MINISTRY OF HEALTH

Pre-exposure Prophylaxis for the Prevention of HIV Infection:

A Toolkit for Providers

NASCOP
National AIDS and STI Control Program

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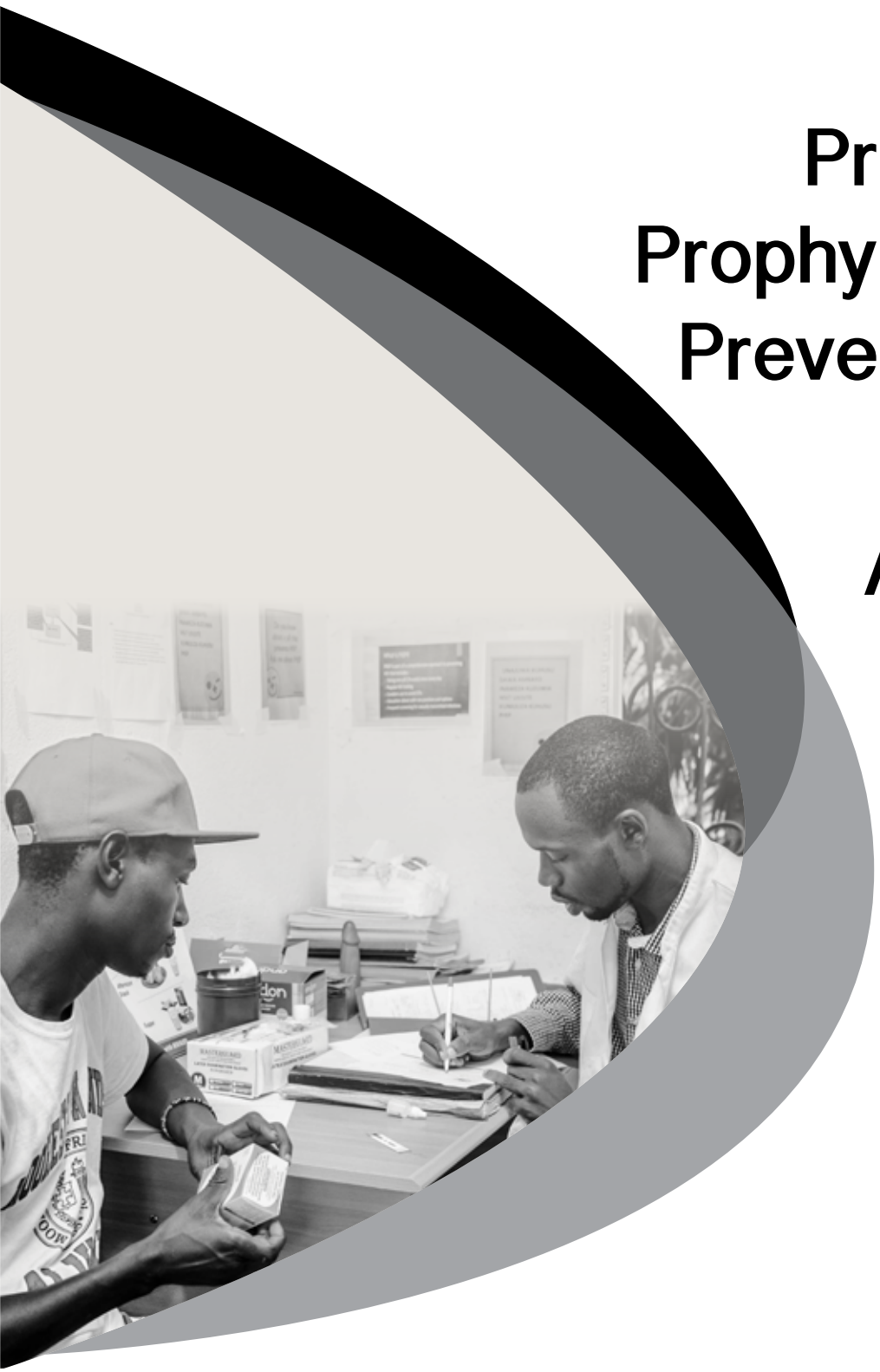

Pre-exposure Prophylaxis for the Prevention of HIV Infection:

A Toolkit for Providers

National AIDS and STI Control Program

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The purpose of this toolkit is to provide additional detailed information for healthcare workers to safely and effectively use PrEP as part of combination prevention of HIV infection. All reasonable precautions have been taken to verify the information contained in this toolkit. However, it is the responsibility of healthcare providers to cross-check and confirm the accuracy of any recommendations herein.

For clarifications contact National AIDS and STI Control Program (NASCOP) on P.O. Box 19361 00202, Nairobi Kenya, Tel: 254 775597297, Email: info@nascop.or.ke, Website: www.nascop.or.ke

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Foreword

Kenya has made tremendous progress in containing the HIV epidemic. The HIV prevalence has dropped by nearly 50% from a peak of 10.6% in 1995/96 to approximately 5.9% in 2015. This decline has been made possible through the aggressive implementation of a combination of evidence-informed interventions including scale-up of antiretroviral therapy. However, the decline in new infections (incidence) has remained modest with nearly 71,000 new infections occurring every year. Combination HIV prevention provides healthcare providers with expanding behavioural and biomedical interventions, which, if used effectively, will further reduce the number of new infections. Recent evidence has shown daily oral antiretroviral agents, taken by HIV uninfected individuals at substantial ongoing risk of HIV infection, can significantly reduce the chances of HIV infection. Based on this evidence, the Ministry of Health in 2016, reviewed the HIV treatment guidelines to incorporate guidance on pre-exposure prophylaxis for the prevention of HIV infection in Kenya.

'Pre-exposure Prophylaxis for the Prevention of HIV Infection - A Toolkit for Health Service Providers' was developed by NASCOP to support the implementation and scale-up of pre-exposure prophylaxis (PrEP). Good quality evidence from clinical trials and demonstration (pilot) projects has shown that PrEP, when used appropriately, is a safe and highly effective means of reducing the risk of HIV infection in HIV uninfected individuals at substantial ongoing risk of HIV infection.

To obtain the full benefits of its use, PrEP must be provided under the supervision of trained healthcare providers, and as part of a combination of HIV prevention interventions tailored to each individual's vulnerability, risk profile and local HIV infection transmission determinants and burden. Providers should assess clients for eligibility, suitability, and offer ongoing monitoring, risk reduction and adherence support.

The purpose of this toolkit is to provide health service providers, agencies and institutions with succinct information and guidance to safely and effectively deliver PrEP. The toolkit contains information on clinical overview for PrEP use, commodity management, modalities of ensuring quality of PrEP services and monitoring and evaluation of PrEP services. It is my hope that all those concerned with health services delivery, will, with a sense of urgency, make PrEP available and accessible to all who need it across the country. I am certain that this toolkit will contribute to increasing access to PrEP for HIV prevention in Kenya.

Dr. Kigen B. Bartilol

Head of the National AIDS &
STI Control Programme.

Acknowledgements

This toolkit has been compiled through the collaborative efforts of individuals from National AIDS and STI Control Programme (NASCOP) and many institutions. The main source of information the toolkit was the 'Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV infection in Kenya, 2016 Edition'. The following institutions provided additional material and information for the toolkit: the DREAMS Project, LVCT Health, Jhpiego and Partners Demonstration Project (University of Washington).

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I take this opportunity to specifically acknowledge all who coordinated and guided the entire process. A comprehensive list of contributing organizations, individuals and reviewers is provided in Appendix 12.

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Abbreviations and Acronyms

ADR	Adverse Drug Reaction
AGYW	Adolescent Girls and Young Women
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARVS	Antiretroviral Drug(s)
CDC	Centers for Disease Control and Prevention
CHVs	Community Health Volunteers
DHIS	District Health Information System
DICEs	Drop In Centers
EMR	Electrical Medical Records
FSWs	Female Sex Workers
GBV	Gender-Based Violence
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
KASF	Kenya AIDS Strategic Framework
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KP	Key Population
LMIS	Logistics Management Information System
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MSM	Men Who Have Sex with Men
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Program
NEPHAK	Network of People Living with HIV/AIDS in Kenya

NHRL	National HIV Reference Laboratory
NPHLs	National Public Health Laboratories
OPD	Out Patient Department
PEPFAR	President's Emergency Plan for AIDS Relief
PMTCT	Prevention of Mother-To-Child Transmission
PrEP	Pre-Exposure Prophylaxis
PPB	Pharmacy and Poisons Board
PWID	People who Inject Drugs
SOPs	Standard Operating Procedures
STIs	Sexually Transmitted Infection
SWOT	Strengths Weakness Opportunity Threats
TDF	Tenofovir Disoproxil Fumarate
TWG	Technical Working Group
USAID	United States Agency for International Development
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

Purpose

The purpose of this toolkit is to provide additional detailed information for healthcare workers to safely and effectively use PrEP as part of combination prevention of HIV infection.

Section 1: Provides an overview of relevant information for HCW who are providing PrEP in clinical settings. It describes important considerations when starting PrEP and monitoring use of PrEP.

Section 2: Provides highlights on PrEP commodities management including PrEP commodity consumption data capture and the reporting HIV (ARVs) LMIS tools and pharmacovigilance system for PrEP.

Section 3: Contains information on quality improvement with emphasis on optimizing client and service delivery outcomes

Section 4: Contains guidance on how to use PrEP data capture and reporting tools and outcome definitions for PrEP.

Section 5: Appendices

Section 1: Clinical Overview

This section provides an overview of relevant information for health care workers (HCW) who are providing PrEP in clinical settings and describes important considerations when starting and monitoring use of PrEP.

1.1 Overview for Pre-exposure Prophylaxis

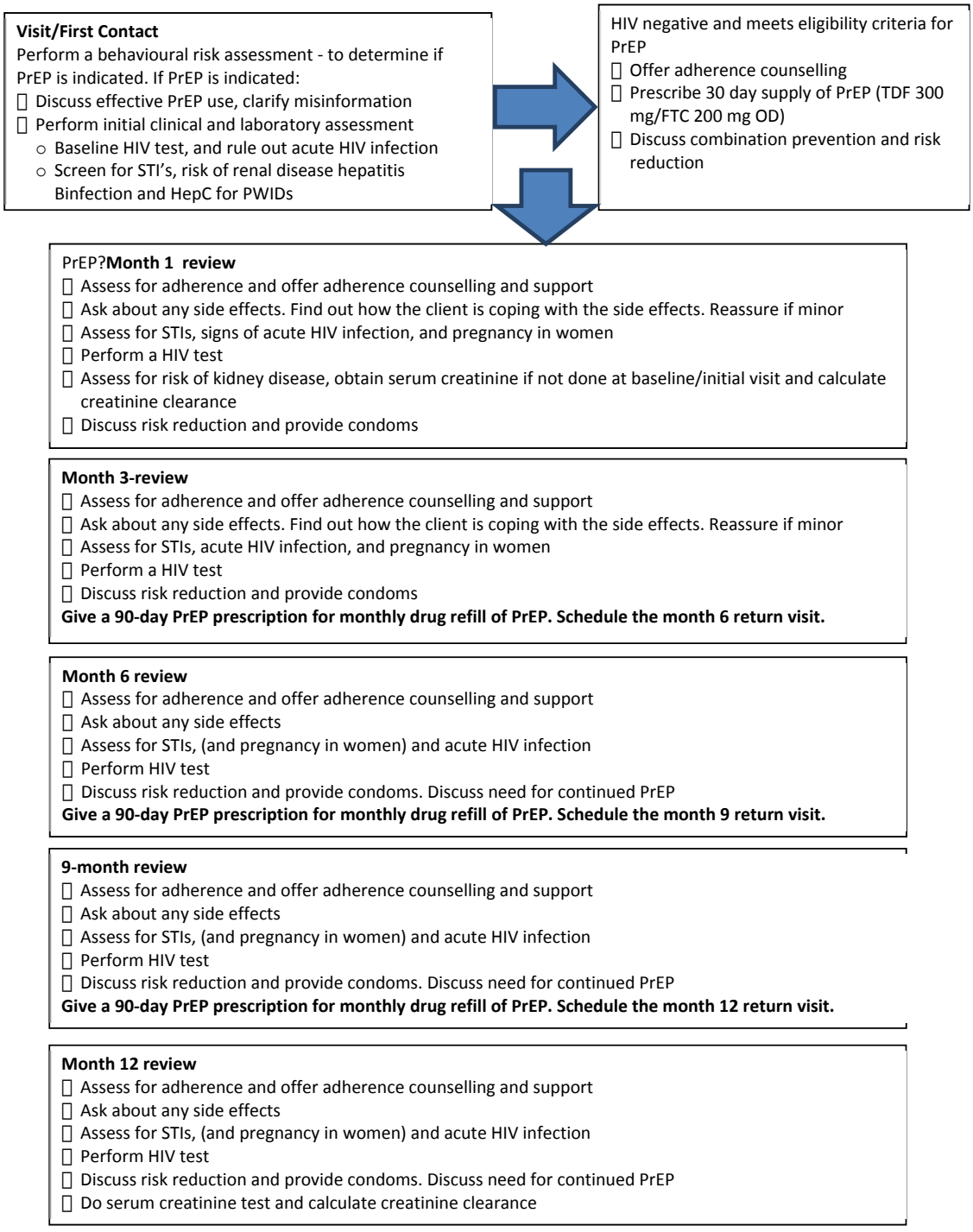
Table 1.1: **Overview of Recommendations for Pre-exposure Prophylaxis**

