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National Framework and Guidelines

for

the Implementation of

Oral Pre-Exposure Prophylaxis (PrEP)

April, 2019

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ABBREVIATIONS AND ACRONYMS

ART	Antiretroviral therapy
ARV	Antiretroviral
eMTCT	Elimination of mother to child transmission
FTC	Emtricitabine
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HIV	Human immunodeficiency virus
HTS	HIV testing services
M&E	Monitoring and evaluation
PEP	Post exposure prophylaxis
PMTCT	Prevention of mother to child transmission
PrEP	Pre-exposure prophylaxis
STI	Sexually transmitted infection
FSW	Female Sex worker
TDF	Tenofovir disoproxil fumarate
TDF/FTC	Tenofovir disoproxil fumarate/Emtricitabine (Truvada)
WHO	World Health Organization

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CHAPTER ONE: FRAMEWORK

Framework for Oral Pre-Exposure Prophylaxis (PrEP) Implementation

1.1 INTRODUCTION

The Government of the State of Eritrea continues to view the HIV/AIDS epidemic response as its first priority for action. The national rate of HIV infection among adults (15-49 years) in Eritrea has shown a downward trend from 2.41% in 2003 to 0.65% in 2017. Despite the marked decline of HIV prevalence in the general population, there are still subgroups such as female sex workers with high HIV prevalence rates that are significantly higher than national prevalence rate. This decline in the general population and high HIV prevalence in some high risk population groups indicate that the HIV epidemic in Eritrea has transitioned from a mixed and geographically heterogeneous epidemic to a concentrated one, with variations across the different geographic zones, showing higher infections in urban areas and affecting younger women and key populations. The main modes of HIV transmission in Eritrea are unsafe heterosexual intercourse and mother to child transmission.

Prevention of HIV infection has been at the core of the HIV response in Eritrea. The strategies implemented include HIV counseling and testing, prevention of mother to child transmission (PMTCT), condom distribution, and diagnosis and treatment of sexually transmitted infections (STI). Key populations such as female sex workers and long-distance truck drivers have been targeted for HIV prevention efforts, aimed at improving their HIV knowledge, change their attitude and behavior towards HIV and motivate them to use condoms consistently. In 2015, WHO has added the use of oral pre-exposure prophylaxis (PrEP) as a highly

effective, safe, biomedical option for HIV prevention among populations and individual at a substantial risk of HIV acquisition.

PrEP for HIV is the use of certain antiretroviral drugs by HIV-negative people to prevent HIV acquisition. In Eritrea, the adoption of PrEP for populations at a substantial risk of acquiring HIV is an important new additional HIV prevention. Making PrEP available will contribute to the country's plans of executing a well-coordinated, aligned and focused strategy towards the vision of *Zero new HIV infections, Zero discrimination, and Zero AIDS-related deaths*, as reflected in the National HIV/AIDS/STI Strategic Plan (ENASP V, 2017-2021).

1.2 SITUATIONAL ANALYSIS

1.2.1 Current Efforts

The fifth Eritrean National HIV/AIDS/STIs Strategic Plan (ENSP V 2017-2021) focuses on prioritization of high impact interventions of known effectiveness in the four core programmes, namely, the elimination of mother-to-child-transmission (eMTCT), scaling up of antiretroviral treatment, scaling up of condom distribution and access, expanding and strengthening services for key populations at high risk (KPHR). Additional resources will also be allocated to programming for KPHR and both and Social and behavioral Change Communication (SBCC) will focus more on the KPHR.

Currently, all persons who test positive for HIV must notify their partner/s of the outcome of the HIV test results and the partners will also be requested to take an HIV test. This is aimed at facilitating behavior change and preventing anyone from putting

others at risk of HIV infection. Furthermore, Pre-marital HIV testing has become a norm in both rural and urban societies of Eritrea, which sustains the culture of HIV testing.

1.2.2 Remaining Challenges

Although HIV prevalence remains low HIV prevalence in the general population over the last 14 years, there are still subgroups with higher HIV prevalence rates that are significantly higher than the estimated national prevalence rate (Table 1).

