

Donation

Order directly from supplier

Other: \_\_\_\_\_

## Laboratory Services

### **Laboratory Services**

76. Please describe where and how laboratory services are covered at you facility.

---

77. List tests currently performed at your facility.

---

## Data Management

### Data Management

78. Describe your system and flow of data to NDoH, donors, and others. \*

79. Do you have direct access to TIER.Net and/or DHIS? \*

*Mark only one oval.*

TIER.Net access

DHIS access

Both

Neither

Other: \_\_\_\_\_

## Funding

### Funding

80. Who funds your facility? \*

---

81. What is the duration of your funding? \*

*Mark only one oval.*

< 6 months

6 months to 1 year

1 to 2 years

2 to 3 years

> 3 years

82. What does the funding support? \*

*Check all that apply.*

Logistics

Staffing

Services

Commodities (including drugs)

Other: \_\_\_\_\_

83. Describe any funding gaps currently experienced. \*

---



84. Do you have any plans to secure future funding? \*

*Mark only one oval.*

- No plans as funding is secured for > 1-2 years
- No plans for future funding, as facility not in a prioritised district
- Funding proposals submitted and awaiting response (please provide detail in next question)
- Funding proposal approved awaiting grant (please provide detail in next question)
- Other: \_\_\_\_\_

85. Please provide detail on future funding (e.g. if funding proposal is approved, who is funding and when is funding expected?) \*