What is PrEP?	PrEP is a form of HIV prevention in which a HIV negative person at high risk of HIV infection takes daily oral antiretroviral agents to prevent HIV infection.
Who can take PrEP? (indications for PrEP)	PrEP is recommended for HIV negative persons at substantial ongoing risk of HIV infection such as: • In a HIV serodiscordant relationship where the sexual partner with HIV has not been on effective (suppressive) therapy for the preceding 6 months, or HIV serodiscordant couples trying to conceive • Pregnant or breastfeeding women whose sex partners are HIV positive or at high risk of HIV infection • Sexual partner/s of unknown HIV status and is/are at high-risk for HIV infection (has multiple sexual partners, has had STIs, engages in transactional sex, injects drugs, or from high HIV burden settings) • Engaging in transactional sex • Recent sexually transmitted infection • Recurrent use of post-exposure prophylaxis • History of sex whilst under the influence of alcohol or recreational drugs as a habit • Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status • Injection drug use where injection equipment is shared
Contraindications to PrEP	• HIV infection (confirmed HIV positive) • Renal impairment - as shown by creatinine clearance < 50 ml/min • Lack of willingness to adherence to daily PrEP and associated follow-up schedule • Adolescents weighing < 35kgs or age < 15 years
Initiating PrEP	PrEP is initiated only after thorough behavioural and risk assessment (to establish level of risk and willingness to use PrEP) and clinical and laboratory evaluation (to exclude HIV infection and establish safety to use PrEP). Clients should also receive adequate adherence and ongoing risk reduction counselling.
What are the recommended PrEP medications?	*Preferred* • TDF/FTC (300 mg/200 mg) as FDC once daily *At initiation, prescribe PrEP for ONLY 30 days to allow for follow-up visits to assess adherence, tolerability and commitment to continue with PrEP. Subsequently, longer prescriptions may be given; however, the medicines should be issued monthly.*

What is effective PrEP use?	PrEP should be offered as part of a comprehensive, individualized prevention plan following behavioural risk assessment and adherence counselling. Combination prevention includes: ● Risk reduction counselling ● Safer sex practices ● Consistent & correct condom use ● VMMC (where indicated) ● Prevention and treatment of STIs ● Substance abuse treatment ● Prevention of gender-based violence (GBV) ● Adherence to PrEP - efficacy of PrEP is dependent on adherence. ● Effective cART for HIV+ persons (Treatment as Prevention) ● After initiation PrEP will be effective after a minimum of 7 days of consistent use.
Follow-up	After starting PrEP, clients require regular follow-up (initially at 1 month) then every 3 months thereafter (i.e months 1, 3, 6, 9, 12, 15, 18 etc) to monitor HIV status (every 3 months), offer risk reduction counselling, adherence assessment and support, and assess for side effects. Obtain creatinine at baseline i.e. before initiation and thereafter annually or earlier/more frequently if clinically indicated.
Duration	PrEP is not meant to be a lifelong intervention. It is a method of HIV prevention during periods when a person is at greatest risk of acquiring HIV.
Discontinuation of PrEP	PrEP should be discontinued in any of the following circumstances ● HIV positive ● change in risk (to low risk) ● renal adverse effect (CrCl < 50 ml/min) ● sustained non-adherence ● sustained viral suppression in the HIV partner of a discordant couple ● client request to discontinue.

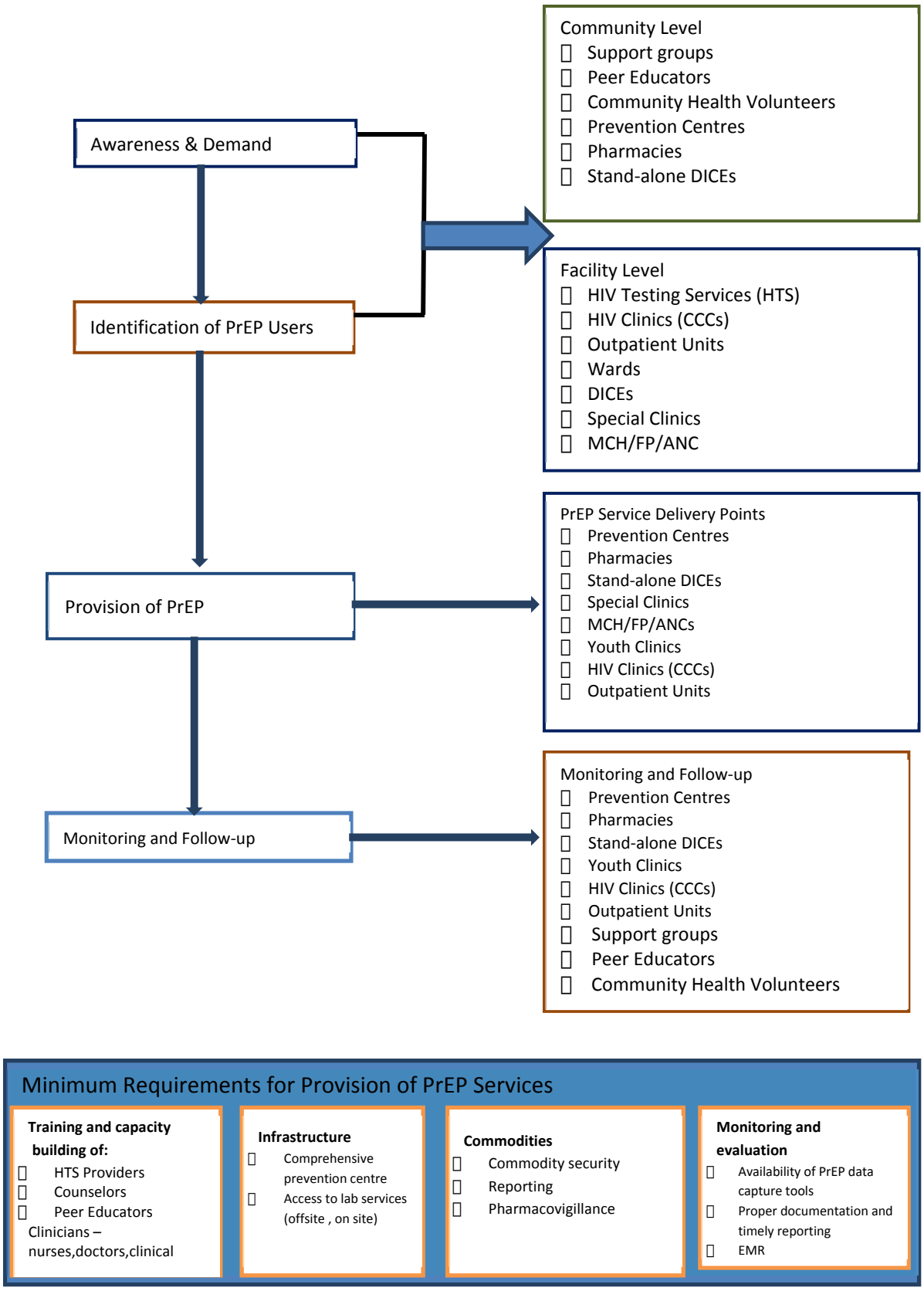
Figure 1.1: **Schema for Managing Pre-Exposure Prophylaxis for HIV Prevention**

After routine care is established, the client should get a 90-day PrEP prescription for monthly drug refills, adherence review and risk assessment; and be scheduled for full clinical assessment every 3 months.



Note: Risk and adherence assessment and support should be offered during each visit including at dispensing refill visits.

Figure 1.2: **Entry Points for PrEP and other HIV Prevention Services**

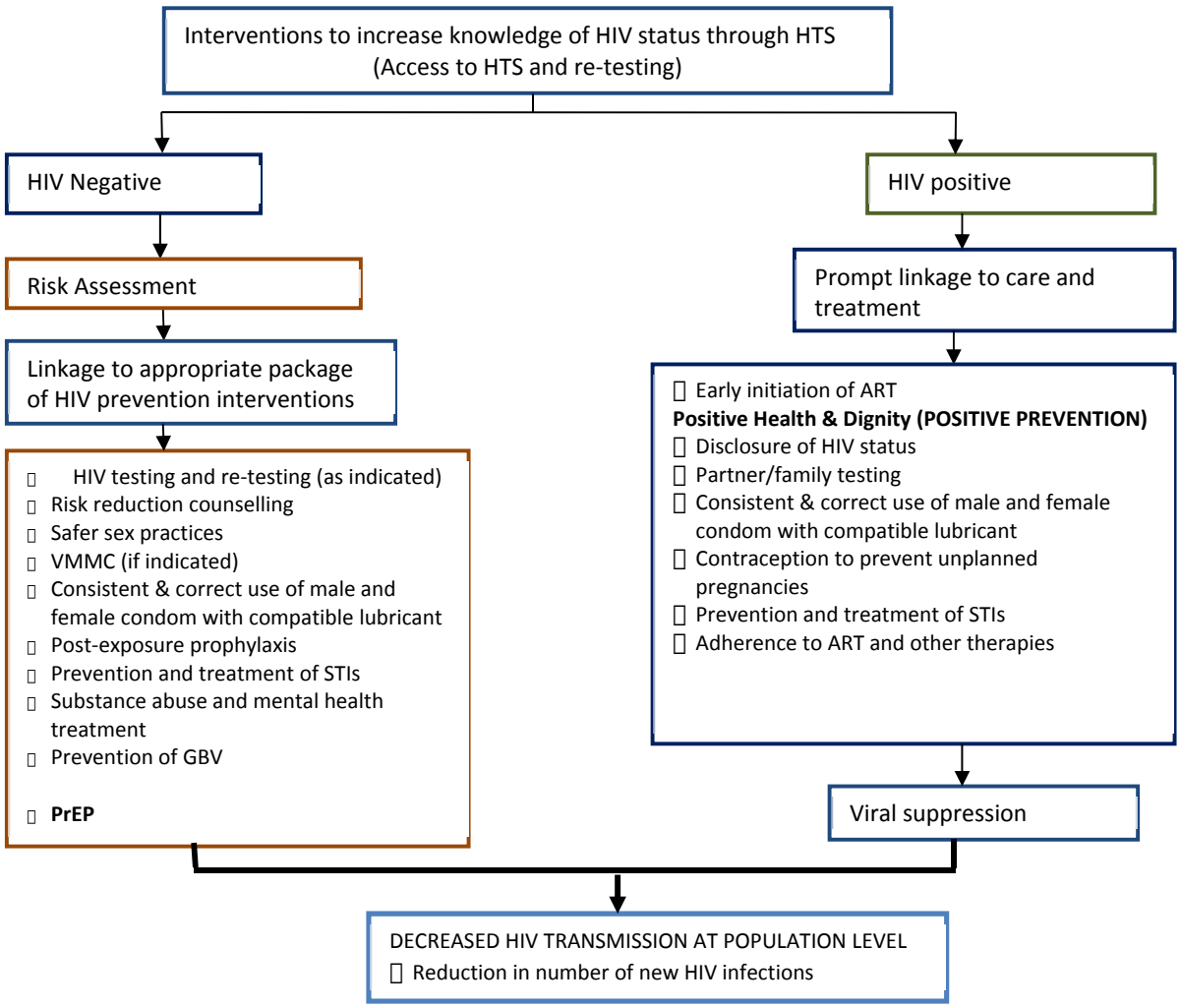


igure 1. 2 Entry Points for PrEP and other HIV Prevention Services

1.2 Comprehensive prevention services

PrEP should not be provided in isolation, but as part of a package of combination prevention individualized to a client's preference, characteristics, risk profile and local HIV disease burden. It's recommended that PrEP services be integrated within the existing HIV prevention services e.g HTS, FP,CCC, DICEs, PWI ,STI screening and treatment, condom and lubricant distribution , PEP, MCH, ANC. The primary purpose of integration in this instance is to make services more convenient and to increase uptake of HIV specific services. Figure 1.3 summarizes steps for combination prevention for clients accessing PrEP services.

Figure 1.3: **Combination Prevention of HIV Infection**



1.3 Indications and Risk Assessment for Pre-Exposure Prophylaxis.

PrEP for prevention of HIV infection is **only** offered for HIV negative individuals at **substantial ongoing** risk of HIV infection by meeting any of the following **indications**;

- An individual whose sexual partner is known to be HIV positive and: not on ART, or on ART but has not achieved viral suppression (often ART for less than 6 months), or on ART but with suspected poor adherence.
- A person whose sexual partner/s are of unknown HIV status and are at high-risk for HIV infection (multiple sexual partners, history of STIs, transactional sex, injection drug use or from high HIV burden settings)
- Engaging in transactional sex
- History of recent (within the last 6 months) or current sexually transmitted infection (laboratory confirmed or self-report or received syndromic treatment)
- Recurrent use of post-exposure prophylaxis (in the last 6 months)
- History of sex whilst under the influence of alcohol or recreational drugs as a habit
- Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status
- Injection drug use where needles and syringes are shared
- Sero-discordant couples trying to conceive (irrespective of treatment status of the HIV positive partner)
- Pregnant or breastfeeding women whose sex partners are HIV positive or at high risk of HIV infection

Potential PrEP users must meet all of the following **eligibility criteria** prior to initiating PrEP

- Substantial on going risk of HIV infection
- No suspicion of acute HIV infection
- Documented HIV negative test
- No contraindications to prep medications (TDF/FTC or TDF/3TC or TDF)
- Willingness to use prep as prescribed, including regular visits to monitor HIV status, adherence and side effects

1.4 Assessing for 'substantial ongoing' risk of HIV Infection.

Screening questions are used to identify (for further discussions and assessment) individuals who may be offered PrEP based on personal circumstances, risk and desire for additional HIV prevention. The questions are framed to elicit people's behaviours and vulnerabilities as opposed to specific sexual practices.

Before starting the sexual behavioural assessment,

- Ensure adequate privacy
- Assure the patient of confidentiality and indicate that the issues to be discussed may be very personal and that he/she is free to answer or decline
- Explain that this is routine practice to help provide appropriate sexual and reproductive healthcare
- Stress that the findings from the conversation will be kept confidential and only used for purposes of providing better care
- Make the patient comfortable

General Screening Questions (any 'yes' should prompt a discussion of the benefits of PrEP)

Preamble statement: I wish to ask you a couple of questions about your sex life. Some of these questions may not be comfortable but are important in helping to explore your risk of HIV infection. I would request that you answer honestly and openly. All the information you provide will be kept confidential and will only be used to better meet your health needs.

