MINISTRY OF HEALTH

NASCOP

PRE-EXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION:

A TOOLKIT FOR HEALTH SERVICE PROVIDERS

October 2022

The purpose of this toolkit is to provide additional detailed information for healthcare workers to safely and effectively provide 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.

Recommended citation for this toolkit is:

Ministry of Health, National AIDS & STI Control Programme (2022). Pre-exposure Prophylaxis for the Prevention of HIV Infection - A Toolkit for Health Service Providers, Nairobi, Kenya: NASCOP.

ISBN:

Foreword

Kenya has made tremendous progress in containing the HIV epidemic. For instance, new HIV infections have reduced by 68.5%, from 101,560 in 2013 to 32,027 in 2021, hence lowering the HIV prevalence rate from 6.9% to 4.3% during the same period. This decline has been made possible through the aggressive implementation of a combination of evidence-informed interventions including scale-up of antiretroviral therapy. However, there is still high level of HIV infection especially among the adolescents and young people (AYP) and adolescents girls and young women (AGYW) contributing 42% and 30% of new infections respectively every year. Healthcare providers are therefore being capacity build to expand behavioural and biomedical interventions for HIV prevention, which, if used effectively will further reduce the number of new infections. Recent evidence has shown that daily oral antiretroviral agents, taken by HIV uninfected individuals at high risk of HIV infection, can significantly reduce the chances of HIV infection. Based on this evidence, the Ministry of Health approved the use of PrE-Exposure Prophylaxis (PrEP) as a biomedical method of HIV prevention and incorporated the guidance on PrEP use in the Antiretroviral (ARV) guidelines.

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. The provider will assess the client for suitability to use PrEP, exclude contraindications to PrEP medications and offer ongoing monitoring, risk reduction and adherence support. PrEP is used strictly as prescribed when at high risk of HIV infection. During follow-up, providers should assess and determine whether PrEP is still necessary. The duration of PrEP use is determined by the level of risk of an individual PrEP user and the adoption and adherence to other HIV prevention interventions.

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). 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.

Acknowledgements

The development of the PrEP toolkit involved a highly consultative process with a wide range of stakeholders including from government both National and County levels; private sector; civil society organizations including those representing people living with HIV, and multilateral development partners.

The ministry of health feels greatly indebted to the National AIDS and STI control program for leading the technical team and steering the consultations both at the National and County levels to develop this toolkit. Specifically, the Ministry of Health would like to thank Dr. Rose Wafula, Head, Division of NASCOP who gave valuable inputs while guiding the whole process. Special thanks to Dr. Jonah Onentiah, Program Manager HTS/PrEP, (NASCOP) for coordinating the development process. We also acknowledge CHAI, LVCT, NHRL, NPHL, JHPIEGO, CHAI, HJFMRI (Walter Reed Project), USAMRU, JHPIEGO and other health partners who participated in the process, for sharing valuable experience that helped enrich this toolkit.

To all individuals and organizations that participated in the development of this operational manual, your contributions are highly appreciated.

Finally, we thank LVCT for their technical and financial support to the development process.

Table of Contents

List of Tables

List of Figures

List of Abbreviation

3TC	Lamuvidine
ADR	Adverse Drug Reaction
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARVS	Antiretroviral Drug(s)
AYP	Adolescent and Young people
CAB-LA	Cabotegravir long-acting
CCC	Comprehensive Care Centre
CHAI	Clinton Health Access Initiative
CHVs	Community Health Volunteers
CHW	Community Health Workers
Cr	Creatinine
DBS	Dried blood spots
DAR	Daily Activity Register
DICE	Drop in Centre
DQA	Data Quality Assessment
DRT	Drug resistant test
DVR	Dapivirine Vaginal Ring
ED	Event-Driven
EMR	Electrical Medical Records
eMTCT	Elimination of Mother to Child Transmission
FAQs	Frequently Asked Question(s)
FSW	Female Sex Workers
FTC	Emtricitabine
GBV	Gender-Based Violence
Hb	Hemoglobin
HIV	Human Immunodeficiency Virus
HRH	Human Resource Health
HTS	HIV Testing Services
IDU	Inject Drug Users
IPC	Infection Prevention Control
IPV	Intimate Partner Violence

KASF	Kenya AIDS Strategic Framework
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KHIS	Kenya Health Information System
KP	Key Population
LMIS	Logistics Management Information System
LRF	Laboratory Requisition Form
LTFU	Lost To Follow Up
M&E	Monitoring and Evaluation Supplies
MEDs	Mission for Essential Drug
MFL	Master Facility List
MOH	Ministry of Health
MSM	Men Who Have Sex with Men
NASCOP	National AIDS and STI Control Program
NGO	Non-Governmental Organization
NHIF	National Health Insurance Fund
NHRL	National HIV Reference Laboratory
NPHL	National Public Health Laboratory
OPD	Out Patient Department
PEP	Post Exposure Prophylaxis
PITC	Provider-Initiated Testing and Counselling
PMTCT	Prevention of Mother-To-Child Transmission
PPB	Pharmacy and Poisons Board
PrEP	Pre-Exposure Prophylaxis
QI	Quality Improvement
SOP	Standard Operating Procedure
STIs	Sexually Transmitted Infection
TDF	Tenofovir Disoproxil Fumarate
TCA	To Come Again
TG	Transgender
TWG	Technical Working Group
VL	Viral load
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

Purpose

The purpose of this toolkit is to provide additional detailed information for healthcare workers (HCW) to safely and effectively provide 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 and community settings. It describes important considerations when starting, monitoring use and switching PrEP.

Section 2: Provides guidance on sample management for drug resistance testing among the PrEP sero-converters.

Section 3: Provides information on quality improvement with emphasis on optimizing outcomes for clients and service delivery.

Section 4: Provides highlight on PrEP commodity management including consumption, reporting and pharmacovigilance system.

Section 5: Provides guidance on how to use PrEP data collection and reporting tools.

Section 1: Clinical overview

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

1.1 Overview for Pre-exposure Prophylaxis

Table 1: Overview of Recommendations for Pre-Exposure Prophylaxis

What is PrEP?	PrEP is a HIV prevention method in which a HIV negative person at high risk of HIV infection uses antiretroviral agents to prevent HIV infection.
Who can use PrEP? (indications for PrEP)	PrEP is recommended for HIV negative persons at high risk of HIV infection such as: • In a HIV sero discordant relationship where the sexual partner is HIV positive: ✓ has not been on ART, ✓ on ART for less than 6 months, ✓ suspected poor adherence to ART, ✓ with detectable viral load or ✓ trying to conceive but having a detectable viral load • **HIV negative** pregnant or breastfeeding women whose sex partner(s) is/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 recurrent STIs, engages in transactional sex, injects drugs) • Engaging in transactional sex • Recurrent 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 • Ongoing Intimate Partner Violence (IPV)/Gender Based Violence (GBV)
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 < 30kgs 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.

<table>
<tr><td rowspan="5">What are the recommended PrEP methods?</td><td>PrEP Dosing Strategies</td><td>Preferred</td><td>Alternative</td></tr>
<tr><td>Daily Oral PrEP</td><td>TDF/FTC (300 mg/200 mg) as FDC once daily</td><td>TDF/3TC (300 mg/300 mg) as FDC once daily</td></tr>
<tr><td>Event Driven Oral PrEP</td><td>TDF/FTC (300 mg/200 mg) as FDC – two pills taken between 2 and 24 hours in advance of anticipated sex; then, a third pill 24 hours after the first two pills and a fourth pill 48 hours after t
he first two pills; 2-1-1</td><td>TDF/3TC (300 mg/300 mg) as FDC – two pills taken between 2 and 24 hours in advance of anticipated sex; then, a third pill 24 hours after the first two pills and a fourth pill 48 hours after the first two pills; 2-1-1</td></tr>
<tr><td colspan="3">*Recommended Long-acting Products: These products are at different stages of approval and availability in Kenya. The Ministry of Health will issue specific implementation guidelines when they become available.</td></tr>
<tr><td>*Long Acting Cabotegravir Injection</td><td>Initiation injections: 600 mg Intramuscular (IM) x 2 doses given 1 month apart (the second initiation injection can be given up to 7 days before or after the date scheduled to receive injection)
THEN
Continuation injections: 600 mg IM every 2months</td></tr>
<tr><td>*Dapivirine vaginal ring</td><td>Dapivirine vaginal ring, 25mg, inserted vaginally every 28 days.</td></tr>
<tr><td colspan="4">Remind individuals using daily oral PrEP that it takes 7 doses (equivalent to 7 days) of continuous PrEP use to achieve adequate levels of the ARVs in tissues for it to be effective. During these days, safer sex practices should be encouraged (including abstinence and condom use). This only applies for individuals born female. Those born male can have protective levels as soon as 2 hours before sex but ideally 24 hours. This is true even for people intending to take daily oral PrEP for ongoing exposure.</td></tr>
<tr><td>What is effective PrEP use?</td><td colspan="3">PrEP should be offered as part of a comprehensive, individualized prevention plan following behavioural risk assessment and adherence counselling. Combination prevention includes:
HIV Testing Services
Risk reduction counselling
Substance abuse treatment
Safer sex practices
Prevention of gender-based violence (GBV)
Consistent and correct condom use
Adherence to PrEP - efficacy of PrEP is dependent on adherence
VMMC (where indicated)
Prevention and treatment of STIs
Effective adherence to ART for HIV+ persons (Treatment as Prevention)
After initiation, oral PrEP will be effective after a minimum of 7 days of consistent use.</td></tr>
</table>

<table>
<tr><td>Follow up;</td><td>After starting daily oral 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, offer risk reduction counselling, adherence assessment and support, and assess for side effects.

Event driven PrEP; One off event – doesn't require follow up.

Dapivirine vaginal ring follow up is after every 28 days – HIV test is done at initiation, after 28 days and thereafter 3 monthly.