---

## Service Delivery

### Service Delivery

86. Describe the model of service delivery at your facility. \*

---

87. Describe the clinical support system in place for NIMART nurses. \*

---

88. How often is outreach conducted to service sites (e.g. clubs)? \*

*Mark only one oval.*

- Daily
- Weekly
- Monthly
- Quarterly
- Other: \_\_\_\_\_

89. How often are mobile services available? \*

*Mark only one oval.*

- Daily
- Weekly
- Monthly
- Quarterly
- Other: \_\_\_\_\_

90. How often are fixed services available? \*

*Mark only one oval.*

- Daily
- Weekly
- Monthly
- Quarterly
- Other: \_\_\_\_\_

91. Please describe any other items relevant to your service delivery. \*

---

## Information, Education, and Communication (IEC) Materials

### **Information, Education, and Communication (IEC) Materials**

92. Does your facility have any IEC materials developed? \*

*Mark only one oval.*

- Yes
- No
- Other: \_\_\_\_\_

93. If you have IEC materials developed, what is the target population? \*

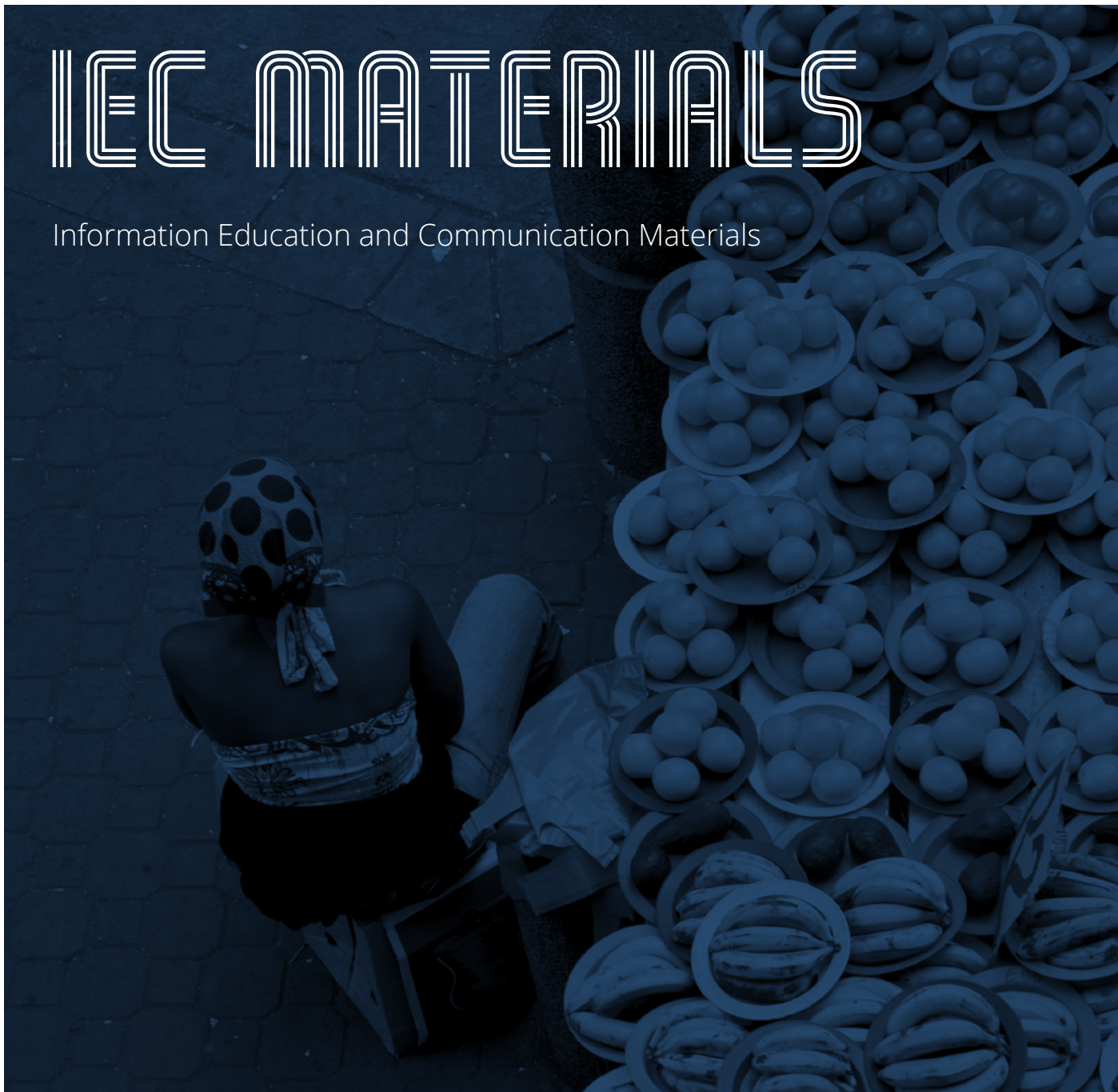
---

94. If you have IEC materials developed, please describe them and share with Hasina and Sarah.

---

# IEC MATERIALS

Information Education and Communication Materials



# IEC MATERIALS

The included memory stick includes the following IEC materials in a print-ready format:

- **PrEP A2 posters**

The poster focuses on announcing PrEP as an additional HIV prevention method to be used as part of a combination prevention strategy. The poster serves as a communication tool to create awareness and stimulate interest for HIV prevention. These posters are placed in fixed clinics, mobile clinics, at outreach posts, and outside certain sex worker hot spots.

- **PrEP fact sheet (A5)**

The fact sheet is a small communication tool that contains all the factual information regarding oral PrEP. It is a printed tool used by healthcare workers, peer educators, and PrEP users to help them understand the basic facts of PrEP and communicate this information in a factually accurate manner to clients. The fact sheet can also be distributed among clients and communities to spread information on oral PrEP.

- **PrEP frequently asked questions (A4 z-fold)**

The FAQ brochure is a particularly informative communication tool to educate PrEP users and peer educators on oral PrEP. All the most pressing questions in relation to oral PrEP are stated and answered within the South African context. This brochure is also a handy tool for healthcare workers communicating with PrEP users. Marketing material and simplified factual content is often used in communicating (by healthcare professionals) for adherence.

- **PrEP pocket book (pocket size)**

The PrEP pocket book is specifically developed for those interested in initiating on oral PrEP. This mini book, which can fit in a pocket, contains all relevant information as to what an individual can expect once they've initiated on oral PrEP, from side effects and time to protection, to clinic visits and follow-up tests.





# MONITORING & EVALUATION

M&E guidelines/job aid [FULL]

# PrEP M&E OVERVIEW

These guidelines/job aid are intended to support clinics providing oral TDF/FTC pre-exposure prophylaxis (PrEP) to key populations in the monitoring and reporting processes. The guidelines supplement the M&E tools used to track clients and monitor adherence, cycling, and outcomes while using PrEP. Specific guidance for filling out each tool is provided in detail on the sheets that follow.

**PrEP Clinical Treatment Form** → This form is printed for each individual client and kept in their patient files at the clinic. It is not shared with or reported to NDoH.

**PrEP Register** → This is an electronic document where all client information should be recorded to inform the reporting forms. As it contains confidential client information, it need not be shared with NDoH.

**PrEP Outcome Reporting Form** → This is an electronic document that summarizes all information from the PrEP register summary months. Clinics do not need to fill out any data on this form, as all data populates automatically if the PrEP Register is populated correctly.

**PrEP/T&T Data Summary** → This is an electronic document that captures information on testing and services offered in the cascade of care, PrEP provision, and T&T provision. The majority of the PrEP section will be automatically populated based on the register, but the remaining two sections must be completed by the clinic.



## REPORTING DEADLINES

The Outcome Reporting Form and PrEP/T&T Data Summary should be sent to Hasina Subedar and Sarah Jenkins on the 7th of every month. For example, data for June 2016 is due on July 7, 2016. Clinics that work within a network must send their data collection forms to a point of contact within their network prior to the 7th if additional review is required.

## DEFINITIONS & ACRONYMS

Several terms and acronyms are used across the reporting forms. The definitions are also included on the PrEP Register.

On PrEP	
Continue	Client continuing to take PrEP
Restart	Client disc or LTF, but restarted
TFI	Transferred in
TF	Tenofovir, client received PrEP drugs
Testing	
Neg	Client tested HIV negative at point in time
Pos	Client tested HIV positive at point in time

Outcomes	
RIP	Died
LTF	Lost to follow-up (60 days after last seen)
TFO	Transferred out
Sero	Client seroconverted, HIV +
DNA	Client did not attend scheduled visit
Disc1	Client elected to discontinue PrEP
Disc2	Clinician recommended discontinuation of PrEP

## PrEP CLINICAL TREATMENT FORM

### PURPOSE OF FORM

The PrEP Clinical Treatment form is used to track every client that tests HIV negative and is offered oral PrEP. These forms are client-specific and kept in the client's personal file. It does not need to be shared with the other reporting forms. This form records individual client information, the steps taken during screening for PrEP interest and eligibility, and records information from each clinic visit related to PrEP. There are sections for notes and client history to inform the record.