In the past 6 months,

- "Have you had sex with more than one person?"
- "Have you had sex without a condom?"
- "Have you had sex with anyone whose HIV status you do not know?"
- "Are any of your partners at risk of HIV?"
- "Do you have sex with a person who has HIV?"
- "Have you received a new diagnosis of a sexually transmitted infection?"
- "Do you desire pregnancy?"
- "Have you used or wanted to use PEP or PrEP for sexual exposure to HIV?"
- "Have you injected drugs that were not prescribed by healthcare provider? If yes, did you use syringes, needles or other drug preparation equipment that had already been used by another person?"
- "Have you received money, housing, food or gifts in exchange for sex?"
- "Have you been forced to have sex against your will?"

- "Have you been physically assaulted, including assault by a sexual partner?"

Screening Questions for People in Discordant Relationships

For the HIV negative individual in a discordant relationship, the following screening questions help to establish the need for PrEP

- "Is your partner taking ART for HIV?"
- "Has your partner been on ART for more than 6 months?"
- "At least once a month, do you discuss whether your partner is taking therapy daily?"
- "If you know, when was your partner's last HIV viral load test? What was the result?"
- "Do you desire pregnancy with your partner?"
- "Do you use condoms every time you have sex?"

Additional questions to ask to elicit increased vulnerability to HIV infection:

- Are you in a new relationship?
- Have you recently ended a long-term relationship and are looking for a new one?
- Have you been forced to leave home?
- Have you recently moved to a new place (with high HIV prevalence)?
- Have you recently lost a source of income (such that you may be forced exchange sex for food, housing or money)?
- Have you dropped out of school?

The risk assessment tool (appendix1) and is to be used to screen clients for PrEP eligibility

1.5 Contraindications for PrEP

- HIV infection (confirmed HIV positive) or suspected acute HIV infection
- Renal impairment - as shown by creatinine clearance < 50 ml/min
- Lack of willingness to adherence to daily PrEP and associated follow-up schedule
- Adolescents weighing < 35kgs or age < 15 years

1.6 Excluding Acute HIV Infection

Inquire about the presence of fever, fatigue, myalgia, rash, headache, sore throat, cervical adenopathy, arthralgia, night sweats, or diarrhoea; in the context of high-risk sexual contact within the past month.

1.7 Managing Suspected Acute HIV Infection

If the baseline HIV test is negative, but the client is suspected to have acute HIV infection (flu-like illness with recent high-risk exposure), PrEP should be delayed and the client advised on safer sex practices. Assess for other STIs. Repeat the HIV test after 4 weeks, and if negative, PrEP may then be initiated (if indicated).

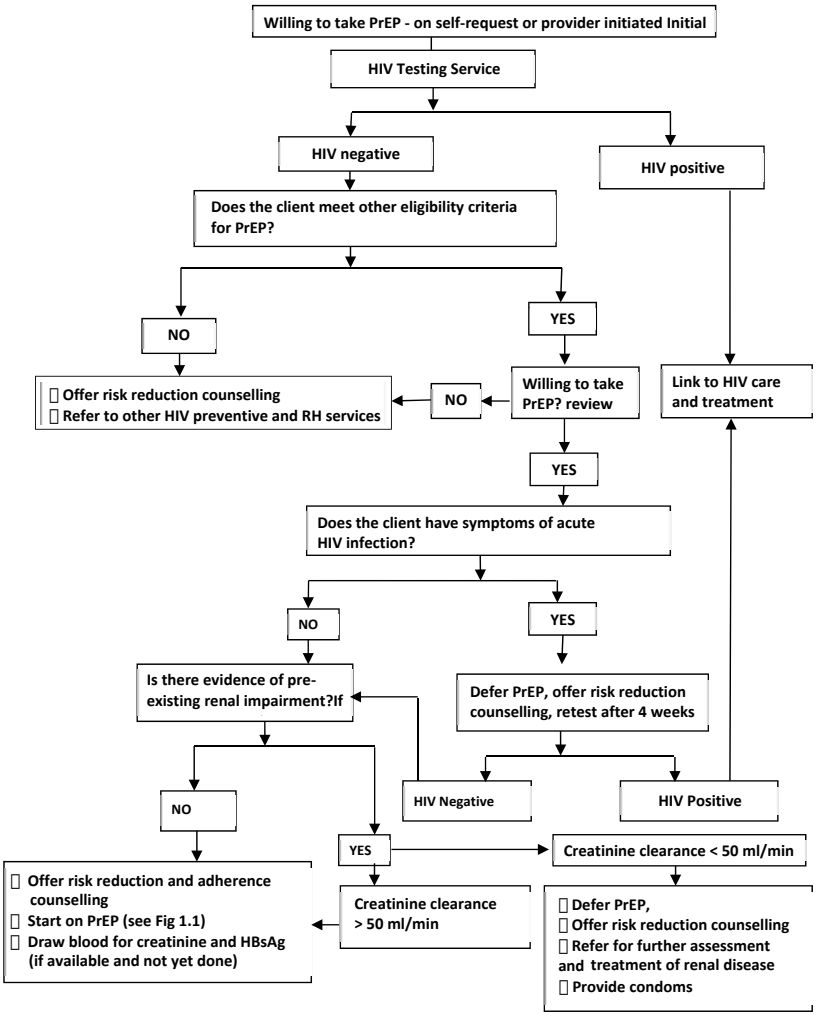
1.8 Managing High Risk Exposure within the last 72 hours

In HIV seronegative clients who have had a high-risk exposure to HIV within the last 72 hours, provide PEP for 28 days. Obtain a rapid HIV test at 28 days, if the test result is negative, transition to PrEP immediately (if the client is eligible for PrEP).

1.9 Initiating Pre-Exposure Prophylaxis

PrEP should only be started after a clinical and laboratory assessment, adequate preparation through health education, and adherence counselling. Figure 1.4 provides the overview of the requisite steps before a client is started on PrEP.

Figure 1.4: **Initiating Pre-Exposure Prophylaxis**



Once a decision is made that a client requires PrEP, further assessment (listed in Table 1.2) should be carried out to establish safety and suitability of PrEP for the individual client.

Table 1.2: **Initial Assessment**

Assessment/Service	Rationale
Complete medical history and examination	● To identify medical conditions that could affect the management of PrEP • Past or current kidney disease • Risk of kidney disease (diabetes mellitus, uncontrolled hypertension, chronic NSAID use) • Use of other nephrotoxic agents e.g acyclovir, amino glycosides ,retinoids e.t.c • Past or current liver disease • Current or past chronic hepatitis (B or C) • Acute HIV infection. If acute HIV infection is suspected, defer PrEP until HIV infection is excluded.
Establish eligibility to use PrEP	● To establish willingness to adhere to PrEP and medical follow-up including HIV retesting ● To screen for substantial risk of HIV infection ● To document HIV status - HIV testing using the national algorithm for HTS ● To complete a symptom checklist to exclude acute HIV infection
Baseline laboratory investigations*	Urinalysis ● Proteinuria is an early indicator of TDF toxicity. An initial urinalysis helps to identify pre-existing proteinuria and risk of renal disease and therefore additional testing (creatinine) and closer monitoring after initiation of PrEP
	Serum creatinine and creatinine clearance ● To identify pre-existing renal dysfunction. PrEP is contraindicated if the baseline CrCl < 50 ml/min
	Hepatitis B surface antigen ● To identify undiagnosed current hepatitis B infection. If negative, consider vaccination against hepatitis B. [Refer to the national guidelines on hepatitis prevention and treatment]
	Hepatitis C antibody (especially in people who inject drugs, PWID). ● If positive, consider treatment for hepatitis C infection.
	Rapid Plasma Reagin ● To diagnose and treat syphilis infection.
	Pregnancy testing ● To guide antenatal care, contraceptive and safer conception counselling, and to assess risk of mother to child transmission. Pregnancy is not a contraindication to PrEP use.
Screening for other STIs	Assess for presence of dysuria, discharge, anorectal itching or pain, rash, or ulcers. To diagnose and treat STI using syndromic or diagnostic STI testing, depending on local guidelines.
Review vaccination history	Consider vaccination for hepatitis A (e.g MSM), human papilloma virus, tetanus and meningitis.

Brief counselling	• To assess whether the client is at substantial risk of HIV. • To discuss prevention needs and provide condoms and lubricants. • To discuss desire for PrEP and willingness to take PrEP. • To develop a plan for effective PrEP use, sexual and reproductive health. • To assess fertility intentions and offer contraception or safer conception counselling. • To assess intimate partner violence and gender-based violence. • To assess substance use and mental health issues. • If proceeding to offer PrEP, offer detailed initial adherence counselling (Table 1.2)

Table 1.3: **Managing Clinical and Laboratory Results on Initial and Follow-up Assessment**

Screening	Action
HIV-positive at initial evaluation	Do not start PrEP, counsel and link to care and treatment
HIV-positive after initiation of PrEP	Discontinue PrEP, counsel and link to care and treatment
Positive STI screen	Thorough genitourinary and anorectal examination, urine dipstix for urethritis, serological testing for syphilis, full STI evaluation if resources available. Refer to guidelines on syndromic management of STIs.
HBsAg-negative	Offer Hep B vaccination
HBsAg-positive	This is not a contraindication to PrEP. However, will require monitoring of liver function and referral for management of liver disease.
Flu-like illness after initiating PrEP	Continue PrEP, test for HIV at first contact and after 28 days, and if negative, continue with usual follow-up.
Side effects of PrEP	**GIT** - nausea, vomiting, weight loss: these are often mild, self-limiting and occur during the first 1-2 months. Provide supportive counselling. Offer symptomatic treatment e.g. anti-emetics like metoclopramide 10 mg 8 hourly for 3 to 5 days.
	Renal - transient increase in creatinine, and rarely proteinuria and Fanconi's syndrome (presenting as polyuria, bone pain and weakness). Where available, measure creatinine (and calculate estimated creatinine clearance) at initiation of PrEP, and annually thereafter or whenever indicated (symptom directed); or earlier/more frequently if at risk of renal disease. If creatinine clearance (eGFR) < 50 mL/min; do not start PrEP, refer for evaluation of underlying renal disease. If the renal function returns to normal, reassess for PrEP and initiate/continue PrEP (if still indicated). Monitor closely for recurrence of renal impairment. PrEP should not be prescribed for individuals using nephrotoxic drugs like acyclovir, aminoglycosides, retinoids, instead, discuss and provide alternative HIV prevention options.
Pregnancy or breastfeeding	Pregnancy and breastfeeding are not contraindications to use of PrEP. Pregnant or breastfeeding women whose sex partners are HIV positive or are at high risk of HIV infection may benefit from PrEP as part of combination prevention of HIV infection. PrEP is also indicated for HIV-negative in discordant partnerships who wish to conceive. PrEP in these situations can be prescribed during the pre-conception period and throughout pregnancy to reduce risk of sexual HIV infection.

1.10 Prescribing Pre-Exposure Prophylaxis

Table 1.4 provides the recommended regimen for PrEP. The first prescription should be for 30 days to allow for scheduling the first follow-up visit to assess adherence, tolerability and adverse effects. After the initial 3 months of follow-up, a 3-month prescription can be issued; however drug refills are done monthly.

Table 1.4: **Recommended Regimen for Pre-Exposure Prophylaxis**

Preferred	**TDF 300 mg/FTC 200 mg once daily as FDC**
Alternative 1	TDF 300 mg once daily
Alternative 2	TDF 300/3TC 300 mg once daily as FDC

NB ; Alternative 1 and 2 to be used only in consultation with NASCOP

Table 1.5: **Initial adherence preparation and counselling**

Theme	**Adherence message/action**
Climate Setting	Introduce yourself to the client, giving your name and role; ensure adequate privacy and reassure about confidentiality
What is PrEP?	PrEP involves HIV-negative people taking daily ARV medications to prevent themselves from becoming infected with HIV. PrEP is provided as part of combination prevention, including efforts at ongoing risk reduction
Does PrEP work?	Evidence from scientific studies involving HIV negative people at risk of HIV infection has shown that PrEP is highly effective if you take it as prescribed and in combination with other HIV prevention interventions.

How is PrEP used?	• PrEP is provided as tablets. You should take one tablet daily at the same most convenient time of day. To ensure you do not forget take PrEP each day:
	  ◦ Make it a habit linked to an activity you do daily such as brushing teeth, taking a meal etc
	  ◦ Disclose PrEP use to a partner or trusted person
	  ◦ Use reminder devices like a cell phone alarm
	  ◦ If available enrol into an SMS reminder system
	• If you forget to take a tablet, take it as soon as you remember; however, do not exceed 2 tablets in a day. PrEP tablets can be taken any time of day, with or without food
	• PrEP use is a personal, responsible choice to protect yourself and your sexual partners from HIV. Discussing PrEP use with trusted friends or other PrEP users may be helpful
	• PrEP can be used safely with family planning pills or injections

Starting PrEP	• You will need a HIV test before starting or re-starting (if you had stopped) PrEP. This is to ensure that you do not already have HIV infection before starting PrEP because PrEP is not effective in treating existing HIV infection. • It takes up to 7 days of daily use of PrEP tablets to achieve maximum protection. During this period, and as much as possible, you are encouraged to practice safer sex practices especially consistent, correct use of male or female condoms.