The prevailing HIV epidemiologic trends as documented in various studies are summarized below:

- Women engaged in sex work are at the highest risk of HIV infection and this subpopulation has the highest HIV prevalence estimated at 14.4%.
- Approximately 36% of annual new infections in 2015 were linked to sex work, occurring amongst the female sex workers, their clients and the stable partners of the clients (Table 1).
- HIV prevalence is also high among women who are engaged in bar/hotel/tea shop work at 1.83%, than in women engaged in other type of occupation.
- Prevalence of HIV among long distance truck drivers and bus drivers is estimated at 2.7% and 3.8%, respectively.

Table 1. Model Estimated Annual HIV Infections by Population

Population	No of New Infections	Incidence Rate per 100,000	% of New Infections
Sex workers	4	69	1.7
Clients of sex workers	44	84	19.7
Partners of sex workers clients	35	118	14.5
Women working in bars/tea shops/hotels	8	71	3.2
Male partners of women working in bars	1	78	1.4
Casual heterosexual sex	8	12	3.4
Partners of casual heterosexual sex	3	73	1.1
Stable heterosexual couples	144	25	53.7

- The 90-90-90 cascade analysis for the CSW shows that only 64% had been tested for HIV in the 12 months period before the survey, with 100% antiretroviral therapy (ART) initiations for those that tested HIV positive, and 80% of those on ART were virally suppressed.

It remains a priority of the Government of Eritrea to ensure that individuals at the highest risk of infection are provided with appropriate and efficient HIV/ AIDS and STI prevention and treatment, to achieve the goal of zero new HIV infections, zero discrimination and zero AIDS-related deaths.

1.3 RATIONALE FOR PREP IN ERITREA

Despite overall good progress made in Eritrea in the reduction of both HIV infection and prevalence, HIV infections remains disproportionately high amongst sex workers, higher than the general population and pregnant women at ANC services. It is therefore essential to consider new innovative ways of expanding HIV prevention, using strategies that are highly effective and safe.

The World Health Organization (WHO) recommends the use of pre-exposure prophylaxis (PrEP) as an additional HIV prevention option for people at substantial risk of acquiring HIV. It is defined as the use of antiretroviral drugs by HIV-negative people, before potential exposure, to prevent the acquisition of HIV. Research has shown that medicines used for PrEP are safe for populations and provides high levels of protection when adhered to consistently (>90% reduction in HIV risk).

The ENASP V has included PrEP as an evidence-based and priority HIV prevention intervention for key populations. It has also committed towards providing a comprehensive package of services for key populations at high risk. These include HIV testing, counselling, condoms and ARV treatment for partners with HIV infection. Broader benefits of providing PrEP as part of the combination prevention interventions include regular HIV testing for KPHR, which will assist in closing the HIV testing gap, resulting in early diagnosis of HIV and linkage to treatment for those that test HIV positive. It provides another option for those that do not use condoms consistently. Those that present to the health care requiring PrEP will also have access to other health services within the comprehensive care package.

Offering PrEP to specific sub-population and individuals that are at a substantial risk of HIV infection, can be cost-saving in long term by averting costs of lifelong treatment resulting in relatively high impact-for cost ratio. Evidence showed that in 2015 the majority of new HIV infections (54%) in Eritrea occurred within stable heterosexual relationships, suggesting that there is a significant proportion of individuals who may not be classified as KPHR, who may benefit from PrEP as an HIV prevention intervention for those at substantial risk of infection such as PrEP.

BOX 1. Benefits of prioritizing PrEP among individuals at significant risk of infection.

The following example illustrates the benefits of offering PrEP to female sex workers. According to the ENASP V, approximately 36% of annual new infections in 2015 were linked to sex work, occurring amongst the female sex workers (2%), their clients (19.7%) and the stable partners of the clients (15%). Offering PrEP to SWs in Eritrea will prevent new HIV infections amongst SWs, who contribute about 2% of new HIV infections annually. This will also prevent onward transmission to their clients, who currently contribute almost 20% of new infections annually. When infections are prevented in the clients of the sex workers, this will in turn prevent HIV transmission to the partners of these sex worker clients, who contribute about 15% of new infections annually.