It is not shared with the NDoH.

### CLIENT INFORMATION

The client's personal and contact information will be filled in at the top of the form (pictured below).

health Department of Health REPUBLIC OF SOUTH AFRICA		PrEP treatment form	
Patient first name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy	Address	
ID Number	Sex: M / F / TG		

## SCREENING SECTION

The “Steps Prior to PrEP Initiation/Re-Initiation” section (pictured below) captures each mandatory step of the screening process for oral PrEP. If a client tests HIV negative, the appropriate counselling is conducted to inform the client of strategies to remain HIV negative. If the client’s lifestyle is high risk, oral PrEP will be presented as an option. If the client expresses interest in PrEP, pregnancy and creatinine tests are done. Test results should be recorded in the appropriate cells, not simply whether or not the test was performed. The creatinine results may not come back the same day, but should be filled in when they are returned to the clinic.

If the client’s test results are adequate and they decide to initiate, the clinician will then move to the “Initiation” section of the form.

**Please Note:** Every person offered PrEP must have one of these forms, regardless of whether they proceed with screening or decide not to initiate.

**Instructions:** Please use the below form to capture clinical initiation, retention, discontinuation, and re-initiation for PrEP. If a patient discontinues, continue the record with the corresponding date of discontinuation. Should a patient re-start PrEP, re-initiation and subsequent visits will be captured into this same form. Adherence support and other notes can be captured further below.

Steps Prior to PrEP Initiation/Re-Initiation						
Date of Visit	HIV Test Result	PrEP Counseling Conducted?	Proceed with Screening?	PrEP Screening		Decide to Initiate?
				Creatinine Clearance Result	Pregnancy Test	
/ /	+/-	Y/N	Y/N		+/-/NA	Y/N
/ /	+/-	Y/N	Y/N		+/-/NA	Y/N
/ /	+/-	Y/N	Y/N		+/-/NA	Y/N
/ /	+/-	Y/N	Y/N		+/-/NA	Y/N
/ /	+/-	Y/N	Y/N		+/-/NA	Y/N
/ /	+/-	Y/N	Y/N		+/-/NA	Y/N

## (RE) INITIATION SECTION

Once a client is screened and decides to initiate, the clinician will move to the “PrEP – Initiation/Re-Initiation and Monitoring” section (pictured below). First, fill in the “Original PrEP Initiation Date” with the date the client receives his or her first month supply of oral PrEP drugs. This date reflects the client’s permanent cohort. If someone initiates on June 15, 2016, they will be part of the June Cohort for their lifetime.

Row 0 will be filled in with the same information from the screening section. This indicates that the client has not been taking oral PrEP yet. Row 1 is the first month follow-up and indicates that the client has been taking oral PrEP for 1 month.

### *Summary/Follow-Up Months*

The client must return to the clinic at the first month, and then every three months. These months are called “follow-up” or “summary” months and are shaded in a dark gray on the form. During these visits, clients should receive counselling and HIV, creatinine, and pregnancy tests should be performed.

**Off Months**

Months that fall between the follow-up months are white and referred to as “off months”. The client must return to the clinic to receive their one month supply of oral PrEP drugs, but tests do not need to be performed. The level of counselling offered on these off months is at the clinic’s discretion.

**Outcome**

If a client stops taking PrEP for any reason, please note this in the two Outcome columns on the far right. You can provide additional detail in the Notes section at the bottom of the form.

PrEP - Initiation/Re-Initiation and Monitoring									
Original PrEP Initiation Date			/ /		Transfer In:		Date		From Clinic:
							/ /		
# of Months on PrEP	Next visit Date:	Actual visit:	Remaining on PrEP?	Test Results (if applicable)				Outcome (RIP, LTF, TFO, Sero, DNA, Disc)	Month of Outcome
				Test Date	HIV	Creatinine Cl	Pregnancy		
0	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
1	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
2	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
3	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
4	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
5	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
6	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
7	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
8	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
9	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
10	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
11	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
12	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
13	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	
14	/ /	/ /	Y/N	/ /	+/-		+/- / NA	/	

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**CYCLING CLIENTS**

Clients will use oral PrEP during periods when they are at high risk of HIV exposure. If this risk decreases for any reason, the client may decide to stop taking oral PrEP. This is completely expected and appropriate. If the client decides to reinitiate after discontinuing for any reason, the clinician will move back to the Screening Section to fully re-screen and re-initiate the client on PrEP. The clinician will then again move into the Re-Initiation Section in the appropriate month.

**Please Note:** The client will remain in their original cohort, regardless of when they reinitiate. For example, a client is in the June 2016 Cohort. They discontinue PrEP use in December 2016, but reinitiate in February 2017. Despite this re-initiation, they are still in the June 2016 Cohort and February 2017 data will be recorded in month 8.

## PrEP REGISTER

### PURPOSE OF FORM

The PrEP Register captures reporting for each client for every month of the first year. The information is recorded client by client and is used to inform follow-up, retention, and adherence. The Register informs the Outcome Reporting form and the PrEP/T&T Data Summary. Since it contains personal client information, it is not shared with NDoH.