Stopping PrEP	Discuss stopping PrEP with your provider. You can stop using PrEP 28 days after your last possible HIV exposure. People can stop PrEP if they are no longer at substantial risk of acquiring HIV infection. Ways to lower risk include: • Adopting safer sexual practices, such as abstinence, or using condoms during all sexual contacts; • Sustained viral suppression in a sero-discordant couple; • Leaving sex work; • Ceasing injection drug use or the sharing injection drug use equipment
Protection from other STIs	PrEP does not offer protection from other STIs such as gonorrhoea, syphilis, herpes etc. Discuss with your provider if you suspect that you have an STI (genital sores or discharge). Using a condom each time you have sex will provide additional protection from HIV and other STIs
PrEP safety	• TDF-based PrEP is generally safe and well tolerated. • Gastrointestinal symptoms are the most common. They include nausea, diarrhoea, vomiting, decreased appetite, abdominal cramping or flatulence; dizziness or headaches. Typically, these symptoms start in the first few days or weeks of PrEP use and last a few days and almost always less than 1 month. Discuss with your provider if these side effects are severe or they persist for longer than one month. • A few people may not be able to use PrEP due to kidney-related side effects
Prevention of pregnancy	PrEP does not prevent pregnancy. Use effective contraception unless you want to get pregnant. If you want to become pregnant, discuss with your provider about safer ways to conceive.
PrEP during pregnancy and breastfeeding	PrEP can be used safely during pregnancy and breastfeeding. The risk of HIV infection is higher during pregnancy and breastfeeding. It is also easier to pass HIV to the unborn or breastfeeding baby if HIV infection occurs during pregnancy or breastfeeding. PrEP does not interfere with male or female fertility.
Client concerns	Clarify misconceptions, address any client concerns

See appendix 2,3,4 for the initial adherence counselling, pre initiation education checklist and pre initiation education assessment checklist

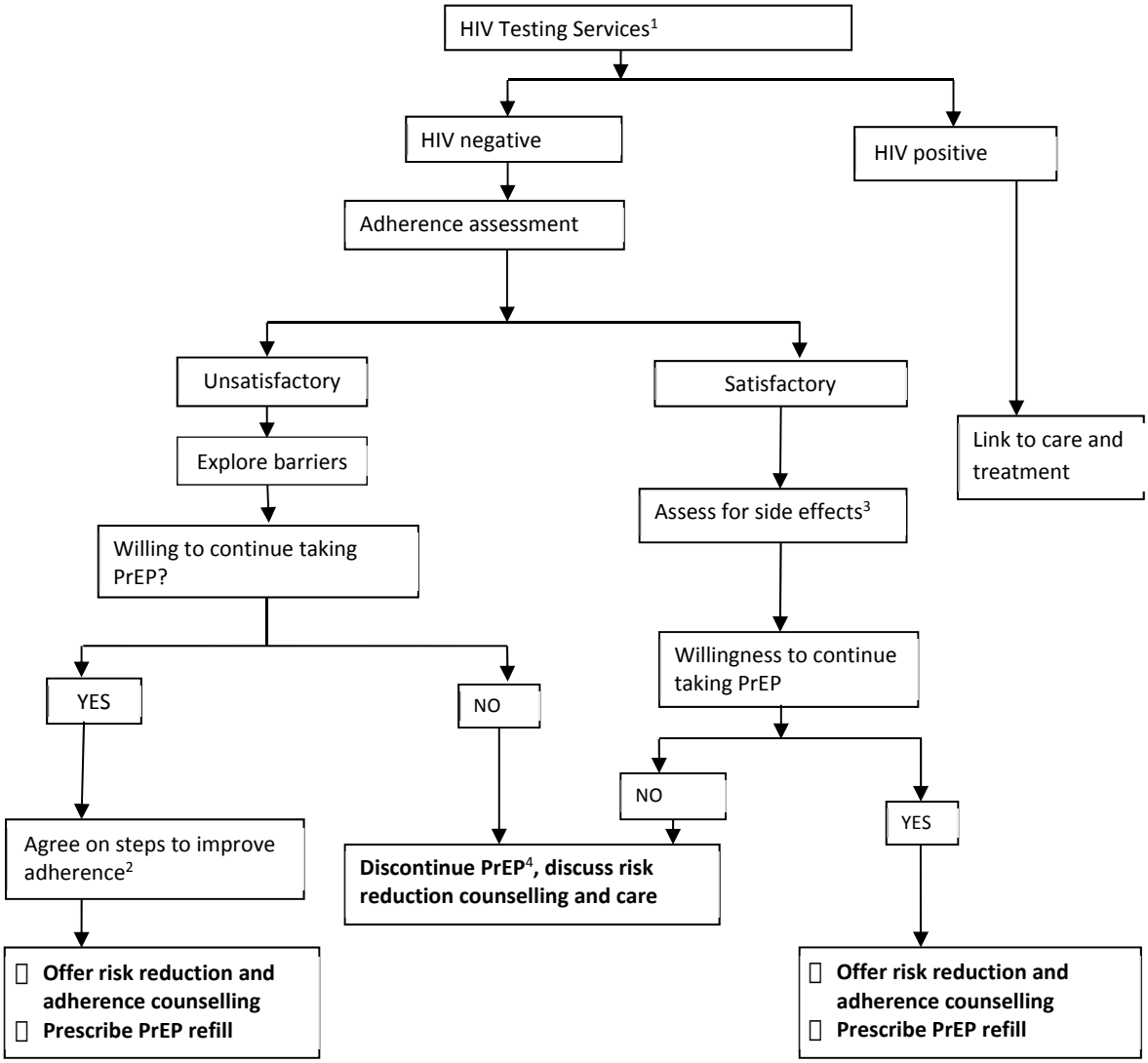
1.11 Follow-up and Monitoring of Pre-Exposure Prophylaxis

PrEP should only be prescribed to clients who demonstrate good understanding and commitment to regular follow-up visits, initially after one month and at least every 3 months thereafter.

The objectives of the follow-up visits are to:

- Assess adherence and provide ongoing adherence counselling and support
- Monitor and manage side effects
- Exclude HIV infection
- Provide other prevention services including risk reduction counselling, condoms, STI screening and treatment, substance abuse treatment etc.
- Review indications for PrEP

Figure 1.5: **Follow-up after initiating PrEP**



1.12 HIV Testing and Managing Suspected HIV Infection during PrEP

Routine HIV Testing during PrEP

Routine HIV testing is part of the package of PrEP services. To prevent development of resistance, frequent testing is required for timely identification of PrEP users who become HIV positive. HIV sero-status should be established and documented at the initiation of PrEP, at 1 month and every 3 months after initiation of PrEP. A HIV test should also be done whenever there are symptoms of acute HIV infection. HIV self-testing, HIVST, (as recommended in the national HTS guidelines) may be used to further increase access to HIV testing.

Managing suspected acute seroconversion illness

Continue PrEP, test for HIV at first contact and after 28 days, and if negative, continue with PrEP and usual follow-up.

Managing Confirmed HIV Infection during PrEP

- HIV seroconversion may occur after starting PrEP. Such seroconversions are usually due to pre-existing HIV infection (prior to initiation of PrEP) or inconsistent use of PrEP.
- Counsel the patient and urgently link to care and treatment for immediate initiation of full antiretroviral therapy
- Explore with the patient the consistency of PrEP use (assess interruptions and barriers to adherence during PrEP).
- Contact the regional or national TWG where you may be advised to obtain a baseline VL and to participate in DRT surveillance. This should, however, not delay initiation of fully suppressive first-line ART (as recommended in the national guidelines).

Table 1.6: **Adherence support during follow-up visits**

Theme	Adherence message/action
Climate Setting	Introduce yourself to the client, giving your name and role, ensure adequate privacy and reassure on confidentiality
Assess	• Understanding and experience with adherence: dosage and timing • Experience with possible side effects • Risk reduction efforts since last visit • Challenges to adherence and risk reduction • Possible acute seroconversion illness[1]
Advice	• In case of problems with adherence, explore approaches to improving adherence • Emphasize need for adherence and ongoing risk reduction including consistent use of condoms to prevent STIs and pregnancy. • For people who inject drugs (PWID) refer to a Needle and Syringe Exchange Program and Methadone Assisted Therapy • Remind clients circumstances under which PrEP can be discontinued
Agree	• Adherence and risk reduction goals based on degree of the client's desire to meet these goals
Assist	• Provide client with any reading material, and if available access to telephone consultation
Arrange	• Schedule next counselling/refill appointment date

1.13 Assessing for medication side effects

a. **Minor side effects -** few people may experience minor side effects like diarrhoea, nausea, decreased appetite, abdominal cramping or flatulence, dizziness or headaches. Such side effects are usually mild and resolve without

stopping PrEP. If necessary, symptomatic treatment such as anti-diarrhoeal, antiemetic or anti-flatulence medication can be prescribed for a brief period.

b. **Elevated creatinine -** where available, serum creatinine should be estimated at baseline and annually (earlier if the patient is at risk of renal disease). Self-limiting mild creatinine elevation occurs in a few individuals. Risk factors for significant creatinine elevation include:

- Conditions such as diabetes mellitus and hypertension
- Age > 45 years Reduced CrCl (< 90 ml/min) at baseline
- Concurrent use of nephrotoxic agents such as NSAIDs
  - If the creatinine clearance (CrCl) is < 50 ml/min, discontinue PrEP immediately and counsel on other HIV preventive measures; refer for further assessment. If the CrCl > 50 ml/min, PrEP may be restarted and creatinine re-assessed after 1 month. Exclude treatable/preventable causes of elevated creatinine such as dehydration, herbal remedies and supplements, NSAID use/abuse, other medications, uncontrolled blood pressure etc.

The formula for calculating estimated creatinine clearance is provided in the information box below.

Cockcroft–Gault equation for Estimating Creatinine Clearance

$$\text{eGFR (adult males)} = \frac{(140 - Age) \times 1.23}{serum\ creatinine\ (in\ micromol/L)}$$

$$\text{eGFR (adult females)} = \frac{(140 - Age) \times 1.23}{serum\ creatinine\ (in\ micromol/L)} \times 0.85$$

Units mL/min

1.14 Discontinuing PrEP

Indications for discontinuing PrEP include:

- The client becomes HIV positive. Counsel and link to care and treatment. The patient should be started on the recommended first-line ART regimen (refer to the national ART guidelines). If there is high likelihood of transmitted HIV drug resistance, refer to the national or regional TWG. Contact NASCOP at ulizanascop@gmail.com ;
- Change in HIV risk status to low risk
- Renal dysfunction with creatinine clearance below 50mL/min
- Client request to stop
- Sustained non-adherence
- Sustained viral suppression of the HIV positive partner in a HIV serodiscordant relationship; however, advise the couple to continue using condoms consistently.

PrEP use can be discontinued at least 28 days from the last high risk exposure to HIV. Exercise caution when discontinuing PrEP in a client with HBV infection. Such clients may experience severe flare-up of hepatitis. Refer to hepatitis guidelines and consult a provider experienced in the management of hepatitis.

1.15 Restarting PrEP

A client who stops PrEP for more than 7 days and wishes to restart should be assessed for resumption of PrEP similar to the assessment done for an initial (first) visit. Importantly, obtain a HIV test. If a high risk exposure occurred in the previous 7 days (i.e acute HIV infection is suspected), defer PrEP and obtain repeat HIV test after 4 weeks; if negative, PrEP can be prescribed if the other criteria are fulfilled.

1.16 Improving adherence to PrEP

Approaches to improve adherence include:

a. Encouraging the client to make it a habit to take PrEP at the most convenient time of day, linked to an activity done daily such as brushing teeth, taking a meal etc.
b. Disclosure of PrEP use to a partner or trusted person
c. Use of reminder devices like a cell phone alarm
d. SMS reminders where available and feasible
e. Exploring and mitigation of other barriers to adherence
f. Peer support

1.17 PrEP in Special Circumstances

HBV infection

TDF and FTC (as used for PrEP) are also effective in the treatment of HBV infection. HBV infection is not a contraindication to PrEP use. However, due to the risk of hepatitis flare-up after discontinuation of PrEP, exercise caution when discontinuing TDF/FTC especially in the first 1-3 months. Monitor clinical symptoms (nausea, anorexia, jaundice, abdominal pain and dark urine); obtain ALT where available and refer to a physician for specialised assessment and treatment.

Pregnancy/Breastfeeding

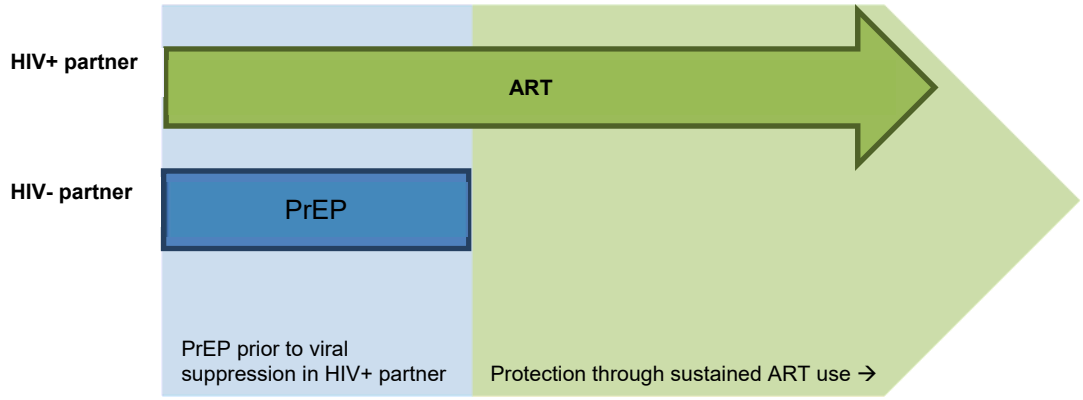
- PrEP does not prevent pregnancy or interfere with male or female fertility. Assess for pregnancy intention in all women of reproductive age who are considering PrEP. Provide counselling on safer conception options including the use of PrEP for those who wish to conceive. If pregnancy is not desired, offer effective contraception.

- Pregnancy and breastfeeding are not contraindications to PrEP. The benefits and potential harm of PrEP should be discussed with the client and the decision to start/continue PrEP individualized based on ongoing risk for HIV infection during pregnancy and breastfeeding.
- There is no evidence that TDF/FTC or 3TC increase the risk of birth defects if used during any gestation of pregnancy.
- PrEP is indicated for women with substantial ongoing risk of HIV infection who become pregnant or desire to conceive, as it decreases the risk of acute HIV infection during pregnancy.
- Risk reduction counselling should be intensified for an uninfected individual who becomes pregnant or is breastfeeding while taking PrEP.
- Once the decision to start/continue PrEP is made, the client should start antenatal care immediately and followed up monthly until cessation of breastfeeding; after which routine follow-up can continue as for general PrEP clients.