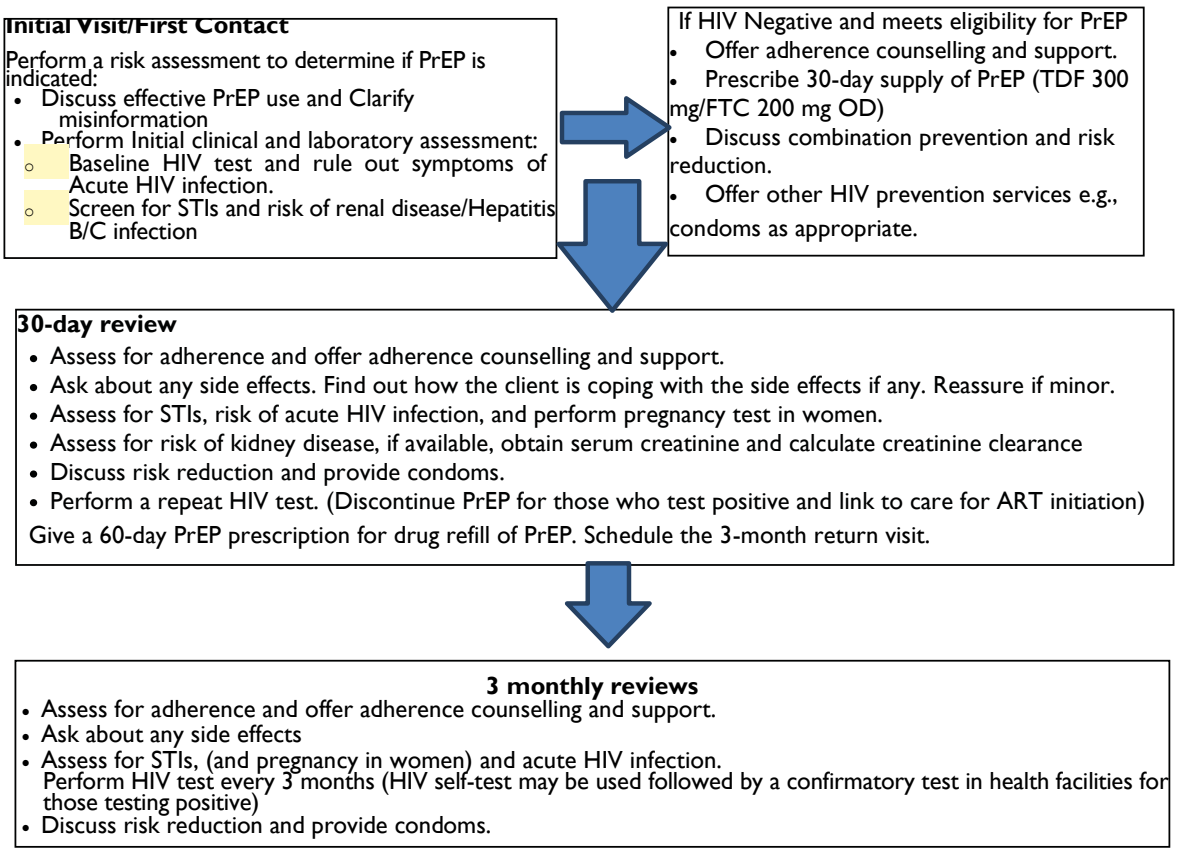
Cabotegravir injectable follow up is monthly – HIV test is done at initiation, at month 1 and thereafter 3 monthly.</td></tr>
<tr><td>PrEP Laboratory tests initiation and follow up</td><td>Initial & follow up laboratory test
<table>
<tr><th>Laboratory Test</th><th>Guidelines for clients initiating PrEP</th><th>Guidelines for clients on follow up</th></tr>
<tr><td>HIV Rapid Test</td><td>Before initiating PrEP as per the National HTS algorithm</td><td>At Month 1, Month 3, thereafter every 3months</td></tr>
<tr><td rowspan="2">Creatinine Test</td><td>Test within 1-3 months of PrEP Initiation</td><td>If client >50years – Screen every 6-12months</td></tr>
<tr><td>Clients of any age with renal comorbidity: recommended before initiating PrEP</td><td>Screen every 6-12months</td></tr>
<tr><td>Hepatitis B Surface Antigen (HBsAg)</td><td colspan="2">Test once within 3 months of initiating PrEP. If negative, offer/refer for immunization</td></tr>
<tr><td>Hepatitis C Virus Serology</td><td>Test once within 3months of PrEP initiation</td><td>Every 12 months for persons at high risk of Hepatitis C infection</td></tr>
</table></td></tr>
<tr><td>Duration</td><td>PrEP is not meant to be a lifelong intervention. It is a method of HIV prevention during periods when a person is at high risk of acquiring HIV.</td></tr>
<tr><td>Switch</td><td>Client may switch PrEP methods due to:
Client preference
Adverse Drug Reactions
Stock outs
Drug interactions</td></tr>
<tr><td>Discontinuation of PrEP</td><td>PrEP should be discontinued if ANY of the following criteria are met.
Positive HIV test during follow up.
Change in risk status (no ongoing risk)
Renal dysfunction with creatinine clearance below 50 ml/min
Client request to stop.
Sustained non-adherence.
Discontinuing daily oral PrEP: Users discontinuing PrEP due to no ongoing risk or requesting to stop should continue PrEP for at least 7 days after the last potential exposure to HIV. Reasons for discontinuation should be documented in the client's record.

Discontinuing event–driven PrEP: If sex continues beyond one day, a user of ED-PrEP can stay protected by taking another pill each day as long as sex continues and stopping 2 days after the last sex act (Refer to the Kenya HIV Prevention and Treatment Guidelines 2022 figure 11. 3).</td></tr>
</table>

Restart	Any client restarting PrEP regardless of the preferred method should be assessed for HIV status and a rapid HIV test conducted: • ***Daily Oral PrEP***: Clients who stop 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, conduct a HIV test before re-starting PrEP. 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. The use of condoms should be recommended during the waiting period. • ***Event driven Oral PrEP***: Clients who have stopped PrEP for more than a week and who are restarting ED-PrEP should commence with a double dose (two pills) of PrEP as new initiators. Risk assessment should be conducted. 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. The use of condoms should be recommended during the waiting period.

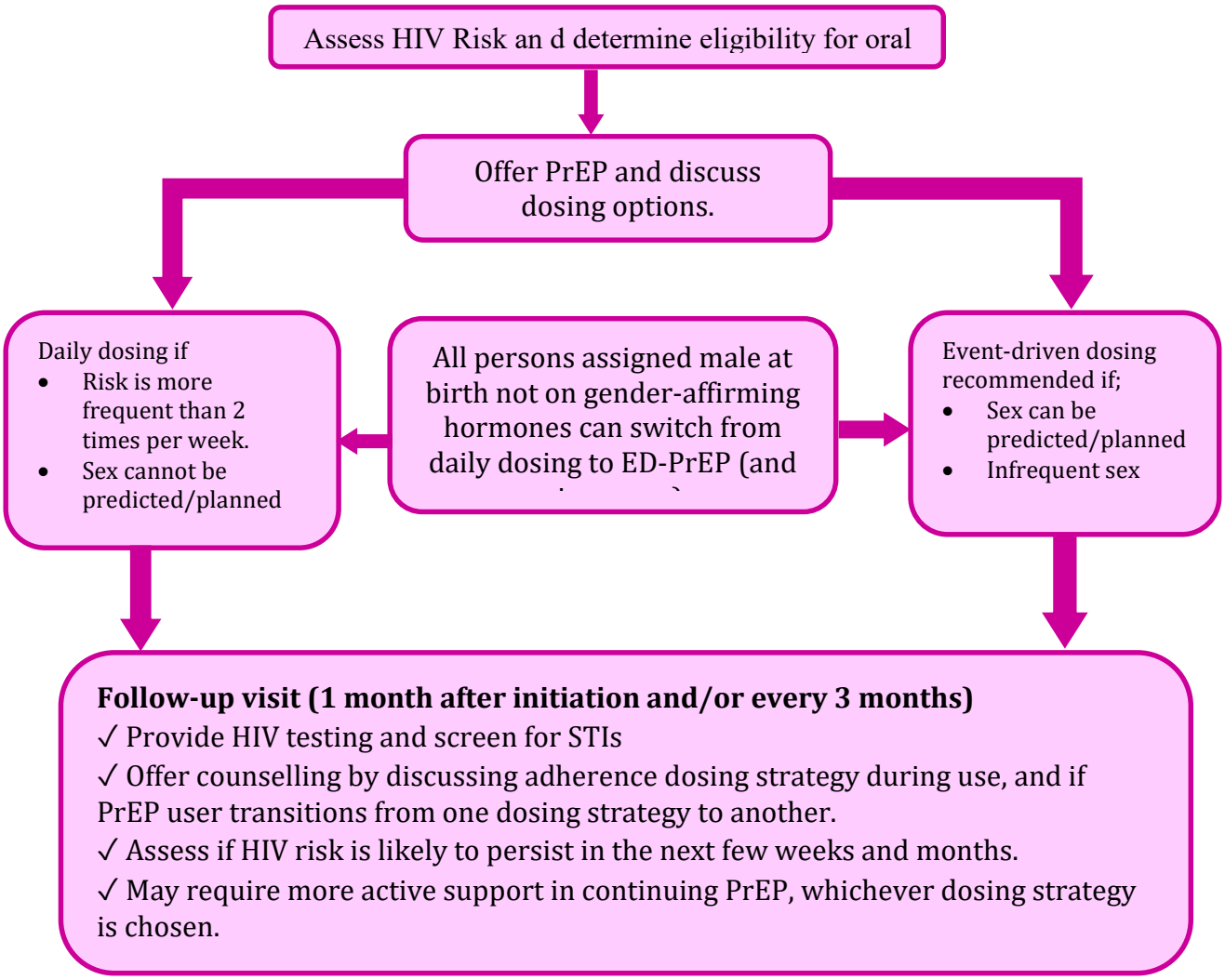
Figure 1: Schema for Managing Pre-Exposure Prophylaxis for HIV Prevention

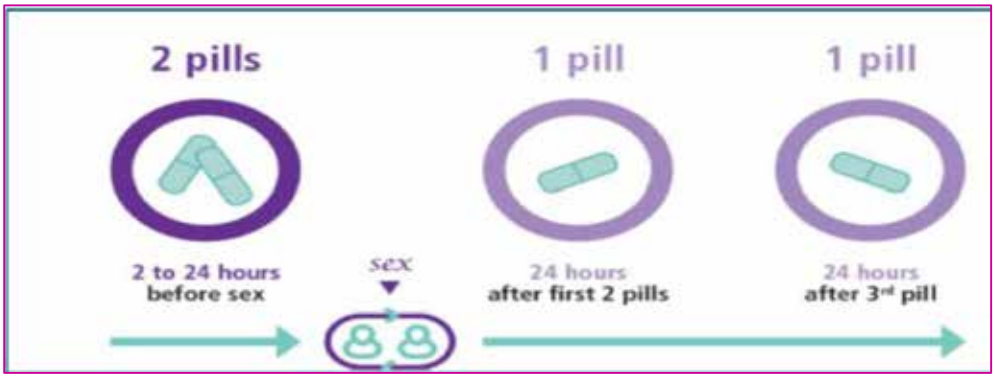
After routine care is established, the client should get a 90-day PrEP prescription for monthly drug refills, adherence review and risk assessment; and be scheduled for full clinical assessment every 3 months.