1.4 GOALS AND OBJECTIVES

1.4.1 Goal

The overall aim of introducing PrEP in Eritrea is to assist in realizing a reduction of 50% new HIV infections and 75% reduction in AIDS related mortality by 2021. (ENASP V).

1.4.2 Objectives

- To reduce new HIV infections amongst key populations and individuals at substantial risk of infection. This will result in reduction of new infections in Eritrea.
- To expand available prevention options and offer PrEP as an additional prevention intervention. PrEP should not displace well-established prevention strategies, but rather complement these and empower key populations who are not able to effectively use other methods
- To improve knowledge of HIV status in KPHR and individuals at high risk of infection through regular HIV testing, ensuring early diagnosis and treatment for those who are HIV infected and not eligible for PrEP.

1.4.3 Guiding principles

The following are the guiding principles for the implementation of PrEP in Eritrea.

- Political leadership, strategic partnerships and stakeholder involvement
- Promotion and protection of human rights
- Targeted approach with focus on key populations at highest risk of HIV infection
- Use of latest available scientific and programmatic evidence for decision making

- Accessible and acceptable strategies to the targeted Eritrean population

1.5 SERVICE DELIVERY

1.5.1 Defining populations at risk and prioritizing for PrEP

Eritrea will offer PrEP to KPHR and individuals at substantial risk of HIV infection as this will render the highest impact in the most cost-effective way. Anyone at substantial risk of HIV acquisition will be provided PrEP. Sex workers and their clients are the sub-populations who will be prioritized for PrEP. The Ministry of Health has planned that Asmara will be prioritized as the first major city for piloting PrEP rollout, as it has the infrastructure to support PrEP provision. Using lessons learnt from this pilot, and epidemiological trends on HIV transmission, PrEP services be scaled-up in the other priority areas.

1.5.2 Defining the package of services

The following services will be integrated with PrEP services (Minimum package)

- HIV testing (National algorithm) is a re-requisite for PrEP initiation. Re-testing while on PrEP is also necessary for early diagnosis of HIV sero-conversion.
- Hepatitis B surface antigen (HBsAg) screening prior to PrEP initiation
- Diagnosis and treatment of sexually transmitted infection
- Access to both male and female condoms
- Access to ART initiation for those that test positive for HIV
- Pregnancy screening and access to contraceptives

1.5.3 Where to offer prep and generate demand

The criteria for selecting appropriate service delivery platforms will be based on:

- Sites where PrEP demand can be generated for the target population
- Integration into existing services that reach the populations at risk
- Facilities with relevant services, such as HIV testing, STI testing, ART, family planning, laboratory access and follow-up capability

1.5.3.1 Social and Behavioural Change Commination (SBCC)

According to the ENASP V, the behavioral change communication (BCC) services will give specific emphasis to the KPHR. These services will be used to **generate demand** for PrEP and facilitating advocacy activities for the sex workers and their clients, through the Ministry of Labor and Human Welfare. This collaboration will maximize on existing structures and create tailored messaging that encourages uptake of PrEP by sex workers, as part of HIV prevention for KPHR. The Ministry of Tourism will ensure that PrEP education is included in their BCC education for sex workers in bars, hotels and tea shops. The SBCC services provided through these two ministries will facilitate and enable access to PrEP as they already have structures where SWs most commonly access other services.

1.5.3.2 HIV testing services (HTS)

HTS services will be the primary platform where PrEP will be offered to eligible individuals. These services have capacity and resources requires for access and provision of PrEP within the health system of Eritrea, at both facility and community level.

Taking into consideration that an HIV negative test is a pre-requisite for PrEP initiation, HTS is an appropriate entry point for HIV prevention services, and because counsellors offering HTS can initiate ART for those diagnosed with HIV, this makes HTS appropriate for the delivery of PrEP services.

- **Client-initiated testing and counseling (CITC)** – individuals at high risk of HIV infection, who voluntarily present themselves for HIV testing, should be offered PrEP if they test negative for HIV.
- **Provider-initiated testing and counselling (PITC)** – If a provider identifies an individual who is at high risk of HIV and who may benefit PrEP, they should refer the patient for HIV testing with the aim of offering PrEP to the client.