### STRUCTURE

The PrEP Register is an electronic Excel form that should be completed on the computer, if possible. A complete list of the terms used appears in the top left corner. Totals for each Summary/Follow-up Month are found at the bottom of the form. There is a space for comments on the far right side of each row.

The form includes Month 0 through Month 13, like the Clinical Treatment Form. Each Follow-up/Summary month is shaded in blue.

***Please Note:*** All Cohorts are captured on this same register.

### RELATION TO OTHER FORMS

The PrEP Register is the first tab of the M&E Excel document.

The Register is critical because the information recorded here will populate the Outcome Reporting form and sections of the PrEP/T&T Data Summary. Ensuring accuracy and consistency on this form is critical; any errors made here will be carried through across the dependent forms.

<b>tenofovir:</b> TF <b>Continue:</b> Patient continuing to take PrEP <b>Restart:</b> Patient disc, but restarted <b>TFI:</b> Transferred in <b>Neg:</b> Tested HIV negative at point in time <b>Pos:</b> Tested HIV positive at point in time		<b>RIP:</b> Died <b>LTF:</b> Lost to follow up (60 days) <b>TFO:</b> Transferred out <b>Sero:</b> Patient seroconverted, HIV + <b>DNA:</b> Patient did not attend scheduled visit <b>Disc:</b> Patient elected to disc PrEP		Sex	Age	0	At 1 month: Report on events between starting PrEP & 1 month				2	3	At 4 months: Report on events between 2 month and 4 months					
Page	Cohort Month	Day started	Client's Name, Surname, folder number and ID number				Received PrEP drugs	Continue/Restart PrEP / TFI	Outcome RIP LTF TFO Seroconvert, DNA, Disc	HIV Test neg -			HIV Test +	Received PrEP drugs	Received PrEP drugs	Continue/Restart PrEP / TFI	Outcome RIP LTF TFO Seroconvert, DNA, Disc	HIV Test neg -
1			Folder #	ID														
2			Folder #	ID														
3			Folder #	ID														
4			Folder #	ID														
5			Folder #	ID														
6			Folder #	ID														
7			Folder #	ID														
8			Folder #	ID														
9			Folder #	ID														
10			Folder #	ID														

Page

## FILLING IT OUT

### General

All cells use a drop-down function to enter information; values not seen on the drop-down list cannot be input into the form. These drop-down menus and all formulas used to calculate totals are locked and cannot be edited. An example of a completed register (through October) is pictured above.

### Summary/Follow-Up Months

Clients should be retested during these months and results of the HIV test must be recorded on the Register. During these months, the clinician should complete the first column if the client is using PrEP, or the second column if the client is no longer using PrEP. The appropriate reasons for each are contained in drop-down lists.

**Please Note:** Completing the Summary Months correctly is critical. These are the months that pull through to the Outcome Reporting Form and the PrEP/T&T Data Summary. The Summary Month should capture what happened to each client in the prior Off Months. For example, if a client was technically lost to follow-up in Month 2, LTF should be noted in both Month 2 and the 4 Month Summary. This is also pictured above.

### **Off Months**

During off months (i.e. Month 2, 3, 5, etc.), the clinician should simply note whether the client received their PrEP drugs. This is noted as “TF” in the drop-down menu. If the client did not come to the clinic, the clinician can choose either DNA or LTF, as appropriate.

### **LTF v DNA:**

A client is not confirmed as LTF until the second missed appointment. This would appear as two DNA's in a row on the register. Once the second consecutive DNA occurs, update the first DNA to LTF. (Make sure to record that LTF in the appropriate Summary Month.)

## PrEP OUTCOME REPORTING FORM

### PURPOSE OF FORM

The PrEP Outcome Reporting form captures all data from the Summary Months. It provides an overview of baseline data, and results and outcomes of each Summary Month by cohort.

Baseline data reported includes the number of people commencing PrEP, as well as the sex breakdown. The Summary Month data reports the number continuing and restarting PrEP, as well as the number discontinuing, deceased, lost to follow-up, transferred out, and seroconverted. The number of people testing HIV positive and HIV negative are also captured.

The baseline and first month summary are pictured in the image, below.

It must be reported to NDoH by the 7th of the month.

### STRUCTURE

Each cohort is a discrete column. Information for the June cohort will always be captured in the column D straight down, July in column E, et cetera.

### RELATION TO OTHER FORMS

The Outcome Reporting form is the second tab of the M&E Excel document.

The Outcome Reporting form pulls directly from the PrEP Register. The clinician or data capturer must only complete the clinic information at the top of the form (district, facility, and year). The rest of the information will automatically populate from the PrEP Register.

**Please Note:** It is critical to complete each Summary Month on the PrEP Register to inform the Outcome Reporting form. Information in the “off months” will not be captured here. Please review this form and make sure the numbers are pulling through correctly and totals are consistent with the information entered on the PrEP Register.

PrEP Outcome Reporting Form													
District:		Facility					Year:						
	Treatment Cohort	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Baseline	Number of people commencing PrEP (PrEP-TOT)												
	Number of males												
	Number of females												
	Number of transgender												
1 month summary	Number returning for 1st month PrEP visit (Continue)												
	Number re-start PrEP 0 - 1 month (Restart)												
	Number PrEP self discontinue between 0 - 1 month (DISC)												
	Number Died 0 - 1 month (RIP)												
	Number Lost to follow-up 0 - 1(LTF)												
	Transferred out 0 - 1 month (TFO)												
	Seroconversion 0 - 1 month (Sero)												
	Number on PrEP remaining HIV negative 0 - 1 month (HIV-)												
	Number on PrEP testing HIV-positive 0 - 1 month (HIV+)												

## PrEP/T&T DATA SUMMARY

### PURPOSE OF FORM

The PrEP/T&T Data Summary form captures basic data for the reach of PrEP, Test & Treat, and the cascade of care.