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

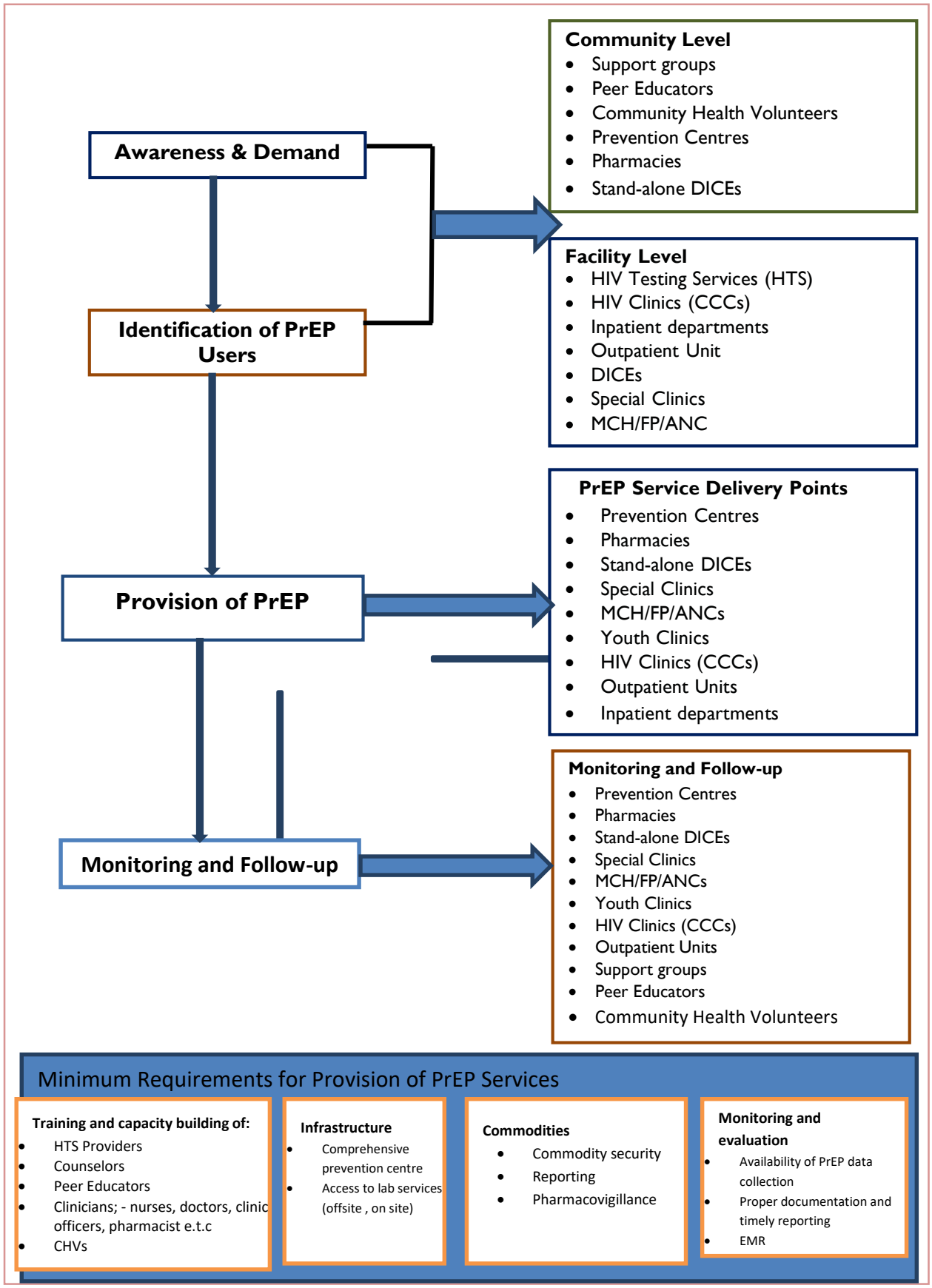
Figure 2: Schema for Initiation and Follow up for Event-driven PrEP





Note: *If sex continues beyond one day, a user of ED-PrEP can stay protected by taking another pill each day as long as sex continues and stopping 2 days after the last sex act.*

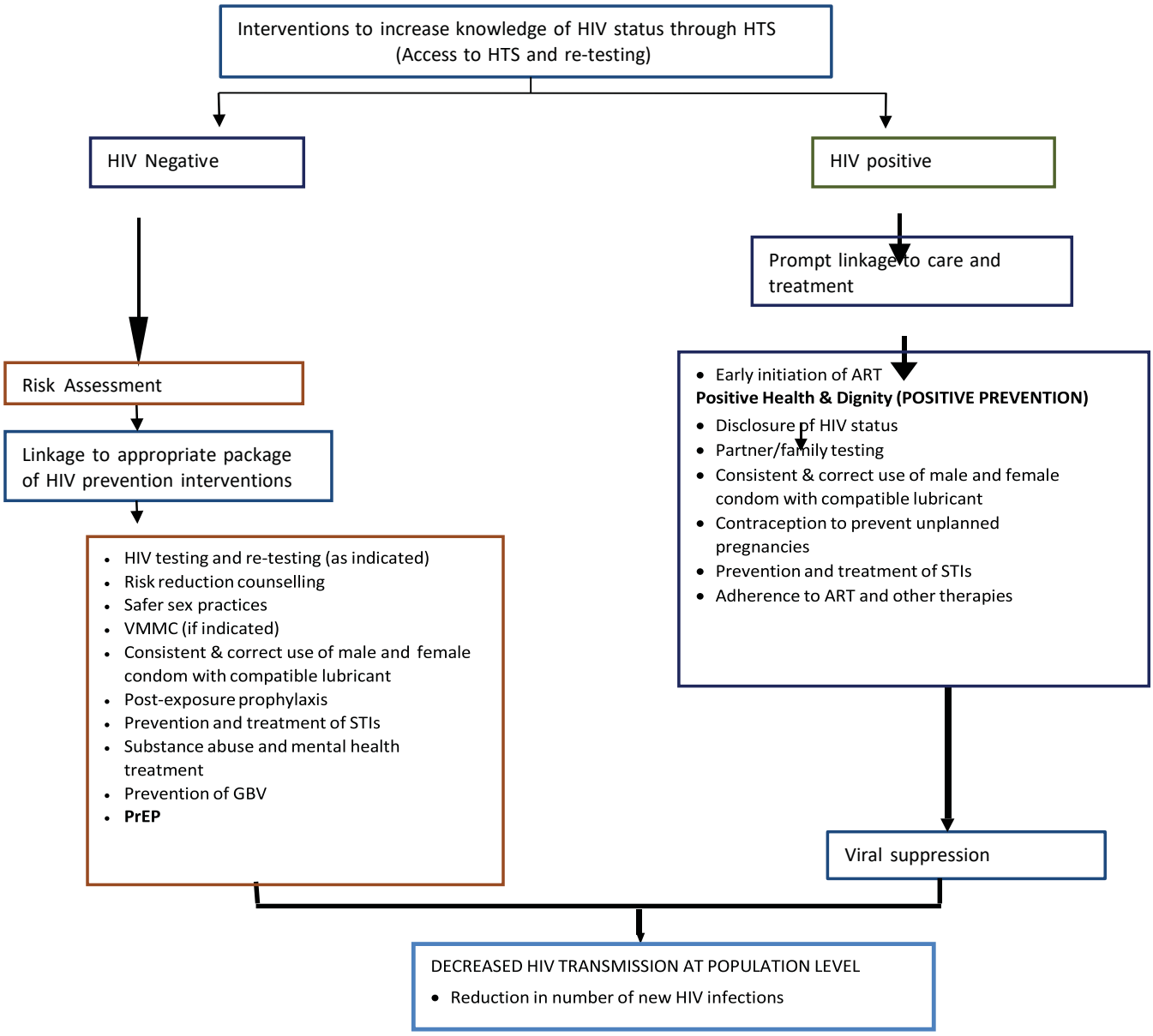
Figure 3: Entry Points for PrEP and other HIV Prevention Services



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, PWID, 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 4 summarizes steps for combination prevention for clients accessing PrEP services.

Figure 4: Combination Prevention of HIV Infection



1.3 Indications and Risk Assessment for Pre-Exposure Prophylaxis

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

In a HIV sero discordant relationship where the sexual partner is HIV positive:

- ✓ has not been on ART,
- ✓ on ART for less than 6 months,
- ✓ suspected poor adherence to ART,
- ✓ with detectable viral load or
- ✓ trying to conceive but having a detectable viral load

- **HIV negative** 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 recurrent STIs, engages in transactional sex, injects drugs)
- Engaging in transactional sex
- Recurrent 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
- Ongoing Intimate Partner Violence (IPV)/Gender Based Violence (GBV)

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

- High risk of HIV infection
- No suspicion of acute HIV infection
- No renal impairment
- Documented HIV negative test
- 15 years and above
- Weighs 30kgs and above
- No contraindications to PrEP medications (TDF/FTC or TDF/3TC)
- Willingness to use PrEP as prescribed, including regular visits to monitor HIV status, adherence and side effects.

1.4 Assessing for high risk of HIV Infection

Screening questions are used to identify individuals who may be at high risk of acquiring HIV infection. The questions are framed to elicit people's behaviours and vulnerabilities as opposed to specific sexual practices.

Before starting the sexual behavioral assessment,

- Ensure adequate privacy
- Assure the patient of confidentiality and indicate that the issue 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 health care.
- 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 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 on ART?"
- "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 < 30kgs 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 and the client is eligible for PrEP, transition to PrEP immediately.

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 5 provides the overview of the requisite steps before a client is started on PrEP.