PrEP use in HIV serodiscordance

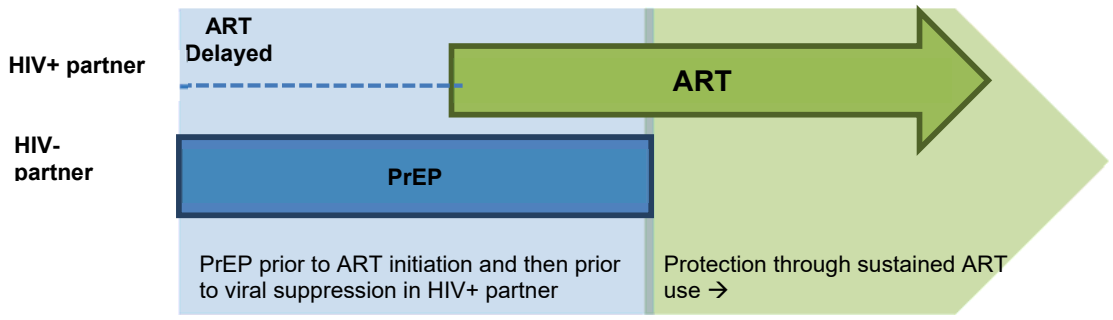
- The circumstances for use of PrEP in a discordant relationship include the following:
    - PrEP can be offered routinely, to the HIV negative partner, at initiation of ART for the HIV positive partner and continued until the HIV positive partner achieves viral suppression.

Scenario 1



- PrEP can be offered to the HIV negative partner if ART for the HIV positive partner is delayed or declined. In such cases, PrEP is continued until effective ART is provided to the HIV positive partner and viral suppression achieved.

Scenario 2



Indications for re-starting PrEP after discontinuationunderdiscontinuation under scenario 1&2 above include:

1.1 HIV positive partner stops taking ART including defaulting from treatment

1.2 Rebound in viral load in the HIV positive partner; assess for and support adherence, evaluate for treatment failure. Provide the full package of care and support for discordant couples (including PrEP until the partner on ART achieves viral suppression)

1.3 Having a new sexual partner of unknown HIV status

1.4 Additional risk of HIV infection such as a new STI

1.5 Conception planning

1.6 During pregnancy and breastfeeding (for the HI V negative female partner)

Section 2: Commodity Management for PrEP Rollout at Facility Level

2.1 Access to PrEP Commodities

There is a national process which ensures HIV commodities get to the service delivery points from the national level on a monthly or quarterly basis. In the current system, all central sites and stand-alone sites as shown in Figure 2.1 receive HIV commodities directly from the national level (KEMSA). The rest of the sites, mainly satellite sites, receive commodities via the central sites. PrEP commodities also utilize this mechanism. Under this, a PULL system is used by service delivery points to order HIV commodities from KEMSA or central sites as per their needs on a monthly basis (for ARVs) or quarterly (for rapid test kits-RTKs). A national order management team composed of KEMSA and NASCOP staff receives and processes facility orders and relays the requests to KEMSA which delivers required supplies to the service delivery points.

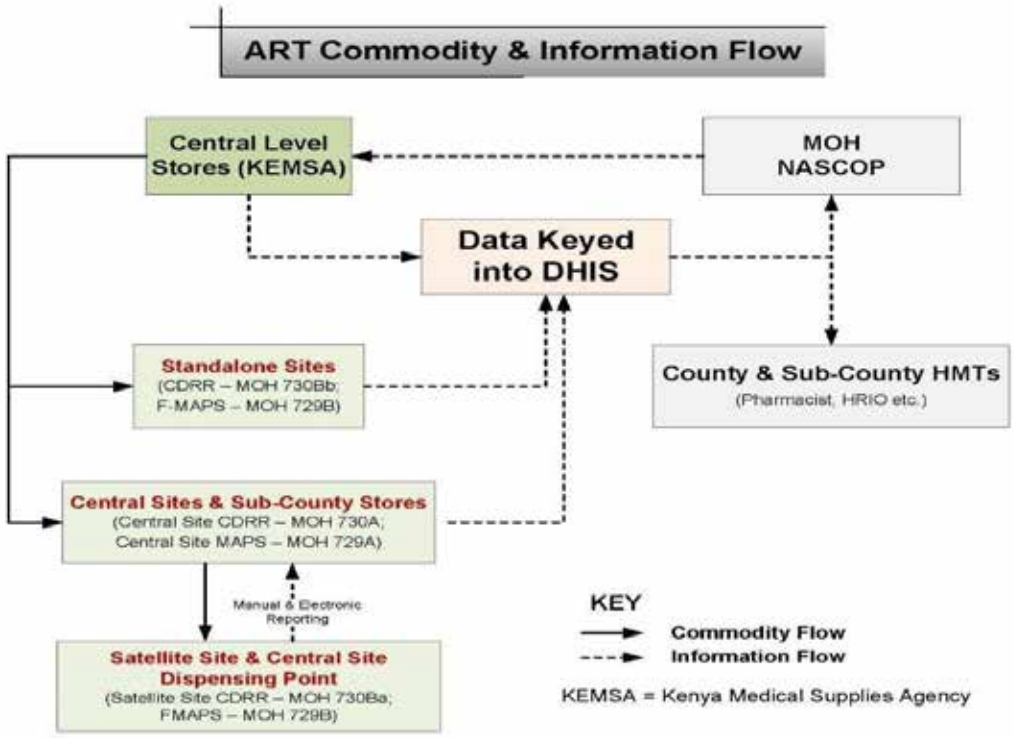
2.2 Monthly PrEP Re-fills

Clients newly initiated on PrEP will receive PrEP enough for one month and will be required to come back to the facility for monthly PrEP re-fills. A re-fill on the 4th month will only be dispensed after the clients have undertaken and received HIV negative test results.

2.3 PrEP Dispensing points

PrEP should only be dispensed against a valid prescription by a qualified and certified health professional. It can be dispensed at various service delivery points depending on facility service delivery models and available resources. Some sites will have PrEP dispensing occurring at the Comprehensive Care Centers (CCCs), the main hospital pharmacy, or at point-of-care (one-stop) at lower level health facilities such as health centres and dispensaries. Other dispensing points include drop-in centers (DICEs), community outlets/community distribution or registered private pharmacies.

Figure 2.1: Shows an overview of the existing national flow pattern for ARVs and opportunistic infections medicines.



2.4 PrEP Commodities Consumption Data Capture and Reporting LMIS Tools

The national logistics management information system (LMIS) tools should be utilized at all PrEP service delivery points to assist in capturing the daily consumption data for dispensed PrEP Product, as well as for rapid HIV test kits. Site level staff should ensure they understand how to use these tools.

These tools include; Daily Activity Register (DAR-) or electronic dispensing tool for ARVs and Opportunistic Infections Medicines; Consumption Data Report and Request (CDRR) forms which are used by service points to make monthly summary reports as well as enable them request for additional commodities, facility monthly ART patient summary (F-MAPs) used to report on the number of clients who received PrEP services within a given month.

Figure 2.2: **Data capture and reporting tools summary**

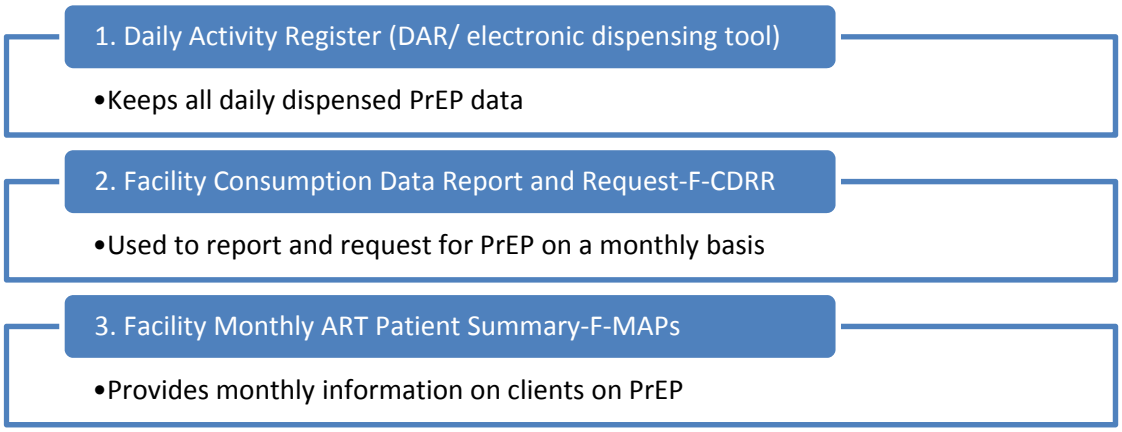


Table 2.1: **Reporting schedule for PrEP commodities**

Report type	Origin	Destination	Deadline
F-CDRR/F-MAPs	PrEP Satellite sites	Central Site	2nd of every month
Central Site-CDRR/D-MAPs	Central sites	NASCOP/KEMSA-	10th of every month

2.6 Pharmacovigilance System for PrEP

Any untoward or adverse drug reactions arising from use of PrEP should be reported using the existing Pharmacy and Poisons Board mechanisms for adverse drug reactions (ADR) national monitoring and reporting. All PrEP users should be vigilant at all times in order to identify, document and report-using the existing pharmacovigilance (PV) tools for any untoward reactions resulting from PrEP use. The PV tools include; the Yellow Form-for ADR reporting; the Pink Form-for poor quality medicines reporting and the White card-patient alert card.

These tools are available in manual and electronic formats and should be filled and forwarded to the Pharmacy and Poisons Board.

2County and Sub-County Health Management Teams will monitor PrEP implementation and ensure timely submission of reports from the satellite sites to the central sites for onward reporting to NASCOP/KEMSA in order to assure continuous availability of PrEP commodities.

Section 3: Quality Improvement In Pre Exposure Prophylaxis

Quality Improvement (QI) is a management science that identifies where gaps exist between services actually provided and expectations for services. QI which is a continuous process then narrows these gaps not only to meet customer needs and expectations, but to exceed them.

Successful implementation of quality improvement initiatives for PrEP requires that providers and facility managers are equipped to initiate and sustain quality in client care and service delivery using routine data to measure improvements in service delivery and processes. The goal should be to optimize client and service delivery outcomes.

3.1 Dimensions of Quality

Safety: Minimizing risk of adverse events due to healthcare interventions

Accessibility: Obtaining service delivery for PrEP that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to client needs.

Acceptability (patient-centeredness): Ensuring respect for dignity, confidentiality, participation in choices, promptness, quality of amenities, access to social support networks and choice of provider

Effectiveness: Ensuring PrEP care achieves the desired outcome (preventing HIV infection)

Efficiency: Achieving desired results with the most cost-effective use of resources

Equity: Delivering health care, which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socioeconomic status.

3.2 How to make Improvement:

3.2.1 Measure Performance:

a. Identify the areas/services that need improvement. Areas for improvement can be identified by use of available data such as the PrEP indicators from routine reporting or by asking staff and clients about the areas they feel need to be improved.

b. Regularly review PrEP data collected routinely to inform progress of care and service provision at the facility level. Based on performance gaps, discuss the

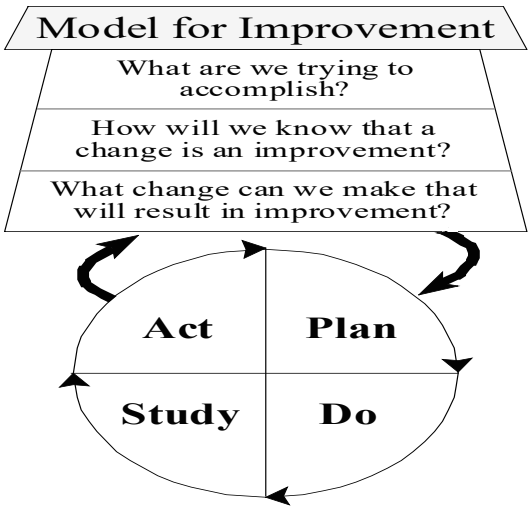
progress of PrEP service provision identifying areas of improvement that will move services from actual to desired states

3.2.2: Set priorities towards action by focusing attention on areas that are considered most important. QI Tools such as the Decision Matrix can be used to prioritize areas/gaps for improvement (Appendix5). The priorities ultimately chosen should:

a. Be important and related to National guidelines
b. Represent key community and clinic staff concerns
c. Be measurable
d. Include areas that the facility team will realistically be able to improve

After identifying the priority problem, apply the Plan-Do-Study-Act cycle, an action-oriented method for QI, to improve the quality of services to identified areas of improvement as shown in figure 3.2. The model for improvement is a method to help accelerate change and increase the odds that the changes we make are an improvement. PLAN by setting goals and objectives of the quality improvement project clarifying the objective by predicting what will likely happen (outcome) and why. Thereafter, DO carry out the tests on a small scale while documenting findings including successes, challenges and unexpected observations.

Figure 3.1: Model for quality improvement.



3.3 How to know that a change is an improvement

On regular basis, **STUDY** the small tests of change on performance against any activity introduced into the process that result to desirable and undesirable results. Changes that introduce desirable outcome should be sustained at the **ACT** stage of implementation. Undesirable changes should be abandoned and new change ideas tested.

3.4 An example of a facility Quality Improvement Project:

Project goal: To provide PrEP to at least 50% of eligible clients who visit facility xyz in 1 year.

Facility XYZ (a DICE) realized from routine reporting registers that none (0%) of the Commercial Sex workers testing HIV negative and discordant couples for HIV clients on treatment had been recorded to have received PrEP in the last 3 months since the launch of Revised 2016 ARV guidelines with PrEP recommendations. This was noted as an important prevention measure gap

AIM statement: The facility work improvement team decided to set up a goal to ensure at least 50% of clients that test HIV negative are screened for eligibility for PrEP and provided with PrEP in the next 12 months. They planned out tasks to achieve this goal.