1.5.3.3 Integration with safer conception

Currently, couples in sero-discordant relationships, who are planning to conceive, are offered PrEP to assist with safe conception. The HIV positive should be initiated on ART as soon as possible and monitored for viral load suppression and the couple encouraged to use a condom at this stage. The HIV negative partner is offered PrEP for protection as soon as possible while waiting for viral load suppression and continue with PrEP while the couple is trying to conceive. PrEP will be offered to such couples on a much larger scale to strengthen safer conception.

There is no safety-related rationale for disallowing or discontinuing PrEP use during pregnancy and breastfeeding for HIV-negative women who remain at risk of HIV acquisition. The risk of mother-to-child-transmission of HIV far outweighs any potential risk of fetal or infant exposure to TDF used in PrEP. In the light of this benefit, women who wish to conceive, but remain in substantial risk of HIV

infection, will be offered PrEP after all the risks and benefits have been explained to them.

1.6 RESOURCES REQUIRED FOR PREP

1.6.1 PrEP providers

HTS will be the primary platform for the delivery of PrEP. The counsellors will be the main PrEP providers. They must be trained on the clinical provision of PrEP, must be able to take blood and perform some tests and give clients results. They must be mentored, supported with structures supervision in place. Peer educators provide education and can assist with advocacy and demand generation for PrEP.

Training of staff must sensitize staff to HIV prevention and include the rationale for offering PrEP and the supporting evidence as well as the needs of specific populations. Additional training will cover key clinical areas such as safety, relevant testing before initiating PrEP, monitoring of PrEP users. Since PrEP is not a standalone intervention, it will be integrated into existing training modules for HIV prevention.

1.6.2 Medicine selection

The 2017 Eritrean ART guidelines have included Tenofovir/Lamivudine (TDF/3TC) and Tenofovir/Emtricitabine (TDF/FTC) as preferred regimens for post-exposure prophylaxis (PEP) and the treatment of hepatitis B infection and are already in the essential list of medicines. The same drugs will be used for PrEP, with the preferred regimen being the TDF/FTC and having TDF/3TC as an alternate regimen. These drugs are safe and have high

efficacy. The same drugs are also used for the treatment of Hepatitis B infection.

The existing procurement and distribution systems will be used to facilitate the supply of PrEP drugs. Forecasting for PrEP drug supply and demand will depend on projections for demand and expected program growth, which will be determined by the supply per client, adherence and retention in PrEP services.

Risk of drug resistance in not common and occurs in those who initiate PrEP when they already have acute, undetected HIV infection. It is therefore critical to exclude acute HIV infection before initiating PrEP to avoid drug resistance.

1.6.3 PrEP Site selection

Implementation of PrEP will be done in a phased-in approach, within a selected number of sites in Eritrea. These will be in Asmara, where it is anticipated that KPHR go for health services and are therefore most likely to access PrEP services.

The selected sites would be those that are already providing HTS, have access to laboratory services and have a counsellor who can prescribe PrEP drugs.

1.7 MONITORING AND EVALUATION

Among biomedical prevention interventions, PrEP is one that requires high adherence to be effective, needs on-going monitoring for safety through laboratory tests and repeated HIV testing and is costlier than options such as condoms. Routine monitoring of the PrEP programme will therefore assess uptake, effective use and safety, as well as assist with the forecast demand

to ensure a sufficient, uninterrupted supply of all the required commodities.

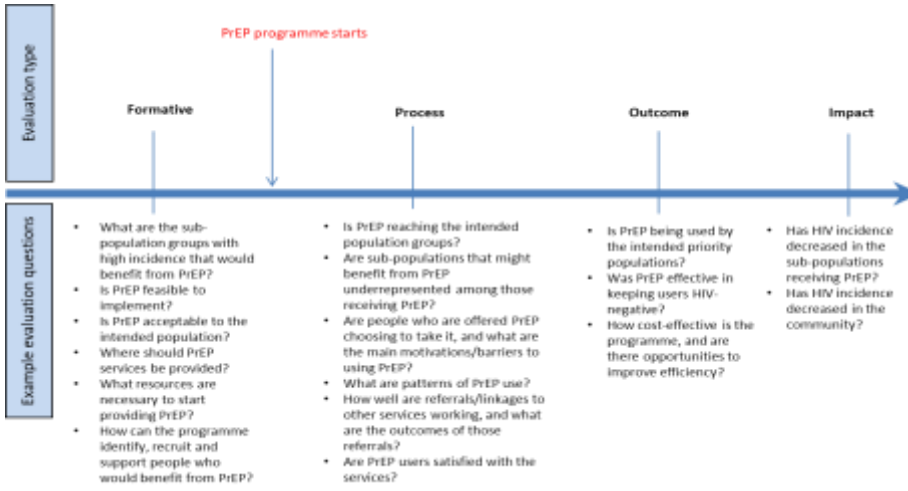
Monitoring of the PrEP programme will be incorporated into facility-based routine reporting, with data collected under the health management information system. The data should be captured continuously in the PrEP register, aggregated periodically (monthly or quarterly).