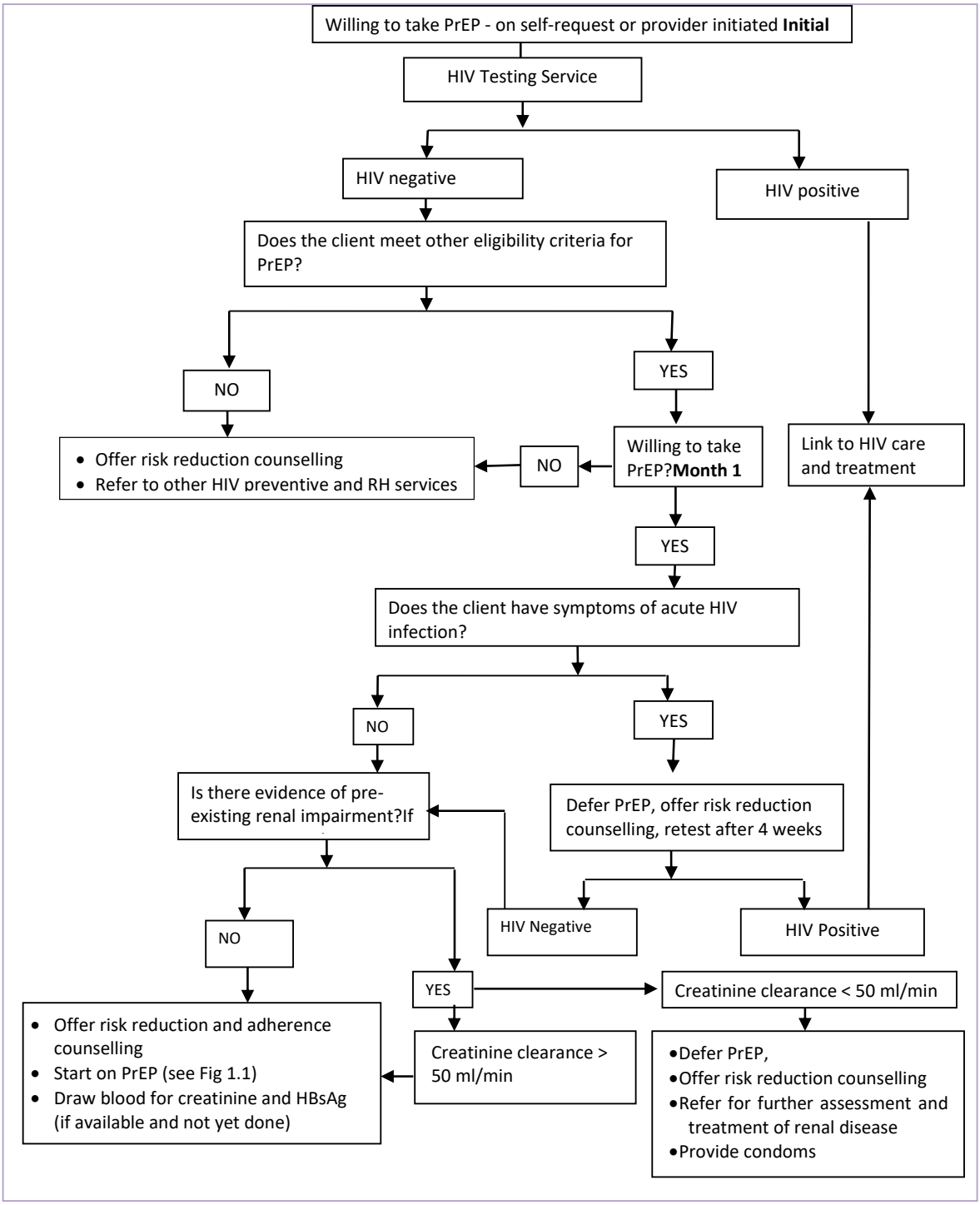


Figure 5: Initiating Pre-Exposure Prophylaxis

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

Table 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 of PrEP	• To establish willingness to adhere to PrEP and medical follow-up including HIV retesting • To screen for high-risk events • 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
	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 HIV transmission. Pregnancy is not a contraindication to PrEP
Screening for other STIs	Assess for presence of STI using the syndromic or diagnostic STI testing. Refer to guidelines on Kenya National guideline for prevention, management and control of STI 2018. Annex the STI chart
Review vaccination history	Consider vaccination for hepatitis B and human papilloma virus.
Brief assessment	• To assess whether the client is at high risk of HIV. • To assess skills for correct, consistent condoms and lubricants use. • To assess willingness to take and adhere to PrEP. • To assess pregnancy 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 1.5).

Table 3: Managing Clinical and Laboratory Results on Initiation 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	Identification of new HIV positive diagnosis among PrEP users should be followed with: • Immediate discontinuation of PrEP • Counselling of client on positive results • Take DBS or plasma sample for drug resistance testing • Linkage to care and ART (immediate ART initiation) • Assessment of barriers to adherence that may affect use of ART • Document sero-conversion in client file, PrEP registers, and monthly reporting as required
Positive STI screen	Refer to guidelines on Kenya National guideline for prevention, management and control of STI 2018.
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
	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
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 and whose HIV Positive partner has a detectable viral load. 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 of 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 4: Recommendation Regimen for Pre-Exposure Prophylaxis

PrEP Dosing Strategies	Preferred	Alternative
Daily Oral PrEP	TDF/FTC (300 mg/200 mg) as FDC once daily	TDF/3TC (300 mg/300 mg) as FDC once daily
Event Driven Oral PrEP	TDF/FTC (300 mg/200 mg) as FDC – two pills taken between 2 and 24 hours in advance of anticipated sex; then, a third pill 24 hours after the first two pills and a fourth pill 48 hours after the first two pills; 2-1-1	TDF/3TC (300 mg/300 mg) as FDC – two pills taken between 2 and 24 hours in advance of anticipated sex; then, a third pill 24 hours after the first two pills and a fourth pill 48 hours after the first two pills; 2-1-1
*Recommended Long-acting Products: These products are at different stages of approval and availability in Kenya. The Ministry of Health will issue specific implementation guidelines when they become available.		
*Long Acting Cabotegravir Injection	Initiation injections: 600 mg Intramuscular (IM) x 2 doses given 1 month apart (the second initiation injection can be given up to 7 days before or after the date scheduled to receive injection) THEN Continuation injections: 600 mg IM every 2months	
*Dapivirine vaginal ring	Dapivirine vaginal ring, 25mg, inserted vaginally every 28 days.	

Table 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 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, vaginal ring and injectable. You should as prescribed by your service provider. 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, google calendar
	  ◦ 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 7 days after your last known HIV exposure. People can stop PrEP if they are no longer at substantial risk of acquiring HIV infection. **Criteria for Discontinuing Oral PrEP** PrEP should be discontinued if ANY of the following criteria are met. • Positive HIV test during follow up. • Change in risk status (no ongoing risk) • Renal dysfunction with creatinine clearance below 50 ml/min • Client request to stop. • Sustained non-adherence. **Discontinuing daily oral PrEP:** Users discontinuing PrEP due to no ongoing risk or requesting to stop should continue PrEP for at least 7 days after the last potential exposure to HIV. Reasons for discontinuation should be documented in the client's record. **Discontinuing event–driven PrEP:** Event-driven PrEP can be stopped after two daily doses following the last sexual exposure.
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. 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.

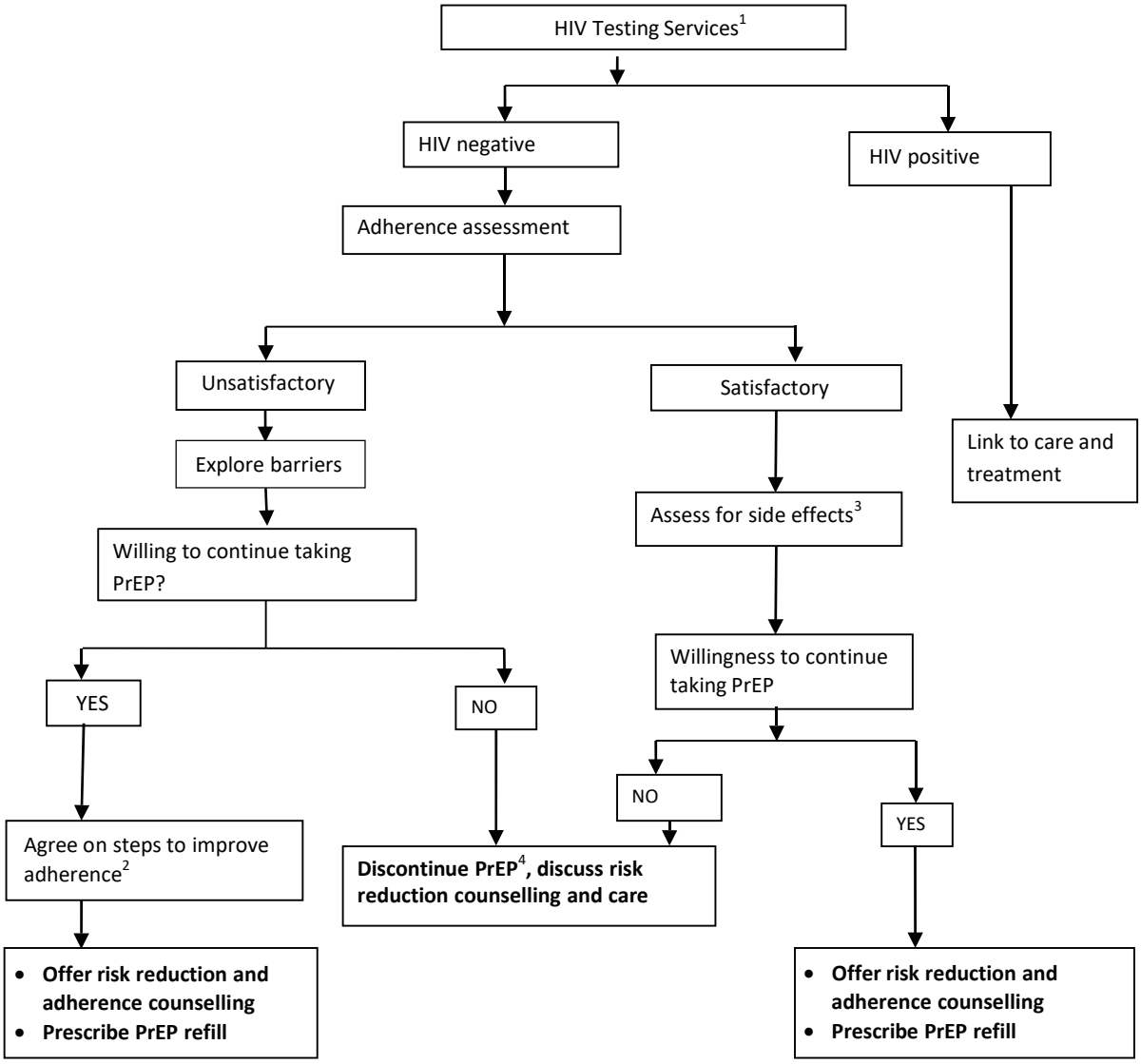
The objectives of the follow-up visits are to:

- 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

Table 6: Summary of PrEP Initial ad Follow-up Assessment

Visit	Action
First (Screening Visit) Clinician Visit	• HIV testing and counselling. • Evaluate for eligibility, willingness and readiness to take PrEP. • Educate about the risks, benefits, and limitations of different PrEP options • Educate client about recognizing symptoms of Acute HIV Infection (AHI) and what to do if such symptoms occur (i.e., urgently return for HIV testing) • Conduct behavior risk assessment • STI screening and treatment • Pregnancy, contraceptive use and counselling (for women); if pregnancy suspected, obtain a pregnancy test. However, pregnancy is not a contraindication to PrEP. • Adherence counselling • Discuss combination prevention. • Laboratory test; serum creatinine test and calculate Creatinine Clearance (CrCl), HBsAg, pregnancy test, Hepatitis C (baseline investigations should not delay initiation of PrEP). ***If no contraindication to TDF and the client is eligible and ready, prescribe TDF/FTC one tablet once daily for 30 days (alternative TDF/3TC one tablet once daily for 30 days); agree on a follow-up date before the prescription is finished.***
Visit 2 (Month 1) Counsellor/Clinician Visit	• Counsellor/ Clinician visit • Assess for side effects and adverse effects • Safety monitoring clinical assessment/ Review lab results • Conduct a HIV test as per the national algorithm • Behavioral risk assessment. • Review for PrEP continuation or discontinuation • Adherence and risk reduction counselling • Give a prescription for PrEP for 2 months. • Offer HBV vaccination if available and HBsAg negative (follow HBV vaccination schedule complete series
Follow up visits - Months 3, 6, 12, 15,..... Clinician/ Counsellor- led visits	• HIV testing and counselling • HIV risk assessment • Review for PrEP continuation or discontinuation • Assess for side effects and adverse effects • Safety monitoring clinical assessment/ Review lab results • Adherence and risk reduction counselling • Give a prescription for PrEP for 3 months • Refill PrEP prescription • Serum creatinine and creatinine clearance

Figure 6: Follow-up after initiating PrEP



1.12 HIV Testing and Managing Suspected HIV Infection during PrEP

(a) 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.