Plan: The facility brainstormed on likely reasons for failing to screen eligible clients for PrEP and used a decision matrix to prioritized possible gaps. Some of the reasons included; Staff were not aware of the new recommendations for PrEP; Staff did not have a screening tools for PreP for HIV Negative clients; Clients did not have information on importance of PrEP; Drugs for PrEP had been dispatched from the county hospital to the facility but were locked in the Nurse in-charge office awaiting staff sensitization.

Do: PrEP drug stock inventory was developed in pharmacy and facility staff sensitization meeting conducted within 2 week. Two staff after capacity building were then re-deployed to screen all HIV negative patients for eligibility for PrEP. One clinician at OPD was tasked to review all eligible clients using an improvised reporting tool. Nurse In-charge tasked herself to follow up on PrEP reporting tools from NASCOP.

Study: Two peer educators was assigned to review the HIV Testing register for the total number of clients accessing HIV testing Service weekly at the VCT and CCC who tested HIV negative. From the register they counted the number of clients that tested HIV Negative who were screened for PrEP and those initiated on PrEP every week. The team plotted this information on a flip chart and discussed findings with the rest of the providers during the following multidisciplinary team meeting.

Act: From weekly plotting, out of a total of 30 patients that tested HIV negative, 15 Clients were screened for eligibility for PrEP and 5 initiated on PrEP. In Week 2, out of a total of 20 clients that tested HIV Negative, 18 clients were screened for eligibility for PrEP and 10 initiated on PrEP. Satisfied with the preliminary results, the facility chose to adapt the introduced changes into the screening process for PrEP ie; Deployment of staff to support screening and initiation of PrEP.

Other Proposed PrEP Quality Indicators:

Discordant couples:

- Establish the proportion of HIV positive clients who have disclosed HIV status
- HIV positive clients in care whose partners have been tested
- Proportion of HIV negative clients in sero discordant relationships assessed for PrEP

Other possible QI indicators:

- Assessment for adverse drug reactions (through chart reviews)
- Assessment for adherence
- Assessment for risk reduction (through chart review)
- Assessment for quality of documentation of client records

For all PrEP quality indicators, establish the facility baseline, assess the barriers e.g root cause analysis and set SMART targets .Implement actions to achieve set targets.

Section 4: Monitoring and Evaluation

The section contains guidance on how to use PrEP data capture and reporting tools and outcome definitions for PrEP.

4.1 PrEP Data collection and reporting tools

The data **PrEP data capture** tools include:

- Rapid Assessment Screening Tool(RAST)
- PrEP clinical encounter form
- PrEP register (MoH 266)
- PrEP Daily Activity Register (DAR) (MoH 267)

The data **Reporting tool** includes:

- MoH 737

4.2 PrEP Clinical Encounter Record

The PrEP Clinical Encounter record is used for recording information of all PrEP package services offered at a health facility as part of HIV prevention (Appendix7)

Purpose: It serves as a primary source of information regarding clients assessed for PrEP and those initiated on PrEP. It is also used to track quality of services for clients on PrEP.

Facilities with EMR will use the electronic encounter record

It has 3 broad sections namely;

1. Client Baseline information which captures ;
    - Client profile
    - Entry point and Transfer status
    - Baseline assessment
    - Behavioral risk assessment
    - Medical assessment and fertility intentions
    - PrEP initiation
    - Next appointment date
2. Clinical follow up section which captures ;
    - Medical assessment and fertility intentions
    - Behavioral risks assessment
    - Follow up laboratory investigations

- PrEP dispensed during the visit
- Date for next appointment

3. Monthly refill section

When Completed: When a client is being initiated on PrEP and during subsequent follow up visits.

Who Completes: The responsibility of complete and accurate documentation lies with the service provider offering PrEP.

Where placed in the Facility: It will be placed at the service delivery point or room where PrEP services are offered.

4.3 PrEP register (MoH 266)

This is a longitudinal register filled during every clinical visit (Appendix8). It captures demographic details of the client, lab investigations, PrEP eligibility, STI screening, PrEP adherence PrEP status. It also captures details of all HIV tests done to the PrEP clients to enable identification of clients who seroconvert while on PrEP

Purpose: It captures PrEP clients' information at enrollment and during subsequent clinical visits

When completed: In the course of PrEP service delivery

Who completes: service provider, Health Records officer or the data clerk who is assigned the responsibility of updating PrEP records at the facility

Where placed in the Facility: It will be placed at the service delivery point or room where PrEP services are offered.

4.4 PrEP Daily Activity Register (PrEP DAR) (MoH 267)

The PrEP DAR contains a summary of reportable data elements that demand immediate collection upon provision of PrEP service (Appendix 9).

Purpose: It captures all clients seeking PrEP services i.e. newly initiated PrEP, visiting for prescribed follow up visits (from PrEP Register) and visiting for the monthly refills (from monthly refill section of the clinical encounter record). It will act as the source document for the PrEP summary tool.

When completed: Immediately after PrEP service is provided

Who completes: Service provider, Health Records officer or the data clerk who is assigned the responsibility of updating PrEP records at the facility

Where placed in the Facility: It will be placed in the PrEP room where PrEP services are offered.

4.5 PrEP Summary Reporting Tool (MoH 737)

This main Monthly summary reporting tool for PrEP services (Appendix 10). It is expected that all health facilities offering PrEP will report every month using this tool.

Information on this summary tool is collected from the PrEP Daily Activity Register.

Purpose: Collects monthly summaries of PrEP reportable data elements – will populate the MOH 731plus

When completed at the end of the reporting month

Who completes: Completed by the service provider, HRIO or data clerk as per facilities procedures

Where placed in the Facility: Each facility will have one summary tool which aggregates data at the HRIO office

4.6 Reportable PrEP Indicators

The PrEP data elements have been disaggregated by Sex and Age

The age disaggregation include: 15-19,20-24, 25-29 and 30+ years

PrEP reportable indicators include:

Number Eligible for PrEP

Number initiated (New) on PrEP

Number continuing (Refills) on PrEP

Number Restarting (Restart) PrEP

Number currently on PrEP (New + Refill+ Restart)

Number tested HIV positive while on PrEP

Number diagnosed with STI

Number discontinued PrEP

4.7 Definition of terms

Deaths- Any confirmed death

Transfer out- Any person who was documented to have transferred to another facility

Transfer in – Any client who was started on PrEP in another facility and documented to have been transferred in to these facility to continue with PrEP services. Such client will be captured below the dotted line in the cohort month the client was initiated on PrEP.

Declined PrEP/- Any person who was documented to have declined PrEP

Discontinue/Stopped: Any person who was documented to have been discontinued or stopped PrEP by the health care providers or self-request.

Lost-to-follow up –

- Any client whose last clinical appointment was scheduled > 90 days before the date the file is reviewed, AND
- Who has not come to the clinic for PrEP services, AND is NOT dead, transfer out or declined/stopped PrEP.

Defaulters –

- Any client whose last clinical appointment was scheduled between 3-90 days before the date the files is reviewed, AND
- Who has not come to the clinic for PrEP services, AND is NOT dead, transfer out, declined PrEP/Stopped PrEP

Re-start- Any client who has not been on PrEP > 7 seven days from the last TCA AND has been reinitiated on PrEP

Active-

- Any person whose last TCA was scheduled <3 days before the file is reviewed or is AFTER the date the file is reviewed.

Missed Appointment: Any person who fails to honor their TCA

Section 5: Appendices

Appendix 1: Screening for Pre-Exposure Prophylaxis

What is your current age?	**_____years**					
In the past 6 months:						
Have you had more than one sexual partner?	Yes*		No		Not sexually active	
Did you use a condom every time you had sex?	Yes		No*		Don't know	
Have you had a sexually transmitted infection?	Yes*		No		Don't know	
Have you had to use PEP due to high risk sexual exposure?	Yes*		No		Don't know	
Do you have a sexual partner who has HIV?	Yes		No		Don't know	
- If 'yes', has he/she been on antiretroviral therapy for at least 6 months?	Yes		No*		Don't know*	
- If 'Yes', has the therapy suppressed the viral load?	Yes		No*		Don't know*	
In the past 7 days						
Have you had sex without a condom with someone whose HIV status you did not know?	Yes*		No		Don't know*	
Have you had a 'cold' or 'flu', sore throat, fevers, sweating, swollen glands, mouth ulcers, headache, muscle pain or rash?	Yes**		No		Don't know	
*Consider offering PrEP; **Consider acute HIV infection						

Appendix 2.Initial Adherence Preparation and Counselling

Theme	Adherence message/action
Climate Setting	Introduce yourself to the client, giving your name and role; ensure adequate privacy and reassure about confidentiality
What is PrEP?	PrEP involves HIV-negative people taking daily ARV medications to prevent themselves from becoming infected with HIV. PrEP is provided as part of combination prevention, including efforts at ongoing risk reduction
Does PrEP work?	Evidence from scientific studies involving HIV negative people at risk of HIV infection has shown that PrEP is highly effective if you take it as prescribed and in combination with other HIV prevention interventions.

How is PrEP used?	• PrEP is provided as tablets. You should take one tablet daily at the same most convenient time of day. To ensure you do not forget take PrEP each day:
	  ○ Make it a habit linked to an activity you do daily such as brushing teeth, taking a meal etc
	  ○ Disclose PrEP use to a partner or trusted person
	  ○ Use reminder devices like a cell phone alarm
	  ○ If available enrol into an SMS reminder system
	• If you forget to take a tablet, take it as soon as you remember; however, do not exceed 2 tablets in a day. PrEP tablets can be taken any time of day, with or without food
	• PrEP use is a personal, responsible choice to protect yourself and your sexual partners from HIV. Discussing PrEP use with trusted friends or other PrEP users may be helpful
	• PrEP can be used safely with family planning pills or injections

Starting PrEP	• You will need a HIV test before starting or re-starting (if you had stopped) PrEP. This is to ensure that you do not already have HIV infection before starting PrEP because PrEP is not effective in treating existing HIV infection. • It takes up to 7 days of daily use of PrEP tablets to achieve maximum protection. During this period, and as much as possible, you are encouraged to practice safer sex practices especially consistent, correct use of male or female condoms.
Stopping PrEP	Discuss stopping PrEP with your provider. You can stop using PrEP 28 days after your last possible HIV exposure. People can stop PrEP if they are no longer at substantial risk of acquiring HIV infection. Ways to lower risk include: • Adopting safer sexual practices, such as abstinence, or using condoms during all sexual contacts; • Following viral suppression in a sero-discordant couple; • Leaving sex work; • Ceasing injection drug use or the sharing injection drug use equipment
Protection from other STIs	PrEP does not offer protection from other STIs such as gonorrhoea, syphilis, herpes etc. Discuss with your provider if you suspect that you have an STI (genital sores or discharge). Using a condom each time you have sex will provide additional protection from HIV and other STIs

Theme	Adherence message/action
PrEP safety	● TDF-based PrEP is generally safe and well tolerated. ● Gastrointestinal symptoms are the most common. They include nausea, diarrhoea, vomiting, decreased appetite, abdominal cramping or flatulence; dizziness or headaches. Typically, these symptoms start in the first few days or weeks of PrEP use and last a few days and almost always less than 1 month. Discuss with your provider if these side effects are severe or they persist for longer than one month. ○ A few people may not be able to use PrEP due to kidney-related side effects
Prevention of pregnancy	PrEP does not prevent pregnancy. Use effective contraception unless you want pregnancy. If you want to become pregnant, discuss with your provider about safer ways to conceive.
PrEP during pregnancy and breastfeeding	PrEP can be used safely during pregnancy and breastfeeding. The risk of HIV infection is higher during pregnancy and breastfeeding. It is also easier to pass HIV to the unborn or breastfeeding baby if HIV infection occurs during pregnancy or breastfeeding. PrEP does not interfere with male or female fertility.
Client concerns	Clarify misconceptions, address any client concerns

Appendix 3. Pre-Initiation Education Check-list

<table>
<tr><th colspan="2">Ensure that the following aspects are covered during client counselling and education</th></tr>
<tr><td>How PrEP works as part of combination prevention</td><td>Explain the need for baseline and follow-up tests including HIV testing.</td></tr>
<tr><td>Limitations of PrEP
Link efficacy to adherence
PrEP reduces but does not eliminate the risk of acquiring HIV
PrEP does not prevent pregnancy or other STIs
May not be suitable in clients with renal impairment or intolerance to the PrEP medicines</td><td>Discuss when and how PrEP may be discontinued.</td></tr>
<tr><td>PrEP use
The medications used (show the client the pills)
How the medications are used (daily)
Number of daily doses required to achieve efficacy (7)
What to do when doses are missed?
Discontinuation of PrEP (need to continue for 28 days from last potential exposure to HIV)
Safety and side effects and what to do in case these are experienced.</td><td>What to do in case of client experiences symptoms of sero-conversion (acute HV infection)</td></tr>
<tr><td colspan="2">Risk reduction counselling and support
Education (risk and safer sex practices)
Managing mental health needs
Couple counselling
Access to, and consistent use of condoms and lubricants
Access to and need for frequent HIV testing
Early access to ART for those who test HIV positive
VMMC (if indicated)
STI screening and treatment
Harm reduction for PWID</td></tr>
</table>

Appendix 4; Pre-Initiation Assessment Check-list

Confirm the following have been done prior to prescribing PrEP
HIV testing and counselling, HIV-negative
Symptoms of acute HIV infection
Behaviour risk assessment
Substance use and mental health screening
Partner information (where available/known)
Pre-initiation education and understanding of PrEP
Readiness and willingness to adhere to prescribed PrEP and follow-up schedule
STI screening and treatment
For Women Pregnancy test **Pregnancy and pregnancy intention** Is the client currently using any contraception? If not, is she interested in using long-term hormonal contraception in addition to condoms? Is the client trying to conceive? Is the client pregnant or breastfeeding?
Serum creatinine and creatinine clearance >50 mL/min
HBsAg
HCV serology (for PWID)
Medication history

Appendix 5: Decision Matrix

A decision matrix can help you to prioritize potential problems/performance gaps with the aim of helping your team to select an appropriate problem to undertake in a QI project cycle.