It must be reported to NDoH by the 7th of the month.

### STRUCTURE

The PrEP/T&T Data Summary form has three sections: (1) Testing + Services, (2) PrEP, and (3) Test & Treat. Each month column is discrete. Formulas in the PrEP section are locked and cannot be manipulated. (Parentheses after the indicator, as shown in the image below, reference the specific data element in the DHIS.)

### PrEP and Test & Treat Monthly Data Summary Sheet

Facility:		Province:		District:		Sub-district:					
Year:		Completed by:				Contact details:					
Area	Indicator	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
TESTING + SERVICES											
Testing	HIV test client 15-49 years (excl ANC) (DE 145)										
	Number of HCT negative (calculated DE145 minus DE146)										
	Number STI screenings done										
Services	STI treated new episode (DE 153)										
	Male condoms distributed (DE 151)										
	Female condoms distributed (DE 152)										
PrEP											
Stock Audit	No. of PrEP packs in stock										
PrEP Offer	Number of HIV negative people offered PrEP										
Age at Initiation (PrEP)	0-15										
	16-18										
	19-24										
	25-34										
	35+										
Sex (PrEP)	M										
	F										
	TG										
PrEP Retention	Number remaining in PrEP care in reporting period (register)										
TEST & TREAT											
T&T Initiation	Number of positive people initiated on ART										
	Number of positive people initiated on ART at CD4>500										
Age at Initiation (T&T)	0-15										
	16+										
Sex (T&T)	M										
	F										
	TG										

Page 1



## RELATION TO OTHER FORMS

The PrEP/T&T Data Summary is the third tab on the M&E Excel document.

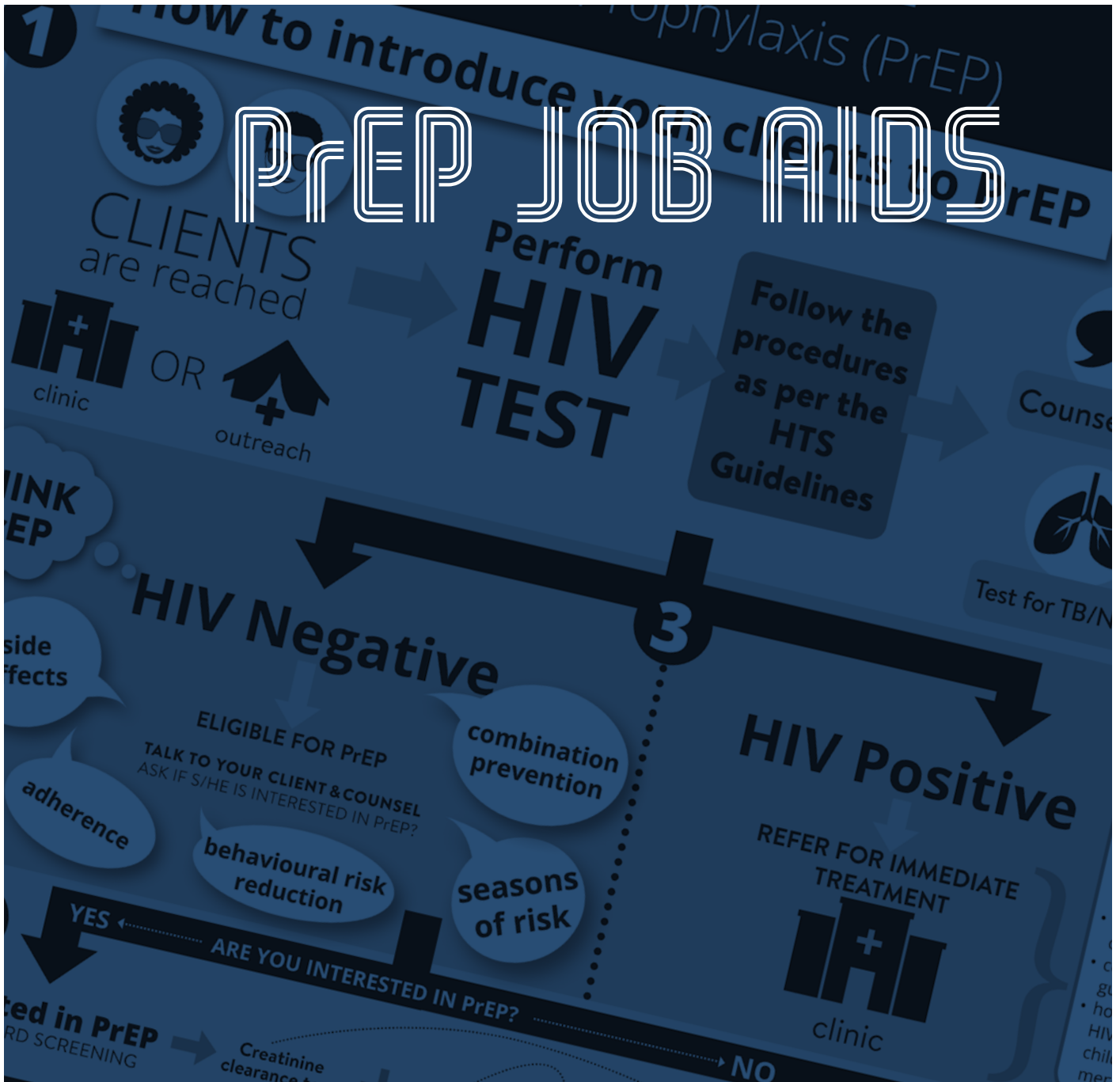
This form is partially populated from the PrEP Register. The majority of the PrEP section will be automatically completed, but the clinician or data capturer must fill in two PrEP fields:

- (1) Complete the stock audit field, "Number of PrEP packs in stock." It is critical to fill this out accurately each month to ensure adequate and uninterrupted supply of PrEP drugs.
- (2) Complete the number of HIV negative people offered PrEP. (This is most simply done by counting the number of clinical forms completed.)

The clinician or data capturer will have to complete in full both the Testing + Services and Test & Treat sections. Much of this information is already reported by other systems (such as the DHIS) and should be simple to complete.

***Please Note:*** Please review the autocompleted information in the PrEP Section to ensure accuracy.

# PrEP JOB AIDS



# PrEP JOB AIDS

The included memory stick includes the following job aids in a print-ready format:

- **PrEP palm card (pocket size)**  
The palm card, aptly named for its small size, fits comfortably into a hand and is used as a quick reference communication tool for peer educators, counselors, and healthcare workers. It contains the absolute basic information needed to provide the initial information on oral PrEP to a client.
- **PrEP poster job aid - introducing your clients to PrEP when counselling/testing for HIV**  
The poster, “The road to PrEP”, is an overview of the steps to follow when peer educators or healthcare workers test clients for HIV. It details, in visual format, the steps required to refer HIV-positive clients for immediate Test and Treat, as well as the counselling and PrEP initiation for HIV-negative clients. The process is set out in a step-by-step manner to assist peer educators and healthcare workers as they discuss oral PrEP as an additional HIV prevention option with their clients.
- **PrEP adherence counselling job aid - triangle desk stand**  
The adherence counselling job aid aims to assist counsellors and healthcare workers in the discussion on PrEP initiation and adherence. It is a comprehensive job aid that assists to support the conversation on the importance of adherence. The job aid highlights topics to engage on and how to talk about these topics; it offers valuable guidance and suggestions for having an open and supportive conversation around making PrEP a positive lifestyle choice.
- **Quick guide PrEP adherence counselling checklist**  
This master checklist contains all of the checklists contained in the adherence counselling job aid and serves as a quick reference for counselling prior to oral PrEP initiation and follow-up. It is a practical checklist allowing counsellors and healthcare workers to refer to topics for discussion and “tick” off the list what has been discussed, while ensuring important talking points are not accidentally left behind.



# ACKNOWLEDGEMENTS

The PrEP Implementation Pack is a collaborative effort between the NDoH and all partners who have supported implementation in South Africa.

# ADDITIONAL READING

## Addressing Gender to Ensure Effective PrEP Introduction

### Technical Brief: Michele Lanham (OPTIONS)

#### Background

Pre-exposure prophylaxis (PrEP)<sup>1</sup> was conceived to fill the urgent need for a woman-controlled HIV prevention method. However, biomedical technology alone will not alter the underlying gender inequalities that make women and girls vulnerable to HIV. As new HIV prevention methods are rolled out, women, girls, men who have sex with men (MSM), and transgender people will face barriers to product access and use that stem from cultural norms, lack of power in relationships and society, and limited access to resources. Gender analyses conducted in Kenya, South Africa, and Zimbabwe identified ways to address these potential barriers during PrEP introduction. Most critically, PrEP introduction plans must prioritize a rights-based, positive approach that normalizes use of the new products and makes them available to those who need them most.

#### Recommendations



##### MEANINGFUL INVOLVEMENT

Ensure that target populations and communities are meaningfully involved in developing PrEP policies, guidelines, and implementation plans. Women's advocates, women leaders, youth, adolescents, and members of other specific target populations for PrEP (e.g., sex workers, MSM, and transgender people) should have a seat at the table throughout the development of policies, guidelines, and implementation plans, and should be involved in assessing policy and program effectiveness. Communities where PrEP is being rolled out should also be involved. Meaningful participation empowers these groups and increases the likelihood that PrEP programs are effective and truly meet the needs of the target populations.



##### TARGET POPULATIONS

Make PrEP available to as many women as possible, not just “most-at-risk” populations. As oral PrEP is rolled out, take care to reduce the potential for stigma against the product and the people who use it. Consider including young women and adolescent girls as target populations, given their high rates of HIV infection and their lack of power to negotiate condom use. Because oral PrEP will likely be promoted primarily to populations considered most-at-risk, it is crucial in areas of high HIV prevalence to offer other PrEP formulations, such as vaginal microbicides, to a wider audience of women as those formulations are proven effective and become available.