NOTE: HIV self-test (HIVST) should not be used as a definitive HIV test for PrEP initiation and follow up monitoring.

(b) Managing suspected acute illness during PrEP use

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

(c) 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 on ART (as recommended in the Kenya HIV prevention and treatment guideline 2022).

Table 7: 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 illness while on PrEP
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 IEC materials, and if available access to telephone consultation *(Contact NASCOP at ulizanascop@gmail.com ; toll free number 1190)
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 and 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 short period.

b. ***Elevated creatinine*** **-** where available, serum creatinine should be done as per the ART guidelines (refer to table 11.5 of the ART guidelines) 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.

1.14 PrEP in Special Circumstances

(a) 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 specialized assessment and treatment.

(b) Pregnancy/Breastfeeding

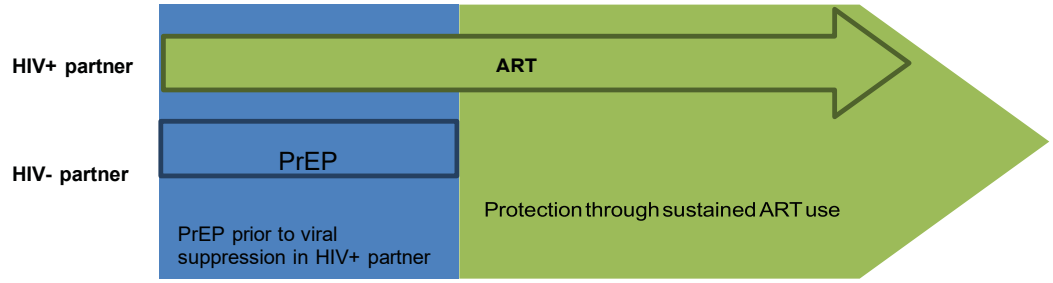
- PrEP does not prevent pregnancy or interfere with male or female fertility. Assess for pregnancy intention in all women of reproductive age who are considering PrEP. Provide counselling on safer conception options including the use of PrEP for those who wish to conceive. If pregnancy is not desired,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

(c) PrEP use in HIV serodiscordance

- The circumstances for use of PrEP in a discordant relationship include the following:

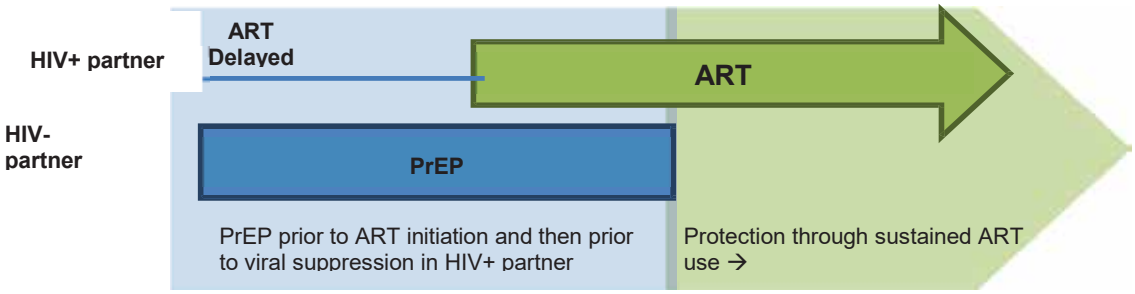
1. PrEP can be offered routinely, to the HIV negative partner, at initiation of ART for the HIV positive partner and continued until the HIV positive partner achieves viral suppression.

Scenario 1



2. 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 discontinuation 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 support, adherence and 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 incase the HIV positive partner is not virally suppressed

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

Section 2: HIV Drug Resistance Testing (DRT) among PrEP sero-converters

PrEP has been shown to substantially reduce the risk of HIV acquisition, however the earlier oral PrEP efficacy trials in different populations have reported an HIV sero- conversion incidence ranging between 0.3% - 6.5% (Parikh UM, Mellors JW 2016). The risk of developing ARV resistance in PrEP is low and a meta-analysis of 5 different PrEP trials showed that of the 579 HIV seroconversions only 2 (0.3%) individuals had resistance to Tenofovir (TDF) (Ambriosi et al. 2021).

2.1 Factors that lead to HIV seroconversion among oral PrEP sero-converters

These factors:

i. Inconsistency in use of PrEP (non-adherence).
ii. Social-behavioral factors e.g., poverty, HIV stigma and relationship status that may affect the ability to use PrEP as prescribed.
iii. Possible infections with drug resistant strains.

2.2 What should be done upon identification of a PrEP sero-converter

- ✓ Counsel the patient.
- ✓ Immediately discontinue PrEP
- ✓ Urgently link the patient to care and treatment for initiation of full antiretroviral therapy
- ✓ Explore with the patient the consistency of PrEP use (assess interruptions and barriers to adherence during PrEP).
- ✓ Consent the patient for sample collection for HIV-DR test.
- ✓ Receive the seroconversion kit and collect blood sample per the package insert and job aid obtained from CASCO office (Appendix 11 and Figure 5.1 respectively).
- ✓ Once the sample has been collected, fill the Lab Requisition Form (LRF) (Appendix 14) and then send the sample and form to NHRL (Account C00339) or KEMRI Lab – Kisumu through G4S. HIV-DRT results will be sent by NHRL or KEMRI Lab - Kisumu to the requesting PrEP facility and Uliza NASCOP and regional TWG for HIV treatment Refer to the Process Flowchart (Appendix 12.
- ✓ The PrEP facility will seek guidance from Uliza NASCOP (Toll-free Hotline 0800724848) or the regional TWG for HIV treatment for management of PrEP seroconverter if drug resistance mutations are.

2.3 Risk of drug resistance with PrEP

The following category of persons are at risk of developing ARV resistance while on PrEP:

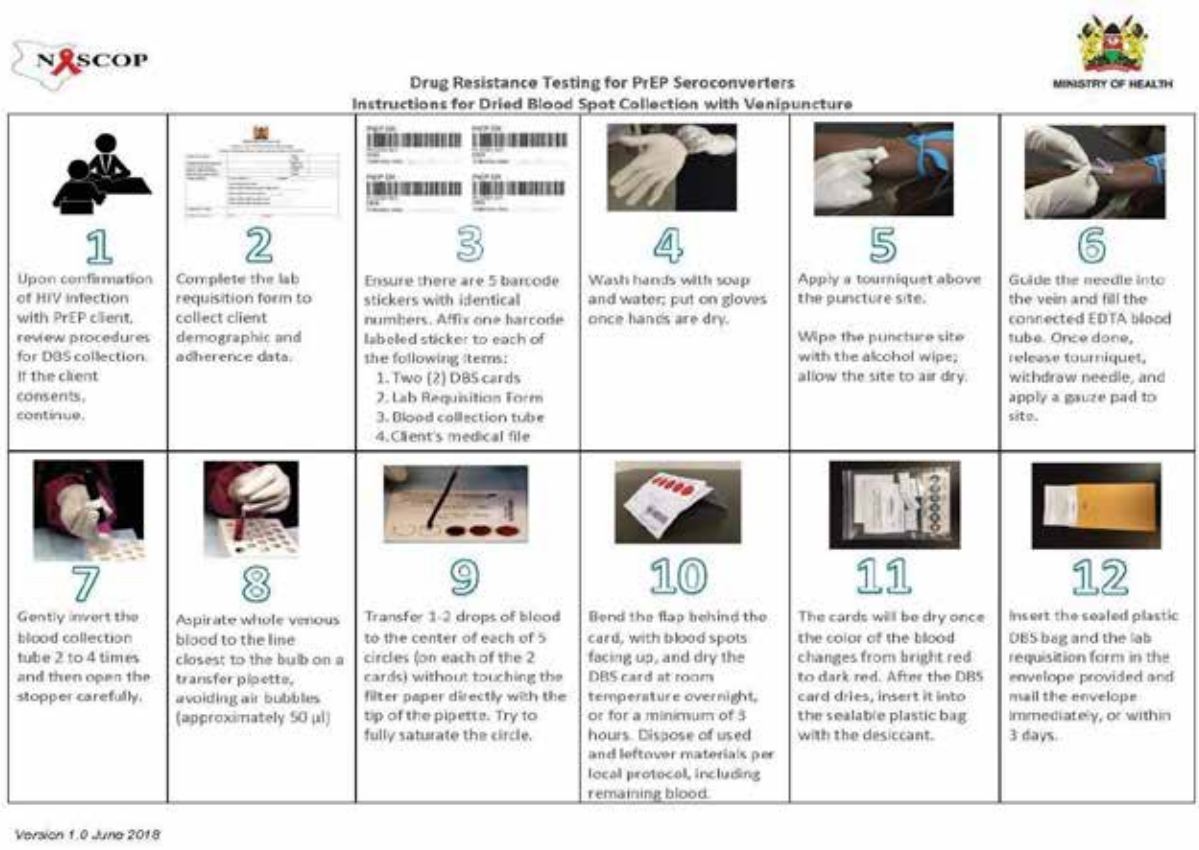
1. HIV negative person who becomes infected while on PrEP and continue using PrEP before the infection is recognised (Breakthrough infection)
2. HIV positive person who starts PrEP during acute infection and continue using PrEP before the infection is recognised.
3. HIV negative person's partner who has a drug resistant virus(transmitted resistance)

Table 8: Key messages on Drug Resistance Testing for PrEP sero-converters

Theme	Message/action
What does a DRT measure?	DRT identifies HIV mutations present in the blood.
Why perform DRT for PrEP sero-converters?	• For the sero-converter – DRT may be used to guide treatment options including recommendations to switch ART therapy if needed. • For the national program; ◦ Analyzing DRT results across all PrEP seroconverters will provide information on the effectiveness of the national PrEP program. ◦ Whether the frequency of HIV testing is adequate to capture sero-conversions on time. ◦ Selection of ARV use for treatment and prevention
When should we request for a DRT for PrEP sero- converters?	DRT should be requested upon identification of a PrEP sero-converter.
Where shall DRT be conducted?	DRT will be performed at a regional WHO accredited DR laboratory/ies within the country.
How should we request for a DRT?	• Perform HIV Testing of the PrEP client as per the national algorithm If positive, • Link to the to the HIV care and treatment • Consent, take blood sample and ship the sample to a DR testing laboratory (NHRL or KEMRI Kisumu) – see figure 7 and appendix 12.
What is required to collect DRT sample?	• DBS collection kit. Refer to the package insert (appendix 11) on contents of the DBS collection kit. • For plasma samples; PPT/EDTA tubes.