You can use the template provided below to develop a decision matrix using the following steps:

a. Under the column titled "Potential performance gaps to be addressed," make a list of areas or processes that should be considered for QI projects

b. Use existing data from performance reviews, staff feedback, client feedback, and other data sources to rank each potential gap on a scale of 1-5 (5=totally meets criteria); you may revise the criteria to include other items, such as cost

c. Review the rankings and select the project with the highest score

An example of a decision matrix template

Potential performance gaps to be addressed	CRITERIA: Rank 1-5 where 5=totally meets criteria				
	Issue seen as important*	Realistic scope (Control)*	Likelihood of success via QI*	Potential Impact of QI project *	TOTAL
1.					
2.					
3.					
4.					

* Issue seen as important refers to a gap that is crucial or gap that does not meet standards set in National guidelines

* Realistic scope (control) refers to gaps that the facility are able to address at a facility level, that do not involve the macrosystem

* Likelihood of success refers to performance gaps that can be addressed easily, the so called quick wins

* Potential Impact of QI project refers to performance gaps that if addressed will have the greatest effect

Appendix 6: Rapid Assessment Screening Tool (RAST)

MINISTRY OF HEALTH
NATIONAL AIDS & STIs CONTROL PROGRAM

PrEP Rapid Assessment Screening Tool (RAST)

Age: _____ **Sex:** _____ **Date:** _____

1. What is your HIV status? ***(if response is positive discontinue assessment else administer all questions)***

   ☐Negative ☐Positive ☐Unknown ☐Unwilling to disclose

2. What is the HIV status of your sexual partner(s)?

   ☐Negative ☐Positive ☐Unknown

In the past 6 months

3. Have you had sex without a condom with a partner(s) of unknown or positive HIV status?

   ☐No ☐Yes

4. Have you engaged in sex in exchange of money or other favors?

   ☐No ☐Yes

5. Have you been diagnosed with or treated for an STI?

   ☐ No ☐ Yes

6. Have you shared needles while engaging in intravenous drug use?

   ☐No ☐Yes

7. Have you been forced to have sex against your will or physically assaulted including assault by your sexual partner(s)?

   ☐No ☐Yes

8. Have you used post exposure prophylaxis (PEP) two times or more?

   ☐No ☐Yes

Refer the client for further PrEP assessment at the health facility If:

HIV status of the sexual partner(s) is Positive or Unknown

*Any **Yes*** to the screening questions

Remarks

_____

_____

_____

Appendix 7: PrEP Clinical Encounter Record

File no:

Version 3.0 (29 August 2017 - WORKING)

Clinical Encounter Record: Oral Pre-Exposure Prophylaxis (PrEP)

Name of facility: _____ Delivery Point: _____ Tier: _____ MFL code: ___ ___ ___ ___ ___
County: _____ Sub county: _____ Ward: _____

A. Client Profile

Unique client record number: ___ ___ ___ ___ ___ / ___ ___ ___ ___ / ___ ___ ___ ___ ___ Initial visit date: *dd / mm / yyyy*

Name: First _____ Middle _____ Last _____ Telephone no: _____

Alien/National ID/passport/Birth Cert No: _____ NHIF No: _____ County of Birth _____

Sex: ☐ Male ☐ Female Date of birth: *dd / mm / yyyy* Age (years): ____ ____ If age <19, attends school: ☐ Yes ☐ No

Marital status (*select one*): ☐ Never married ☐ Cohabiting ☐ Married monogamous ☐ Married polygamous ☐ Separated/divorced ☐ Widowed

Population Type: ☐ Gen Population ☐ Discordant couple ☐ Key Population (Specify) → ☐ MSM ☐ MSW ☐ FSW ☐ PWID

B. Entry Point & Transfer Status

Referred from (*select one*):
☐ HBTC ☐ VCT site ☐ OPD ☐ MCH ☐ TB clinic ☐ IPD ☐ CCC
☐ Peer ☐ Outreach ☐ Self-referral ☐ Community ☐ Other: _____

If transferred in:
PrEP start date: *dd / mm / yyyy* Regimen: ☐ TDF-FTC ☐ TDF ☐ TDF-3TC
Facility transferred from: _____ MFL code: __ __ __ __ __ County: _____

C. Baseline Assessment

Behaviour risk assessment

Mark all that apply:

☐ Sex partner(s) is HIV+ and (*mark all that apply*): *(If yes to any)*
- ☐ Not on ART
- ☐ On ART <6 months
- ☐ Suspected poor adherence to ART
- ☐ Detectable HIV viral load
- ☐ Couple is trying to conceive

☐ Sex partner(s) high risk & HIV status is unknown
☐ Has sex with >1 partner
☐ Ongoing IPV/GBV
☐ Transactional sex
☐ Recent STI (past 6 months)
☐ Recurrent use of post-exposure prophylaxis (PEP)
☐ Recurrent sex under influence of alcohol/recreational drugs
☐ Inconsistent or no condom use
☐ Injection drug use with shared needles and/or syringes

Complete section if sex partner is HIV+

HIV+ partner CCC number: ___ ___ ___ ___ _____/___ ___ ___ ___ ___
or ☐ NA (not enrolled at a CCC)
or ☐ CCC number/enrollment status unknown

HIV+ partner ART start date: *dd / mm / yyyy*
or ☐ not on ART at initial visit

Time known to be HIV-serodiscordant: ___ ___ years + ___ ___ months

Sex without a condom with HIV+ partner in past 30 days: ☐ Yes ☐ No

Number of living children with HIV+ partner: ___ ___

Medical assessment & fertility intentions

Blood pressure (mm Hg): ___ ___ ___ / ___ ___ ___ Temperature: ___ ___ °C
Weight (kg): ___ ___ ___ Height (cm): ___ ___ ___
Signs/symptoms of STI : ☐ Yes; Use codes provided: _____ ☐ No

Chronic illnesses & comorbidities		Treatment
Liver disease:	☐ Yes ☐ No	
Kidney disease:	☐ Yes ☐ No	
1. *Other description*		
2. *Other description*		

Male only:
Circumcised: ☐ Yes ☐ No ☐ Unknown

Female only:
LMP: *dd / mm / yyyy*
Pregnant: ☐ Yes ☐ No
If pregnant: ☐ Planned ☐ Unplanned
Breastfeeding: ☐ Yes ☐ No
On family planning: ☐ Yes ☐ No FP methods: _____
Plan to have children (*select one*):
☐ Trying to conceive ☐ Future ☐ No ☐ Don't know

Clinical notes:

D. PrEP initiation

Lab results (*Investigations should not delay PrEP initiation. To be recorded when available.*)

Test	Result	Additional steps
Hepatitis B (HBsAg)	☐ Positive ☐ Negative ☐ Not done	If negative, vaccine series initiated: ☐ Yes ☐ No Date sample collected: dd/ mm / yyyy
Hepatitis C	☐ Positive ☐ Negative ☐ Not done	Date sample collected: dd/ mm / yyyy
Serum creatinine	___ ___ ___ (µmol/L) or ☐ Not done	If done, CrCl (mL/min): ___ ___ ___ *If creatinine is out of range, or CrCl<50 mL/min, refer for further assessment.*

Previous PrEP use: ☐ Yes ☐ No Condom Issued: ☐ Yes ☐ No
Willing to start PrEP: ☐ Yes ☐ No Adherence Counseling Done: ☐ Yes ☐ No
If not willing, reason (*mark all that apply*): ☐ None ☐ Side effects (ADR) ☐ Stigma ☐ Pill burden ☐ Taking pills for a long time ☐ Too many HIV tests

Signs/symptoms of acute HIV: ☐ Yes ☐ **No**
Medically ineligible to start PrEP: ☐ Yes ☐ **No**
Contraindications for TDF-FTC /TDF-3TC/TDF: ☐ Yes ☐ **No**

→ **Eligible for PrEP**

Prescribed PrEP at initial visit: ☐ **Yes** ☐ **No**
Regimen: ☐ TDF-FTC ☐ TDF ☐ TDF-3TC
# of months: ___ ___
Date of initiation: *dd / mm / yyyy*

Next appointment date: *dd / mm / yyyy* **Clinician initials:**

Appendix 8: PrEP Register (MoH 266)

PrEP REGISTER

Facility Name _____ Delivery _____

Serial No	Name in full (First, Middle, Last)	Sex	Client ID	DOB (dd/mm/yyyy)	Age in completed Yrs	Populate type (Use the codes: 01. General Population 02. Discordant Couple 03. MSM/ MSW 04. FSW 05. PWID	PrEP Initiation							Follow up visit month 1, 15, 30 & 45										Follow up visit month 3, 18, 33 & 48									
							HTS: HTS Done (Yes/No); HTS Result (N=Negative P=Positive)	Eligible (Yes/No)	Reason for PrEP eligibility at entry point (use ALL codes that apply1,2,3.....)	Date PrEP Initiation (dd/mm/yyyy)	STI screened (Yes/No); Results (STI Diagnosis)	Creatinine clearance-Done (Yes/No); Test Results (In ml/min)	HBsAg (Yes/No); Test Results (P/N)	Date of follow up visit	HTS: HTS Done (Yes/No); HTS Result (N=Negative P=Positive)	STI screening: Screened (Yes/No); Results(STI Diagnosis)	Risk of HIV Infection: Is the client at risk of HIV infection? (Yes/No); If yes, insert the reason for HIV risk(Use Codes)	Adherence: Good, Fair, Bad,	Reason for non-adherence: Use codes provided	Adherence Counselling: Received Adherence Cunselling (Yes/No)	Condoms Issued (Yes/No)	PrEP Status: Continue, Discontinue, Restart; Reason for Discontinuation	Date of follow up visit	HTS: HTS Done (Yes/No); HTS Result (N=Negative P=Positive)	STI screening: Screened (Yes/No); Results(STI Diagnosis)	Risk of HIV Infection: Is the client at risk of HIV infection? (Yes/No); If yes, insert the reason for HIV risk (Use Codes)	Adherence: Good, Fair, Bad, Sustained non-adherence	Reason for non-adherence: Use codes provided	Adherence Counselling: Received Adherence Cunselling (Yes/No)	Condoms Issued (Yes/No)	PrEP Status: Continue, Discontinue, Restart; Reason for Discontinuation
(a)	(b)	(c)	(d)		(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)	(r)	(s)	(t)	(u)	(w)	(x)	(y)	(z)	(aa)	(ab)	(ac)	(ad)	(ae)	(af)
1														1									3								
														15									18								
														30									33								
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														15									18								
														30									33								
														45									48								

Reference column code	(j)	(k)	(p), (z), (ai), (ar), (ba)	(q), (aa), (aj), (as), (bb)	(r), (ab), (ak), (at), (bc)	(s), (ac), (al), (au), (bd)	(w), (af), (ao), (ax),(bg)
	Reason for PrEP eligibility at Entry Point: 1. Sexual partner of Known HIV+ status 2. Engaging in transaction sex 3. History of recent STI	**STI Diagnosis:** Genital Ulcer Disease (GUD), Vaginitis and/ or Vaginal Discharge	**STI Diagnosis:** Genital Ulcer Disease (GUD), Vaginitis and/or Vaginal Discharge (VG), Cervicitis and/or	**HIV Risk Factors:** 1. Sexual partner of Known HIV+ status 2. Engaging in transaction sex 3. History of recent STI	**Adherence:** Good: missed 0-3 doses in past 1 month Fair: missed 4-5 doses in past	**Reasons for Non-Adherence:** 1. Forgot 2. lost/out of pills 3. seperated from HIV+ partner	**Reasons for Discontinuation:** 1. HIV test is positive 2. low risk of HIV 3. renal dysfunction

Appendix 9: PrEP Daily Activity Register (MoH 267)

PrEP DAILY ACTIVITY REGISTER

Facility Name: ____________ Delivery point: ____________ Month: ____________ Year: ____________

No	Date	Unique Identifier	Age in completed years	Populate type (Use the codes: 01. General Population 02. Discordant Couple 03. MSM 04. MSW 05. FSW 06. PWID)	Client eligible for prEP – Tick as appropriate for age								Client started (New) on PrEP – Tick as appropriate for age								Client Continuing(Refills) on PrEP – Tick as appropriate for age								Client restarting(Restart) on PrEP – Tick as appropriate for age								Client retested HIV positive while on PrEP – Tick as appropriate for age								Client diagnosed with STI – Tick as appropriate								Client discontinued PrEP – Tick as appropriate							
					15-19 yrs (M)	15-19yrs (F)	20-24 yrs (M)	20-24 yrs (F)	25-30 yrs(M)	25-30 yrs (F)	31+ yrs (M)	31+ yrs (F)	15-19 yrs (M)	15-19 yrs (F)	20-24 yrs (M)	20-24 yrs (F)	25-30 yrs (M)	25-30 yrs (F)	31+ yrs (M)	31+ yrs (F)	15-19 yrs (M)	15-19 yrs (F)	20-24 yrs (M)	20-24 yrs (F)	25-30 yrs (M)	25-30 yrs (F)	31+ yrs (M)	31+ yrs (F)	15-19 yrs (M)	15-19 yrs (F)	20-24 yrs (M)	20-24 yrs (F)	25-30 yrs (M)	25-30 yrs (F)	31+ yrs (M)	31+ yrs (F)	15-19 yrs (M)	15-19 yrs (F)	20-24 yrs (M)	20-24 yrs (F)	25-30 yrs (M)	25-30 yrs (F)	31+ yrs (M)	31+ yrs (F)	15-19 yrs (M)	15-19 yrs (F)	20-24 yrs (M)	20-24 yrs (F)	25-30 yrs (M)	25-30 yrs (F)	31+ yrs (M)	31+ yrs (F)	15-19 yrs (M)	15-19 yrs (F)	20-24 yrs (M)	20-24 yrs (F)	25-30 yrs (M)	25-30 yrs (F)	31+ yrs (M)	31+ yrs (F)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)	(r)	(s)	(t)	(u)	(v)	(w)	(x)	(y)	(z)	(aa)	(bb)	(cc)	(dd)	(ee)	(ff)	(gg)	(hh)	(ii)	(jj)	(kk)	(ll)	(mm)	(nn)	(oo)	(pp)	(qq)	(rr)	(ss)	(tt)	(uu)	(vv)	(ww)	(xx)	(yy)	(zz)	(ab)	(ac)	(ad)	(ae)	(af)	(ag)	(ah)	(ai)	(aj)
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TOTAL this Month																																																													