The following four indicators will be collected:

PrEP uptake: It assesses uptake of PrEP among those who are eligible. It will have three categories – those who initiated PrEP for the first time, those who may have discontinued and restarted PrEP in the reporting period, as well as those who are continuing PrEP.

Continuation in PrEP: The indicator measures the continuation of PrEP among those who start PrEP and assesses drop-out or loss to follow-up. Research has shown that many users who discontinue oral PrEP do so during the first few months. If the percentage of people who continue PrEP at three months is low, further investigation into the reasons that people stopped taking PrEP (whether due to side-effects, changes in behaviour/risk or structural factors) could be determined and programmes adjusted as needed.

PrEP toxicity prevalence: The indicator measures the discontinuation or disruption of PrEP as result of serious side effects, defined as a life-threatening illness, death, disability, hospitalization or any adverse drug reaction that resulted in PrEP discontinuation.


Evaluation type
PrEP programme starts
Formative
Process
Outcome
Impact
Example evaluation questions
What are the sub-population groups with high incidence that would benefit from PrEP?
Is PrEP feasible to implement?
Is PrEP acceptable to the intended population?
Where should PrEP services be provided?
What resources are necessary to start providing PrEP?
How can the programme identify, recruit and support people who would benefit from PrEP?
Is PrEP reaching the intended population groups?
Are sub-populations that might benefit from PrEP underrepresented among those receiving PrEP?
Are people who are offered PrEP choosing to take it, and what are the main motivations/barriers to using PrEP?
What are patterns of PrEP use?
How well are referrals/linkages to other services working, and what are the outcomes of those referrals?
Are PrEP users satisfied with the services?
Is PrEP being used by the intended priority populations?
Was PrEP effective in keeping users HIV-negative?
How cost-effective is the programme, and are there opportunities to improve efficiency?
Has HIV incidence decreased in the sub-populations receiving PrEP?
Has HIV incidence decreased in the community?

CHAPTER 2: GUIDELINES

Guidelines for the safe use of Oral PrEP

2.1 PRE-EXPOSURE PROPHYLAXIS

Oral PrEP for HIV is the use of antiretroviral drugs by HIV-negative people to prevent HIV infection, beginning before and continuing after potential HIV exposure. The WHO recommends that PrEP (containing tenofovir disoproxil fumarate) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of a combination of prevention approaches. Oral PrEP should not displace prevention strategies currently implemented in Eritrea, which include HTS, counselling, male and female condoms, and ART for HIV-positive partners in sero-discordant relationships.

In Eritrea, PrEp will be offered to individuals who have had any of the following risk factors in the past six months:

- Inconsistent use of condoms with more than one partner,
- A recent history (in the last six months) of an STI
- Individual who request PrEP (requesting PrEP has been shown to be an indicator of substantial risk)
- HIV negative persons in sero-discordant relationships until the HIV positive partner is virally supressed.