Return of DR results	• Upon availability of the DR results at the DR lab; • The DR lab results will be sent to the requesting PrEP site, the national Uliza NASCOP and to regional TWG for HIV treatment • ULIZA NASCOP and/or regional TWG for HIV treatment will review the DR results and give recommendations on the optimal treatment options The results will also be sent to the requesting facility who will seek guidance from ULIZA NASCOP for the patient results as they will link patient for ART services receiving HIV care (Refer to the DR results flowchart in (appendix 13).

Figure 7: DBS Collection Aid



NASCOP

MINISTRY OF HEALTH

Drug Resistance Testing for PrEP Seroconverters
Instructions for Dried Blood Spot Collection with Fingerprick

 1 Upon confirmation of HIV infection with PrEP client, review consent for DBS collection. If the client consents, continue.	 2 Complete the lab requisition form to collect client demographic and adherence data.	 3 Ensure there are 4 barcode stickers with identical numbers. Affix one barcode labeled sticker to each of the following items: • Two (2) DBS cards • Lab Requisition Form • Client's medical file	 4 Both healthcare worker and client should wash their hands with soap and water, and the healthcare worker should put on gloves once hands are dry.	 5 Wipe the client's finger with the alcohol wipe; allow the finger to air dry.	 6 Twist off the protective cap on the lancet to break the seal.
 7 Place the open end of the lancet against the sterilized finger, making sure that placement is slightly off-center; do not remove the lancet from the finger until an audible click is heard.	 8 Wipe away the first drop of blood with a tissue or gauze. Gently squeeze the finger, but do not milk the finger.	 9 Drip two spots of blood on the center of each of the circles, do not press finger on card directly. The blood should fill in the entire circle; fill as many circles as possible.	 10 Bend the flap behind the card, with blood spots facing up, and dry the DBS card at room temperature overnight, or for a minimum of 3 hours. Dispose of used and leftover materials per local protocol.	 11 The cards will be dry once the color of the blood changes from bright red to dark red. After the DBS card dries, insert it into the sealable plastic bag with the desiccant.	 12 Insert the sealed plastic DBS bag and the lab requisition form in the envelope provided and mail the envelope immediately, or within 3 days.

Version 1.0 June 2018

Section 3: Quality Improvement in Pre Exposure Prophylaxis

Quality Improvement (QI) is a management science that identifies where gaps exist between services provided and expectations. 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.

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 PrEP provider.

Effectiveness: Ensuring PrEP care achieves the desired outcome (preventing new HIV infections).

Efficiency: Achieving desired results with the most cost-effective use of resources e.g integrating PrEP into existing service delivery models

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

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.

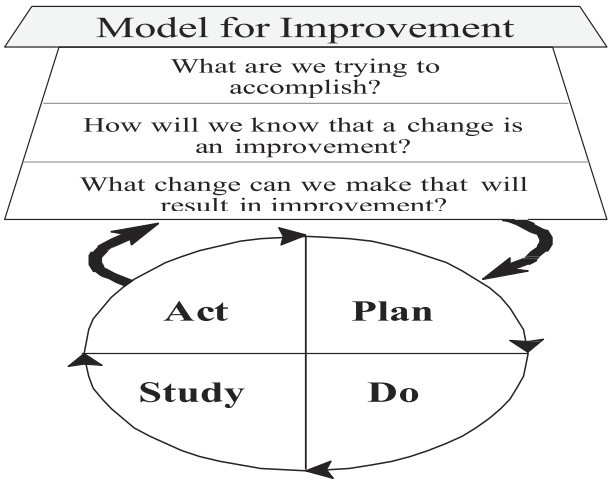
QI Tools such as the Decision Matrix can be used to prioritize areas/gaps for improvement (Appendix 5). The priorities ultimately chosen should:

a. Be important and related to National guidelines
b. Represent key community and health provider concerns
c. Be measurable
d. Include areas that the health providers will realistically be able to improve

3.2.3 After identifying the priority problem, **apply the Plan-Do-Study-Act cycle:**

This is an action-oriented method for QI, to improve the quality of services to identified areas of improvement as shown in figure 3.1. 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 8: 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 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 Kenya HIV Prevention and Treatment Guideline 2022. 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 prioritize possible gaps. Some of the reasons included; Staff were not aware of the new recommendations for PrEP; Staff did not have a screening tool 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 weeks. 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 screen clients using RAST and assess for PrEP eligibilty. Nurse In-charge tasked herself to follow up on PrEP reporting tools from the county.

Study: Two peer educators were 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 i.e.; Deployment of staff to support screening and initiation of clients on PrEP.

3.5 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 PrEP 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: Commodity Management for PrEP Rollout at Facility Level

4.1 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/MEDS). 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/MEDS 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 MEDS and NASCOP staff receives and processes facility orders and relays the requests to KEMSA which delivers required supplies to the service delivery points.

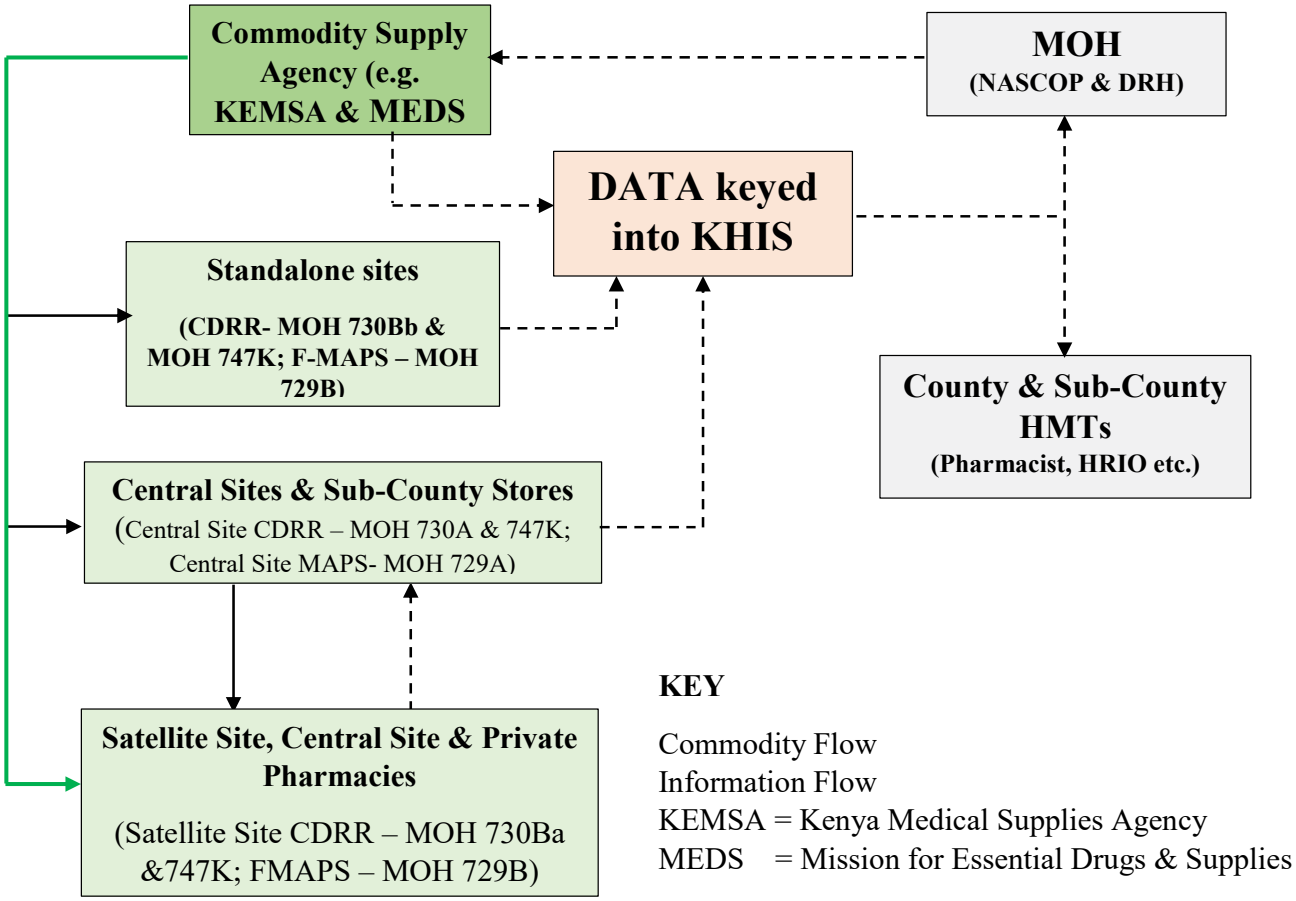
4.2 Monthly PrEP Re-fills

Clients newly initiated on PrEP will receive medicine enough for one month and will be required to come back to the facility for monthly re-fills. A re-fill on the 3rd month will only be dispensed after the client has undertaken and received HIV negative test results and thereafter quarterly

4.3 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 centers and dispensaries. Other dispensing points include drop-in centers (DICEs), community outlets/community distribution or registered private pharmacies.

Figure 9: Existing national pipeline for ARVs and opportunistic infections medicines



4.4 PrEP Commodities Consumption Data Collection 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, 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 10: A summary of data collection and reporting tools

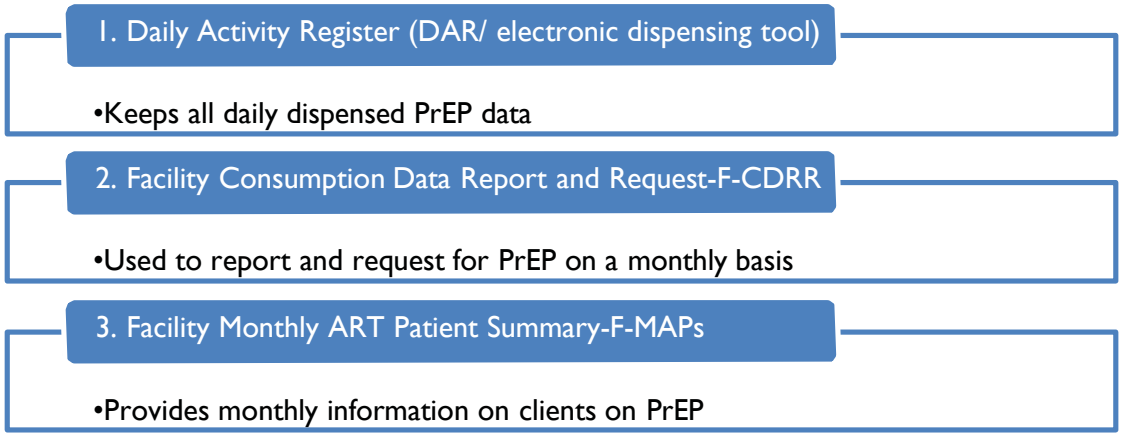


Table 9: Reporting schedule for PrEP commodities

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

4.5 Pharmacovigilance System for PrEP

Any 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 adverse 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.