<sup>1</sup> Refers to all antiretroviral-based HIV prevention options including oral PrEP and vaginal ring.



### POLICY

Create a supportive policy environment and clear guidelines for delivery of PrEP products that respect, protect, and fulfill the human rights of all people to HIV prevention services regardless of age, sex, gender identity, gender expression, sexual practices, or marital status.



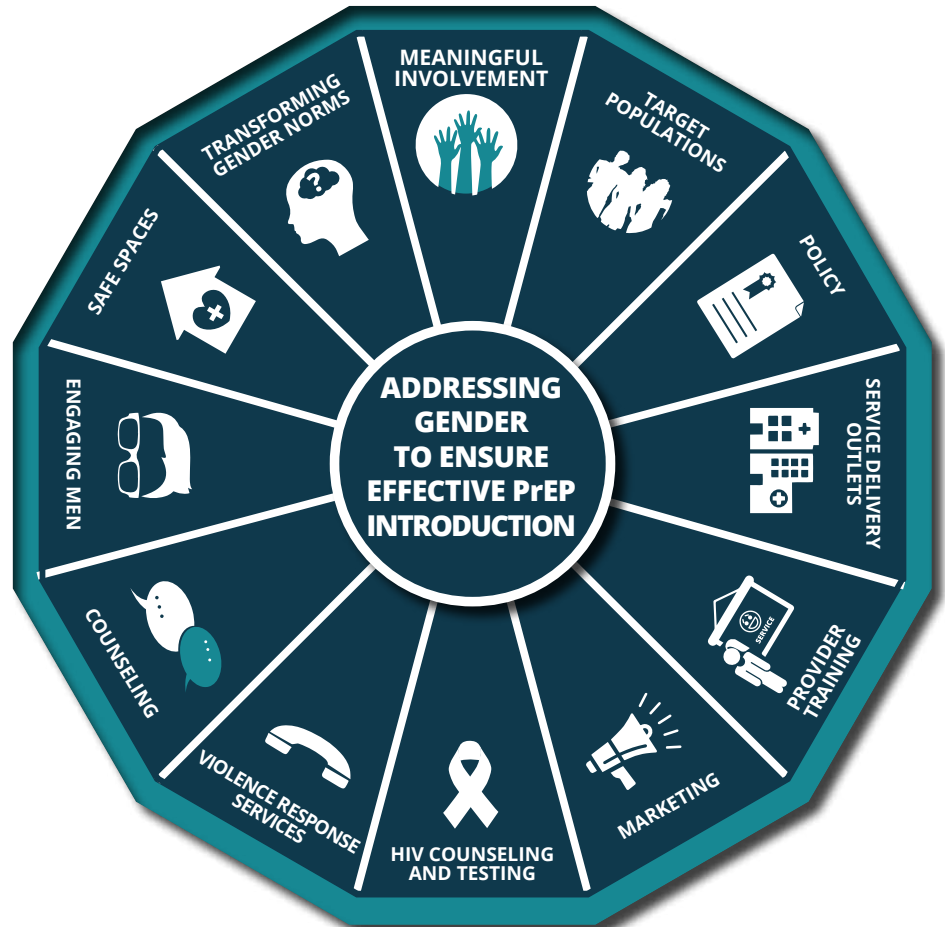
### SERVICE DELIVERY OUTLETS

Offer PrEP for free or at low cost and integrate it into services women, adolescents, and other target populations currently use to reduce obstacles to uptake. Though PrEP will likely be offered only in clinics at first, implementation plans should consider how to make PrEP available outside of clinics in the long term, to increase access, uptake, and continuation. PrEP should be offered at clinics and drop-in centers providing services for specific target populations, including adolescents, sex workers, MSM, and transgender individuals, because these facilities are often viewed as safe spaces that provide high-quality, non-stigmatizing care. New HIV prevention methods also need to be available in general health facilities to reach those who are at risk but do not identify themselves as members of one of these groups. For example, women engaged in transactional sex may not want to be considered sex workers.



### MARKETING

Tailor PrEP marketing for specific contexts and groups. Marketing should aim to minimize any stigma associated with the products and the people using them. Local message development is vital to determining the most appropriate content. Members of target audiences should be involved in developing messages and identifying communication channels. Messages should target women in different life stages and situations and should normalize product use. Some messages could target couples to promote partner communication about the products.





## PROVIDER TRAINING

Train healthcare providers and staff to deliver non-judgmental, gender-sensitive PrEP services and provide them with ongoing support and accountability. Providers and staff often hold the same gender-inequitable attitudes as the broader community, and those views affect how and to whom they provide services. For example, providers may not provide HIV prevention services if they think clients should not be sexually active (e.g., adolescents), should not be at risk of HIV (e.g., married women), or should not engage in certain behaviors (e.g., MSM, sex workers). Programs should institute systems for reporting discrimination in healthcare settings, including breaches in confidentiality, and should ensure that providers know they will be held accountable.

“Gender norms and inequalities increase women’s and girls’ vulnerability to HIV due to multiple factors, including limited ability to negotiate safer sex, engaging in transactional sex, and curtailed ability to test, disclose and access HIV treatment because of fear of violence and abandonment. Norms around gender and sexual identity [also] put transgender populations and others who are perceived to have transgressed those norms at greater risk for both gender-based violence and HIV.”