2.1.1 Eligibility for PrEP

The following criteria will be used to offer PrEP:

- HIV-negative by routine rapid antibody test
- Absence of symptoms of acute HIV infection (recent acute viral illness)
- Willing and able to take PrEP as prescribed,
- No contraindications to TDF, FTC or 3TC

2.1.2 Contraindications to PrEP

The contraindications for PrEP are:

- Pre-existing HIV infection
- Possibility of recent exposure to HIV
- Signs or symptoms of acute HIV infection, (refer to table 1)
- Poor renal function (estimated creatinine clearance < 60 mL/min)[1]
- Allergy or contra-indication to TDF, FTC or 3TC
- Unwilling or unable to return for follow-up monitoring visits

Table 2. Acute Viral Symptoms of HIV Sero-conversion

Symptoms	Signs
Malaise, anorexia, myalgia, headache, sore throat, rash, fever,	viral meningitis, generalised lymphadenopathy, hepatosplenomegaly, pharyngitis, orogenital herpetiform ulceration, oral/oesophageal candidiasis, cervical adenopathy

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

[1] **Creatinine Clearance** = [[140 - age(yr)]*weight(kg)]/[72*serum creatinine

2.2 PREP INITIATION

2.2.1 Baseline clinical investigations

Table 3. Baseline Investigations prior to PrEP initiation

Investigation	Rationale and Plan of action
HIV test (use algorithm in national HTS guidelines)	Assess HIV infection status. If positive, client must not be initiated on PrEP, but should be immediately referred for ART.
Serum creatinine	If creatinine clearance is <60 mL/min (abnormal renal function), test must be repeated after two weeks. If renal function returns to normal and other PrEP criteria are met, PrEP may be initiated.
Hepatitis B surface antigen (HBsAg)	To identify undiagnosed hepatitis B infection. If positive, refer for further testing and assessment for long-term HBV treatment.
Screening for STIs (syndromic/diagnostic)	Diagnose and treat STIs
Pregnancy testing	To identify if the client is pregnant. Pregnancy is not a contraindication for PrEP. Offer PrEP after all the risks and benefits have been explained to the client.

2.2.2 Counselling

Table 4. Key messages for counselling before PrEP initiation.

Topic	Key Messages
What is PrEP?	PrEP is an additional HIV prevention option and where possible, should be used in combination with condoms. PrEP does not protect against other STIs or prevent pregnancy.
PrEP is not for life	PrEP is taken for as long as the individual is at risk for HIV infection. PrEP can be discontinued if the individual is no longer at risk.
PrEP works if taken	For PrEP to be effective, it must be taken every day. Consistent use requires that PrEP be included in the daily routine. If a dosage is missed, the client must take PrEP as soon as he or she remembers, and continue to take daily as before.
Side effects	PrEP is safe, with no side effects in most of the users. Some individuals may report minor side effects in the first few weeks of PrEP use, such as diarrhea, headache, abdominal pain and nausea. Major side effects associated with PrEP are very rare.*
Drug interactions	Taking alcohol will not reduce the effectiveness of PrEP. PrEP can be taken with any kind of contraception.

Starting and stopping PrEP	7 days of PrEP are needed before achieving full protection from HIV PrEP should be continued for 28 days after the last potential HIV exposure in those wanting to cycle off PrEP. The client must notify the provider if he or she decides to stop taking PrEP.
Safe conception	PrEP can be used throughout pregnancy and breastfeeding
Visit schedule	The client must return for follow-up HIV testing, counselling and safety monitoring visits.
*Major side effects are rare and include renal toxicity and metabolic complications decreased bone mineral density (which is reversible), extremely small risk of lactic acidosis and hepatic steatosis or steatohepatitis.	

2.2.3 Prescription of PrEP drugs

The recommended regimen is:

- TDF/FTC (300/200mg) as a fixed-dose combination: 1 tablet by mouth daily.
- TDF/3TC (300/300mg) may be offered as an alternate regimen: 1 tablet by mouth daily.

Prescription intervals:

- At initiation – provide 1 month supply.
- At 1 month follow-up visit – provide 1 month supply.
- At 2 months follow-up visit – provide 1 month supply.
- At 3 months and every 3 months thereafter – provide 3 months supply if the client reports good adherence.

2.3 PrEP FOLLOW-UP

2.3.1 Safety monitoring and maintenance

On-going education, counselling and monitoring should be provided to the client at each PrEP visit as detailed in Table 4 below.