Yellow Form	Pink Form	Alert Card
• Suspected adverse drug reaction reporting	• Suspected poor quality medicines reporting	• Client hypersensitivity documentation

These tools are available in manual and electronic formats and should be filled and forwarded to the Pharmacy and Poisons Board (https://pv.pharmacyboardkenya.org).

County 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 5: Strategic Information and Research

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

5.1 PrEP Data collection and reporting tools

The **PrEP data collection** tools include:

1. PrEP clinical encounter form
2. PrEP Daily Activity Register (DAR)

NB- RAST will be used as a job aid

The data **Reporting tool** is MoH 731:

5.2 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 (Appendix 6).

Purpose: Captures all the details of the PrEP client in the initial visit and subsequent follow ups. This could be filled either electronically or on Paper.
When Completed: At the time of enrolling a client for PrEP services or when a client Transfers in
Who Completes: The clinician offering clinical services to the client.
Location: at every service delivery point in the facility where PrEP services are integrated

It has 3 broad sections: Client Baseline information, Clinical follow up section and Monthly refill section.

1. **Client Baseline information:**

It captures;-

- ✓ Client profile
- ✓ Entry point and Transfer status
- ✓ Baseline assessment
- ✓ Behavioral risk assessment
- ✓ Medical assessment and fertility intentions
- ✓ PrEP initiation
- ✓ Next appointment date and sign off section

2. **Clinical follow up section:**

It captures;-

- ✓ Medical assessment and fertility intentions
- ✓ Behavioral risks assessment
- ✓ Follow up laboratory investigations

- ✓ PrEP dispensed during the visit
- ✓ Date for next appointment and sign off

3. PrEP refill section

It captures;-

- ✓ Behavioral risk assessment
- ✓ Adherence counselling
- ✓ PrEP status- Continue / Discontinue PrEP
- ✓ Reasons for discontinuation
- ✓ Next appointment dates
- ✓ Remarks

5.3 PrEP Daily Activity Register (PrEP DAR)

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

Purpose: It is a summary of reportable data elements that demand immediate collection upon provision of PrEP service

Location: Placed in the PrEP Service delivery points

When completed: Immediately after PrEP service is provided

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

Acts as a source document for the PrEP summary tool

5.4 PrEP Summary Reporting Tool

PrEP services are reported using MOH 731 (together with other HIV services). MOH 731is the main Monthly summary reporting tool for PrEP services (Appendix 8). 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 on PrEP reportable data elements and populate it in the MOH 731.

When completed: At the end of every 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 or at the facility incharge office.

5.5 Reportable PrEP Indicators

Reportable indicators in MOH 731 are:

- ✓ Number of clients initiated on PrEP disaggregated by age and sex
- ✓ Number of seroconversions while on PrEP

The PrEP data elements have been disaggregated by Sex and Age. The age disaggregation include: 15-19, 20-24, 25-29 and 30+ years.

5.6 Definition of terms

Deaths- Confirmed death in relation to PrEP clients.

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 this 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 8-90 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 <7 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.

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.
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

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

Topic		Check
✓	Explain how PrEP works as part of combination HIV prevention	
✓	Explain the need for baseline and follow-up tests including regular HIV testing	
✓	Explain PrEP use: include the following: (refer to the different types of PrEP available for details) o The medications used (show the client the pills or other PrEP options o How the medications are used (frequency of dosing for the various options) o Number of doses required to achieve efficacy (7 doses for daily oral PrEP, loading dose for event driven oral PrEP) o What to do when doses are missed (continue for daily doses) o Discontinuation of PrEP, how and when it can be discontinued. o Side effects and what to do in case these are experienced (including when to consult the clinician)	
✓	Discuss what to do in case client experiences symptoms of seroconversion (acute HIV infection)	
✓	Discuss the Limitations of PrEP o PrEP reduces but does not eliminate the risk of acquiring HIV. o PrEP does not prevent pregnancies and STIs.	
✓	Risk reduction counselling and support education o Managing mental health needs o Couple counselling o Access to, and consistent use of condoms and lubricants o Access to and need for frequent HIV testing. o Early access to ART o VMMC o STI screening and treatment o Harm reduction for PWID	

Appendix 4: Pre-Initiation Assessment Check-list

ITEM	Y/N
Screening and Support for GBV	
HIV Testing	
Check symptoms of acute viral infection in last 6 weeks	
Behavior risk assessment	
Substance use and mental health screening	
Partner information	
Pre-initiation education and understanding of PrEP	
Client readiness and willingness to adhere to prescribed PrEP and follow-up schedule	
STI screening and treatment	
For women • Pregnancy test, pregnancy intention and / or breastfeeding • Screen for contraception use using appropriate contraceptive screening tool • Highlight the need for condom use	
Discussed plans for continually accessing PrEP	
Additional laboratory tests (Availability of these test should not delay initiation of PrEP) • Serum creatinine and creatinine clearance • HBsAg • HCV serology *NB: absence of these tests should not hinder initiation*	
Medication history and potential drug interactions	

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:

- ✓ Under the column titled "Potential performance gaps to be addressed," make a list of areas or processes that should be considered for QI projects
- ✓ 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
- ✓ 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: PrEP Clinical Encounter Record

File no:

Clinical Encounter Record: Pre-Exposure Prophylaxis (PrEP)

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

A. Client Profile

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

Name: First _____ Middle _____ Last _____ Telephone no: _____
Sex: Male Female Date of birth: *dd / mm / yyyy* Age (years): ____ ____ In School Yes No Marital Status: Single Married
Population Type: Gen Population Discordant couple Key Population (Specify) → MSM MSW FSW PWID TG

B. Entry Point & Transfer Status

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

Transferred in: PrEP start date: *dd / mm / yyyy*
Type: Daily oral PrEP ☐ED ☐PrEP ☐Current Regimen:TDF-FTC ☐TDF-3TC ☐ CAB-LA ☐Dapivirine Ring ☐
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*):
Not on ART
On ART <6 months
Suspected poor adherence to ART
Detectable HIV viral load
Couple is trying to conceive

(If yes to any) →

Complete section if sex partner is HIV+

HIV+ partner Unique client number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___
or ☐ NA (not enrolled at a CCC)
or ☐ Unique client number or 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: ___ ___

Sex partner(s) high risk & HIV status is unknown
Has sex with >1 partner
Ongoing IPV/GBV
Transactional sex
Recurrent 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

Medical assessment & fertility intentions

Blood pressure (mm Hg): ___ ___ ___ / ___ ___ ___
Temperature: ___ ___ °C
Weight (kg): ___ ___ ___ Height (cm): ___ ___ ___
BMI/MUAC___ ___
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	Date sample collected:
HIV	Positive	Negative	Not done		dd/ mm / yyyy
Hepatitis B (HBsAg)	Positive	Negative	Not done	If negative, vaccine series initiated: Yes No	dd/ mm / yyyy
Hepatitis C	Positive	Negative	Not done		dd/ mm / yyyy
Serum creatinine	___ ___ ___ (µmol/L)	or	Not done	If done, CrCl (mL/min): ___ ___ ___	

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 ☐ 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 Yes **No**

→ **Eligible for PrEP**

Prescribed PrEP at initial visit: ☐ **Yes** ☐ **No**
Types: Oral ☐ CAB-LA ☐ Dapivirine Ring ☐
Oral Regimen: TDF-FTC ☐ TDF-3TC ☐
Date of initiation: *dd / mm / yyyy* **# of Months:** _____

Next appointment date: *dd / mm / yyyy* **Clinician Name:** _____ **Signature:** _____

I. Revisit form

To be filled when a client is provided oral/CAB-LA/Ring during visits when they do not require HIV testing.

NB: Reasons for discontinuation; 1. HIV test positive 2. Low risk of HIV 3. Renal dysfunction 4. Client request 5. Not adhered to PrEP 6. Viral suppression of HIV+ partner 7. ADR 8. Self-discontinuation 9. Death 10. Too many HIV tests 11. Transfer out 12. Others___

Date of Visit	Behaviour risk assessment (Yes/No)	Adherence counselling (Yes/ No)	Continue /Discontinue PrEP (indicate appropriately)	Reasons for Discontinuation	Next appointment date	Remarks
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	

Follow Up Visit

Unique client number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ **Name of Client:**_____

Visit date: *dd / mm / yyyy* **Visit type:** ☐ **scheduled** ☐ **unscheduled**

E. Medical assessment & fertility intentions

Clinical Notes

Summary of Findings

Blood Pressure	___ ___ ___ / ___ ___ ___ mm Hg
Weight	___ ___ ___ kg Temperature___ ___ °C
Signs/symptoms of STI(s)	☐ yes ☐ no If yes use the codes provided_____
Signs/symptoms of acute HIV	☐ yes ☐ no
If male, circumcised since last visit	☐ yes ☐ no ☐ na (already circumcised)

Possible adverse drug reaction ☐ None

1.	*Description*
	☐ mild ☐ moderate ☐ severe ☐ life threatening ☐ not graded
	Action (*mark all that apply*) ☐ stop ☐ changed PrEP method other_____
2.	*Description*
	☐ mild ☐ moderate ☐ severe ☐ life threatening ☐ not graded
	Action (*mark all that apply*) ☐ stop ☐ changed PrEP method other_____

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

Plan to have children		☐ trying to conceive ☐ future ☐ no ☐ don't know ☐ client/partner is pregnant
If female	LMP: _____	
	Pregnant	☐ yes ☐ no
	Breastfeeding	☐ yes ☐ no
	On family planning	☐ none or methods (Indicate the code):_____
	If ended pregnancy since last visit	*Outcome date* *dd / mm / yyyy*
		Outcome ☐ term live ☐ preterm live ☐ induced abortion ☐ *loss*
		Birth defect(s) ☐ yes ☐ no ☐ don't know

F. Behaviour risk assessment

Mark all that apply

- ☐ Sex partner(s) is HIV+ and:
  - ☐ not on ART
  - ☐ <6 months ART use
  - ☐ poor adherence to ART
  - ☐ detectable HIV viral load
- ☐ couple is trying to conceive
- ☐ Sex partner(s) at high risk for HIV & HIV status unknown
- ☐ Has sex with >1 partner
- ☐ Ongoing IPV/GBV
- ☐ Transactional sex
- ☐ Recent STI
- ☐ Recurrent use of PEP
- ☐ Recurrent sex under influence of alcohol/recreational drugs
- ☐ Inconsistent or no condom use
- ☐ IDU with shared needles/syringes

G. Follow up laboratory investigations

HIV test	☐ Positive ☐ negative ☐ not done	*If positive, collect sample for drug resistance. Client linked to care* ☐ Yes ☐ No
Serum creatinine (as per guidelines)	___ ___ ___ µmol/L or ☐ not done	*If creatinine is out of range, or CrCl <50 mL/min, refer for further assessment*
If creatinine done, CrCl ≥50 mL/min	☐ yes ☐ no	
Other (*write in test, results & units [if applicable]*)	1.	
	2.	