PEPFAR Gender Strategy

### Provider and staff training should include:

- 1 identifying and addressing their own discriminatory attitudes and behaviors;
- 2 providing confidential, rights-based services;
- 3 meeting the specific health needs of adolescent girls and young women, sex workers, MSM, and transgender women<sup>2,3,4</sup>;
- 4 asking about sexual risk behaviors in a non-judgmental way so they can accurately assess each client’s HIV risk;
- 5 identifying and addressing gender-specific product adherence issues;
- 6 counseling women about whether to discuss product use with their partners or other family members; and
- 7 identifying, supporting, and referring people experiencing violence to violence-response services, when available.



## HIV COUNSELING AND TESTING

Strengthen HCT, including couples’ counseling, and evaluate different testing models to increase uptake, both for first-time testers and for women doing repeat testing while using PrEP. Women face gender-related barriers to getting tested, so the requirement for regular HIV testing could deter women from using PrEP. The need for a partner’s permission to get HIV tested and fear of a male partner’s negative reaction have been identified as two of the primary reasons that pregnant women decline HIV testing. Many women fear that if they disclose a positive HIV test result to a partner, he will blame her for bringing HIV into the relationship, accuse her of having outside partners, be violent toward her, or abandon her. Countries need to determine what frequency of HIV testing is feasible for women using PrEP and how to support women’s discussions about HIV status with partners and family members. They should continue to promote demand for HCT, evaluate different models (such as self-testing, home-based testing, and mobile testing), and scale up effective models of couples’ HCT that facilitate uptake of testing as well as gender-equitable decision-making and communication.

2 High-impact practices in family planning (HIPs). Adolescent-friendly contraceptive services: mainstreaming adolescent-friendly elements into existing contraceptive services. Washington (DC): USAID; 2015. Available from: <https://www.fphighimpactpractices.org/afcs>.

3 Brown A, Tureski K, Bailey A, Rogers S, Cushnie A, Palmer Q, Adelaja A. Layered stigma among health facility and social services staff toward most-at-risk populations in Jamaica. Washington, DC: FHI360/ C-Change; 2012.

4 The nexus of gender and HIV for sex workers, men who have sex with men, people who inject drugs, and transgender people in Kenya. Washington, DC: FHI 360/LINKAGES; August 2016.



## VIOLENCE RESPONSE SERVICES

Integrate violence-response services within PrEP delivery. Experiencing violence increases HIV risk, limits HIV testing, and decreases disclosure of HIV status. Experience with or fear of intimate partner violence also affects whether women disclose PrEP use to their partners and their ability to adhere to consistent use. In areas where violence response services are available, providers delivering PrEP should be trained to screen for violence and provide first-line response; referral networks should be developed to meet the holistic needs of clients who have experienced violence. All referral points — especially those that may be a first point of contact — should be able to share time-sensitive information on HIV services, such as post-exposure prophylaxis.

*The OPTIONS programme is made possible by the generous assistance from the American people through the U.S. Agency for International Development (USAID) in partnership with PEPFAR. The contents of this technical brief do not necessarily reflect the views of USAID or the United States Government.*

## COUNSELING

Support women in their decisions about whether and how to discuss PrEP use with their partners.<sup>5</sup> In PrEP trials, prevailing gender norms about sexuality and complex relationship dynamics affected those decisions. Couples were more likely to discuss HIV risk, get tested, and use condoms at the beginning of a relationship. For some men, a partner's use of PrEP was a sign that she suspected he was unfaithful or that she had outside partners. Women found ways to work within the existing patriarchal gender relations, such as negotiating PrEP use without openly challenging male authority or voicing suspicions of infidelity. Many women, especially those in steady relationships, wanted to tell their partners about PrEP and obtain their support. Partner support can range from permission or tacit agreement to active assistance, including reminders to use the product, accompanying a partner to the clinic, or giving her money for transport to the clinic. Some women, including those in casual or violent relationships, may elect not to tell their partners. All women have the right to decide when or whether to discuss product use with their partners.

## ENGAGING MEN

Engage male partners to promote couples' communication and support women's PrEP use.<sup>6</sup> Educating men about PrEP can alleviate their concerns and help normalize product use. Encouraging men to communicate with their partners about HIV protection and sex more broadly can contribute to better relationship dynamics and encourage more gender-equitable attitudes and behaviors. However, while encouraging men to take a more active role in HIV prevention for women — including supporting their use of PrEP — care must be taken to ensure that male involvement facilitates, rather than inhibits, the rights, wishes, and well-being of women.

## SAFE SPACES

Create safe spaces in which target populations can discuss sex and sexual health. In these spaces, women and other target populations can learn from each other about PrEP and strategies for effective use. Women can develop strategies for discussing PrEP with their partners or using it without their partner's knowledge. Drop-in centers, peer networks, and social media can be particularly effective ways of reaching youth, MSM, sex workers, and transgender people with information and referrals.

## TRANSFORMING GENDER NORMS

Remember that PrEP can contribute to, but not replace, efforts to transform gender norms. If product rollout includes strategies to address gender barriers, it has the potential to increase couples' communication, improve relationships, increase women's knowledge about sexuality, and enhance women's power to prevent HIV. However, to truly transform gender norms and improve the status of women, a more comprehensive approach is required.<sup>7,8</sup> ●

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