Table 5. PrEP Management Checklist

ALWAYS ENSURE ADHERENCE ○ Assess adherence and commitment at EVERY visit. ○ If signs and symptoms of acute HIV are present at any follow-up visit, continue PrEP while awaiting HIV test results. ○ Schedule visits every 30 days (monthly) for clients who report poor adherence.
1-month FOLLOW-UP VISIT ○ Confirmation of HIV-negative status ○ Address for side effects ○ Adherence counselling (also enquire about missed) ○ Issue 1 month supply of PrEP medication ○ Schedule next month visit
2-month FOLLOW-UP VISIT ○ Address for side effects ○ Adherence counselling ○ Issue 1 month supply of PrEP medication ○ Schedule next monthly visit
3-month FOLLOW-UP VISIT (and every 3 months thereafter) ○ Confirmation of HIV-negative status ○ Address for side effects

- Adherence counselling
- Creatinine clearance test (every 3 months in first year, then annually thereafter)
- If adherence has been good, issue 3 months' supply of PrEP medication
- STI screening and treatment
- Schedule next 3 monthly visit

2.3.2 Risk Reduction Counselling

- As an approach to decreasing acquisition of HIV and other STIs, providers should offer male and female condoms to all clients at each visit.
- In addition, HIV prevention counselling, sexual reproductive health and contraceptive counselling should be offered at all follow-up visits.
- If clients have partners with HIV, providers should emphasize the evidence that transmission risk is negligible if the individual with HIV infection in a serodiscordant partnership has a fully suppressed viral load.

2.3.3 Sero-conversion on PrEP

Oral PrEP must be taken daily for it to be effective. However, HIV sero-conversion following PrEP initiation may occur and this could be due to:

- **PrEP failure:** People who take PrEP consistently as prescribed and get infected with HIV while taking PrEP,
- **People who take PrEP inconsistently** or do not take it as prescribed.

- **People who stop PrEP for a variety of reasons**. It is important to quantify and assess this group and the reasons for their disengagement in care in order to inform programme improvement.

The provider must engage the client and assess which of the factors stated above may have led to sero-conversion. This must be documented in the PrEP Register.

As soon as an HIV-positive test has been confirmed, the client must be informed and counselled and Referred for ART.

2.4 DISCONTINUING PrEP

The client should be advised to inform the provider when he or she wants to discontinue PrEP. The provider should discontinue PrEP in any client who:

- Has a confirmed positive HIV test
- Has abnormal renal function (estimated creatinine clearance < 60 mL/min), after repeat testing
- No longer wishes to take PrEP
- Is non-adherent to PrEP
- Is no longer at risk of HIV acquisition
- Allergy or contra-indication to TDF, FTC or 3TC

Hepatitis B is endemic in Eritrea, and the medications used for PrEP (TDF and FTC) are both active against hepatitis B. Exposure to TDF and FTC may treat unidentified chronic hepatitis B infection, and drug discontinuation may result in **life-threatening rebound viraemia**. To avoid this risk, every PrEP user should be tested for hepatitis B surface antigen (HBsAg). Individuals with detectable HBsAg should be investigated further and managed appropriately

2.5 MONITORING AND EVALUATION

Routine monitoring of the PrEP programme will be essential to assess uptake, effective use and safety. Monitoring and evaluation (M&E) will ensure that PrEP is being delivered safely and effectively and that services focus on those who would benefit most.

At the time of writing the guidelines, the WHO suggests using the following 4 core indicators for the routine monitoring of PrEP programmes to assess uptake, retention and safety. The data should be captured continuously in the PrEP register, aggregated periodically (monthly or quarterly).

Table 6: Core Indicators for monitoring PrEP

Core indicator	Definition	Point of collection
Uptake	Percentage of eligible people who received oral antiretroviral PrEP at least once in the last 12 months.	At PrEP initiation
Continuation on PrEP	Percentage of PrEP users who continue on oral PrEP for three months after initiating PrEP in the last 12 months.	At the 3 month follow-up visit
PrEP Associated Toxicity Prevalence	Percentage of people who have received oral PrEP who have discontinued or interrupted PrEP due to a serious ARV-associated toxicity in the last 12 months.	When the client confirms that he/she will no longer take PrEP due to drug toxicity

HIV positivity among people who have been prescribed PrEP	Percentage of people who test HIV-positive who received PrEP at least once in the last 12 months and had at least one follow up HIV test.	At the follow-up visit where sero-conversion is confirmed