Appendix 10; PrEP Reporting Tool (MoH 737)

MOH 731 PLUS PrEP SUMMARY REPORTING TOOL

Facility Name			
MFL Code			
Sub-County		County	
Reporting Month		Year	

1. Number Eligible for PrEP

	15 - 19 Yrs		20-24 Yrs		25-30 Yrs		> 30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM								
FSW								
PWID								
Discordant Couple								
Total								

2. Number initiated (New) on PrEP

	15 - 19 Yrs		20-24 Yrs		25-30 Yrs		> 30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM								
FSW								
PWID								
Discordant Couple								
Total								

3. Number continuing (Refills) PrEP

	15 - 19 Yrs		20-24 Yrs		25-30 Yrs		> 30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM								
FSW								
PWID								
Discordant Couple								
Total								

4. Number Restarting PrEP

	15 - 19 Yrs		20-24 Yrs		25-30 Yrs		> 30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM								
FSW								
PWID								

5. Number currently on PrEP (New + Refill+ Restart)

	15 - 19 Yrs		20-24 Yrs		25-30 Yrs		> 30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM								
FSW								
PWID								
Discordant Couple								
Total								

6. Number tested HIV positive while on PrEP

	15 - 19 Yrs		20-24 Yrs		25-30 Yrs		> 30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM								
FSW								
PWID								
Discordant Couple								
Total								

7. Number diagnosed with STI

	15 - 19 Yrs		20-24 Yrs		25-30 Yrs		> 30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM								
FSW								
PWID								
Discordant Couple								
Total								

8. Number discontinued PrEP

	15 - 19 Yrs		20-24 Yrs		25-30 Yrs		> 30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM								
FSW								
PWID								

Appendix 11: Frequently Asked Questions about Pre-Exposure Prophylaxis

What is PrEP?

PrEP stands for Pre-Exposure Prophylaxis. PrEP is anti-HIV medication taken by HIV negative people who are at high risk of HIV infection to reduce their chances of becoming infected.

How is PrEP different from regular ARV drugs?

PrEP is oral ARV medication used for HIV negative people for HIV prevention. However, the same ARV medication can be used by HIV positive people in combination with additional ARV drugs.

How is PrEP (Pre Exposure Prophylaxis) different from Post-Exposure Prophylaxis (PEP)?

Even though PrEP and PEP are both taken by HIV negative people to prevent HIV infection, they are different. PrEP is used by HIV negative people who are at ongoing risk of HIV before exposure to reduce their chances of getting HIV. PEP is used by HIV negative people after a possible exposure to HIV but must be taken within 72 hours.

How does PrEP work?

When a person is exposed to HIV through blood, sexual intercourse or coming into contact with infected body fluid, PrEP significantly reduces the chances of being infected with the HIV by killing the virus before it establishes infection.

What are the benefits of PrEP?

PrEP can help people who are HIV-negative with ongoing risk of HIV infection to remain HIV negative. It is more effective when combined with other prevention methods such as condoms.

PrEP offers

Decreased anxiety

Increased communication, disclosure, trust

Increased self-efficacy

Among HIV discordant couples, PrEP is a means to

Reduce risk of HIV transmission

Meet their fertility desires

Cope with HIV sero-discordance.

When can I use PrEP?

Any person who is at high risk for acquiring HIV, and meets ANY of the following indications;

Has a sexual partner who is known HIV positive and either: not on ART, has not been on ART for 6 months, suspected of poor adherence to ART, or who has not achieved viral suppression.

Sexual partner(s) are of unknown HIV status and are at high-risk for HIV infection i.e. has multiple sexual partners, has had STIs, engages in transactional sex, injects drugs

Engaging in transactional sex (sex in exchange of gifts etc.)

History of recent sexually transmitted infection

Recurrent use of post-exposure prophylaxis (PEP)

History of sex while under the influence of alcohol or recreational drugs as a habit

Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status

Injecting drug use where needles and syringes are shared

HIV serodiscordant couples (where one partner is infected with HIV and the other is not) who are trying to conceive

Can I use PrEP with other medicines?

It is important to seek doctors' advice on which medicines one can use together with PrEP

When should I not use PrEP?

You should not use PrEP if:

If you are HIV positive

If you do not know their HIV status

If you cannot use your PrEP pill daily

If you have been advised by a health care provider not to use PrEP

Should I use PEP if I suspect that am exposed to HIV when taking PrEP?

Ideally, if you are taking PrEP every daily as prescribed, you do not need to use PEP because PrEP already provides a high degree of protection from any potential HIV exposure. Continue taking your PrEP pill and discuss with your healthcare provider if you are concerned about possible HIV infection

What are the side effects of PrEP?

Some people who take PrEP experience side effects that last for a short period. These may include headache, weight loss, nausea, vomiting, and abdominal discomfort and often reduce or stop after a few weeks of taking the PrEP. Inform your provider about any discomfort that persists or if you are concerned about how you feel after starting PrEP.

How should I take PrEP Pills?

The PrEP Pill should be taken once a day for as long as a person remains at risk of HIV infection (or as advised by the Health care provider). You should not take 2 pills at the same time or on the same day to make up for a missed dose.

Can I still use condoms when taking PrEP?

PrEP does not protect users from STI or pregnancy. PrEP is provided as part of combination prevention including condom use, VMMC, risk reduction counselling and support etc.

Does PrEP contribute to increase in risky sexual behavior?

PrEP is provided part of a package of combination prevention including risk reduction counselling and support. Provided this way, PrEP does not contribute to behavioural disinhibition and risk taking.

Am I protected from HIV if I miss a PrEP pill or pills?

When you miss one or more pills, you greatly reduce the ability of the PrEP to provide you with full protection against HIV infection. Evidence has showed that PrEP provides the best protection from HIV if it is taken consistently every day.

Can I share PrEP with others?

PrEP should only be taken by the person prescribed and should not be shared with others. Everyone who wants to use PrEP should discuss the intention with a health provider.

How long can I take PrEP?

Someone can take PrEP for as long as they remain at risk of HIV infection. However it is important to continue consulting a health provider for advice.

Can I use PrEP along with other medicines?

It is important to seek doctors' advice on which medicines one can use together with PrEP

When should I stop/discontinue taking PrEP?

You should stop/ discontinue PrEP if you meet ANY of the following criteria are met:

HIV positive

If you reduce your risk for getting infected with HIV

If the health care provider informs you that your kidney (Renal) function is low after doing some test

If you request to stop

If you are not adhering to the drugs well

If you are in a discordant relationship and your HIV positive partner has achieved sustained viral suppression. But you should continue to consistently use condom

Can a pregnant woman take PrEP? What happens if a woman who is taking PrEP becomes pregnant?

Yes, if you are pregnant or intending to get pregnant and your partner is HIV positive, you can take PrEP.

Can One Develop Resistance to PrEP

Resistance occurs sometimes when antiretroviral agents are used for treatment.

Extremely rare with PrEP, and limited to those with unrecognized acute HIV infection when starting PrEP.

Resistance can only occur if there is continued PrEP use in the background of unrecognized HIV infection.

The benefits of PrEP far outweigh the risk and concerns about drug resistance

Appendix 12: List of Contributors and Reviewers

Names of Contributors	Organization
Abraham Rono	HEALTH RIGHT INTERNATIONAL
Alice Karanja	JHPIEGO
Alita Monroe wise	UNIVERSITY OF WASHINGTON
Anabel Gomez	AVAC
Anangwe M. Samson	DOD
Ann Njoki	NASCOP/MOH
Anthony Gichangi	JHPIEGO
Beth Mbugua	NASCOP/MOH
Brenda Bakobye	NEPHAK
Brian Wakhutu	JHPIEGO
Christine Akinyi	LVCT HEALTH
Daniel Were	JHPIEGO
Dicson Mwakangah	CDC
Dorcus Abuya	NHRL
Dorothy Mwagae	NASCOP/MOH
Dr Lilly Nyaga	NASCOP/MOH
Dr Martin Sirengo	NASCOP/MOH
Dr Micah Anyona	JHPIEGO
Dr Nelly Mugo	KEMRI
Dr Sarah Masyuko	NASCOP/MOH
Dr. Bill Sinkele	SAPTA
Dr. Bob Agwata	NASCOP/MOH
Dr. Elizabeth Irungu	PARTNERS IN HEALTH AND DEVELOPMENT(PHRD)
Dr. Godwin Mugo	CHAK
Dr. Henry Tabifor, ,	UNAIDS
Dr. Jared Mecha	UON/KNH
Dr. Josphat Kosgei	KEMRI /WRP
Dr. Michelle Ogolla	GSK
Dr. Misiko Linda	NASCOP/MOH
Dr. Kigen Bartilol	NASCOP/MOH
Beatrice King'ori	NASCOP/MOH
Dr. Mugwanya Kenneth	PARTNERS IN HEALTH AND DEVELOPMENT(PHRD)
Dr. Omwoyo Willis	MOH
Dr. Peter Cherutich	MOH

Names of Contributors	Organization
Dr. Stellah Bosire	KMA
Dr. Ulrike Gilbert	UNICEF
Dr. Urbanus Kioko	AVENIR HEALTH
Dr. Ahmed Sheikh Hussein	MOH
Dr. Barbara Mambo	NASCOP/MOH
Dr. Brian Chirombo	WHO
Dr. Evans Imbuki	NASCOP/MOH
Dr. Irene Inwani	KNH
Dr. Irene Mukui	NASCOP/MOH
Dr. Violet Oramisi	NASCOP/MOH
Dr. Jebet.K. Boit	MATHARI NTRH
Dr. John Kinuthia	KNH
Dr. Joyce Wamicwe	NASCOP/MOH
Dr. Maureen Kimani	NASCOP/MOH
Dr. Muthoni Karanja	NASCOP/MOH
Dr. Rose Wafula	NASCOP/MOH
Dr. Teresa Alwar,	UNICEF
Edward Omondi	NASCOP/MOH
Elizabeth Kubo	UON
Emma Mwamburi	USAID
Eunice Mutisya	PS KENYA
Eunice Njeri	NASCOP/MOH
Fatuma Mohamed	NASCOP/MOH
Fredrick Maweu	LVCT HEALTH
Fredrick Otieno	NRHS
Geoffrey Njenga	JHPIEGO
George Victor Owino	KAVI
Gloria Gakii	SWOP/UON
Godfrey Odhiambo	JHPIEGO
Harriet Kongon	UNAIDS
Jacque Wambui	NEPHAK
Jane Mutegi	JHPIEGO
James Kabiro	ORDER PHARMACY
Japheth Gituku	NASCOP/MOH
Japheth Nyambane	NASCOP/MOH
Jason Reed	JHPIEGO

Names of Contributors	Organization
Jeremia Hongo	PS KENYA
Jill Peterson	FHI360/GEMS
Joab Khasewa	NACC
Joel Mutinda	NASCOP/MOH
Johnson Birgen	SAUTI SKIKA
Jordan Kyongo	LVCT HEALTH
Joshua Kimani	UOM SWOP
Judy Mwangi	JSI
Justus Oganda	CHAI
Kennedy Murithi	CHAI
Lenet M. Bundi	NASCOP/MOH
Lucy Maikweki	PS KENYA
Mary Mugambi	NASCOP/MOH
Maureen Inimah	NASCOP/MOH
Mercy Kamau	JHPIEGO
Michael Macharia	NASCOP/MOH
Mohamud Mohamed	NASCOP/MOH
Nancy Bowen	NHRL
Naomi Siele	NASCOP/MOH
Nicholas Ngugi	UNAIDS
Norton Sang	SEARCH
Obwiri Kenyatta	EGPAF
Olivia Njathi	CHAI
Pacific Akinyi	NASCOP/MOH
Parinita Bhattacharjee	NASCOP/MOH
Patricia K. Macharia	NASCOP/MOH
Patricia Oluoch	CDC
Patricia Ong'wen	JHPIEGO
Patriciah Jeckonia	LVCT HEALTH
Patrick Mutua	NASCOP/MOH
Paul Ereng	MSF FRANCE
Pauline Mwololo	NASCOP/MOH
Peter Michira	PARTNERS IN HEALTH AND DEVELOPMENT(PHRD)
Peter Njane	ISHTAR
Philip Muchiri	CHAI
Precious Otieno	NASCOP/MOH

Names of Contributors	Organization
Prince N Bahati	IAVI
Prince N bahati	IAVI
Prof Bukusi Elizabeth	KEMRI
Roseline Warutere	NASCOP/MOH
Sarah Goretti	WRP
Serah Maloba	NASCOP/MOH
Soud Tengah	JHPIEGO
Stephen Wanjala	MSF FRANCE
Timothy Nzomo	NHRL
Tom Marwa	JHPIEGO
Urvi Parikh	UNIVERSITY OF PITTSBURGH/GEMS
Victor Waweru	ISHTAR
Violet Otindo	NASCOP/MOH
Wcyliff Lihanda	IRC
Winnie Owiti	NASCOP/MOH

Notes

NASCOP

National AIDS and STI
Control Program

National AIDS & STI Control Programme
Afya Annex, Kenyatta National Hospital Grounds
P.O. Box 19361 - 00202, Nairobi, Kenya.
Tel: +254 - 729 213 755 / +254 - 775 597 297
Email: info@nascop.or.ke