H. PrEP

Self-assessment of adherence since last visit	☐ Good ☐ Fair ☐ Bad ☐ n/a (did not pick up PrEP at last visit)
If Fair/ bad, reason(s) *(mark all that apply)*	☐ forgot ☐ lost/out of pills ☐ separated from HIV+ partner ☐ no perceived risk ☐ side effects ☐ sick ☐ stigma ☐ pill burden ☐ shared with others ☐ none ☐ other _____
Adherence Counseling done	☐ yes ☐ no **Condoms issued**: ☐ yes ☐ no
PrEP status	☐ continue ☐ restart ☐ discontinue
Prescribed PrEP today If yes, regimen & duration	☐ yes ☐ no Current regimen/Type: TDF-FTC ☐ TDF-3TC ☐ CAB-LA ☐ Dapivirine Ring ☐ # of months ___ ___
Regimen/Type Switch:	☐ yes ☐ no Date: *dd/mm/yyyy* Regimen/Type: TDF-FTC ☐ TDF-3TC ☐ CAB-LA ☐ Dapivirine Ring ☐
Reason for switching	1. Client preference ☐ 2. Stock-out ☐ 3. Adverse Drug Reactions ☐ 4. Drug interactions ☐ 5. Discontinuing Inj. PrEP ☐
If discontinued, reason(s) *(mark all that apply)*	☐ HIV test is positive ☐ Low risk of HIV ☐ Renal dysfunction ☐ Client request ☐ Not adherent to PrEP ☐ Viral suppression of HIV+ partner ☐ Too many HIV tests ☐ Transfer out ☐ other _____

Next appointment date: *dd / mm / yyyy* **Clinician Name:**_____ **Signature:**_____

Adherence
Good: missed 0-3 doses in past 1 month
Fair: missed 4-5 doses in past 1 month
Bad: missed 6-7 doses in past 1 month

Creatinine clearance

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

GFR (adult females) = $\frac{(140-Age)\ x\ 1.23}{serum\ creatinine\ (in\ micromol/L)}$ X 0.85

FP Methods:
C = Condoms
TL = Tubal ligation/female sterilization
FA = Fertility awareness method/periodic abstinence
D = Diaphragm/cervical cap
LAM = Lactational Amenorrhea Method
IUD = Intra uterine device
IMP = Implant
INJ = Injectable
OC = oral contraceptive pills
ECP = Emergency contraceptive pills dispensed
V = Vasectomy (partner's)

STI Diagnosis:
Genital Ulcer Disease (GUD),
Vaginitis and/or Vaginal Discharge (VG),
Cervicitis and/or Cervical Discharge (CD),
Pelvic Inflammatory Disease (PID),
Urethral Discharge (UD),
Anal Discharge (AD),

Remarks

Appendix 7: PrEP Daily Activity Register (PrEP DAR)

Serial No	Date	Unique Identifier	Client Status Client: N- New C- Continuing D-Discontinued R-Restart	Age in completed years	Sex (M/F, others (specify)	Population type (Use the codes: 01. General Population 02. Discordant Couple 03. MSM 04. MSW 05. FSW 06. PWID 07. Transgender 08. Others (specify)	PrEP Method offered/current (Use codes: 01. Daily oral PrEP 02. Event driven PrEP for men 03. Dapivirine Vaginal ring 04. Cabotegravir Injectable 05. Others (specify)	Month on PrEP Indicate month 0, 1, 2, 3, …..	HIV Test done (Y/N) Results (P/N or N/A)	HIV Diagnosis while on PrEP (P/N or N/A)	STI Diagnosis (P/N)	Remarks
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)		(j)	(k)	(l)
TOTAL this Page												
TOTAL this Month												

	Number initiated (New) on PrEP							
	15 - 19 Yrs		20 - 24 Yrs		25 - 29 Yrs		≥30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM/MSW								
FSW								
PWID								
Discordant Couple								
TG								
Others								
TOTAL								

	Number Restarting PrEP							
	15 - 19 Yrs		20 - 24 Yrs		25 - 29 Yrs		≥30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM/MSW								
FSW								
PWID								
Discordant Couple								
TG								
Others								
TOTAL								

	Number diagnosed with STI							
	15 - 19 Yrs		20 - 24 Yrs		25 - 29 Yrs		≥30 Yrs	
	M	F	M	F	M	F	M	F
General popn								
MSM/MSW								
FSW								
PWID								
Discordant Couple								
TG								
Others								
TOTAL								

Indicator/PrEP method	Number on each PrEP method					
	Daily Oral PrEP	Dapivine Vaginal ring	CAB Inj	ED PrEP	Others	Total
Number initiated (New) on PrEP						
Number continuing (Refills) PrEP						
Number Restarting PrEP						
Number on PrEP for at-least 3 months						
Sero Converting while on PrEP						

Appendix 8: Summary Reporting Tool (MoH 731) - PrEP Section

MOH 731 - SUMMARY TOOL FOR HIV SERVICES

County:	
Sub-County:	
Health Facility:	
MFL CODE:	
Service Delivery Point:	
Start date:	

1.3. PrEP Initiation

		Male		Female
General population	HV01-22		HV01-23	
Discordant Couple	HV01-24		HV01-25	
MSM	HV01-26			
FSW			HV01-27	
PWID	HV01-28		HV01-29	

1.4. PrEP Initiation by age and sex

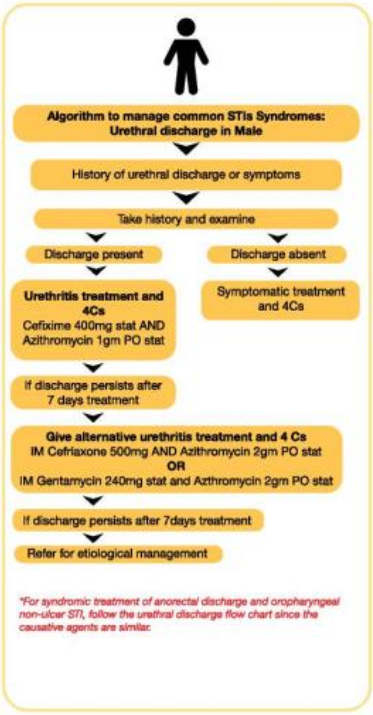
		Male		Female
15-19 yrs	HV01-30		HV01-31	
20-24 yrs	HV01-32		HV01-33	
25+ yrs	HV01-34		HV01-35	

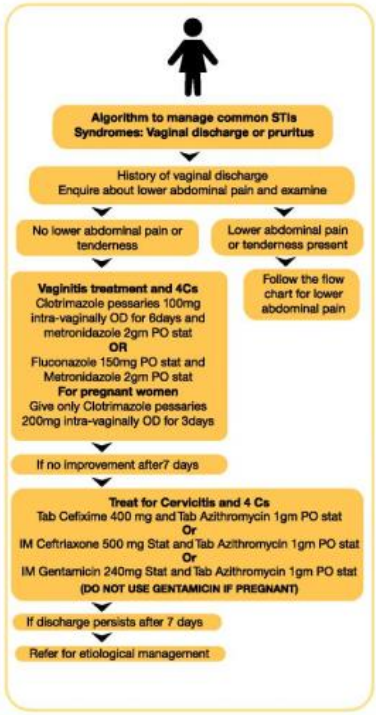
1.5. Seroconversions While on PrEP

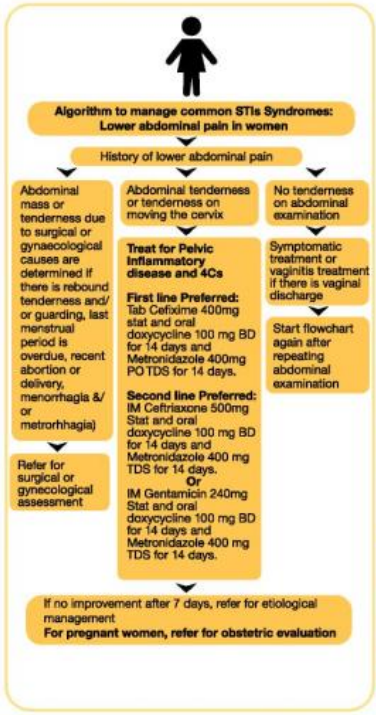
Number of Seroconversions while on PrEP	

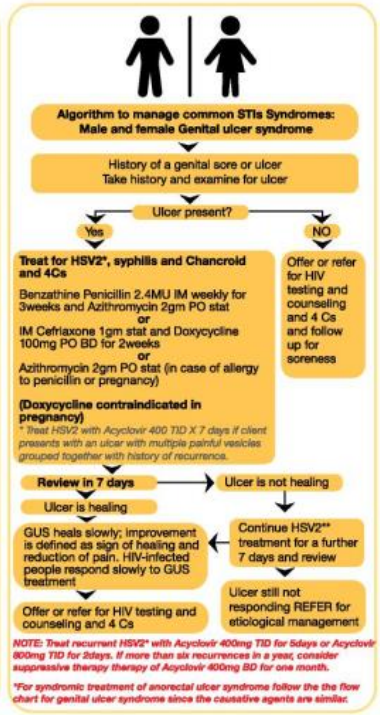
MINISTRY OF HEALTH
NATIONAL AIDS AND STI CONTROL PROGRAMME

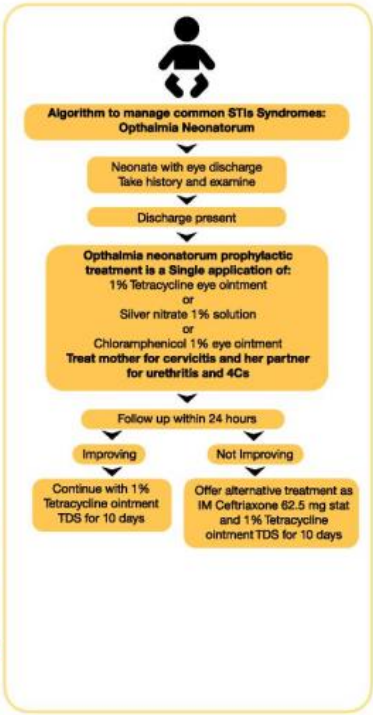
Algorithms for Managing Common STI Syndromes











FIGHT AIDS! REMEMBER THE 4Cs OF GOOD STI MANAGEMENT

Counselling

- Emphasize on the risks of STIs including HIV
- Discuss other 3 Cs
- Offer HIV testing and counseling services

Compliance

Your patient should:
- Avoid self medication
- Take the full course of medication and not to share or keep it
- Follow your other instructions

Condoms

- Proper use of condom is the only other alternative to abstinence to protect from STIs
- Give condoms to your patients
- Explain and demonstrate the correct use of condoms

Contact treatment

Your patient should:
- Tell all his/her sexual partners to seek medication

REPUBLIC OF KENYA, NATIONAL AIDS/STD CONTROL PROGRAMME (NASCOP),
P. O. BOX 19361-00200 NAIROBI, WEBSITE: www.nascop.or.ke

Appendix 10: Frequently Asked Questions about Pre- Exposure Prophylaxis

1. **What is PrEP?**

   PrEP (Pre-Exposure Prophylaxis) is an antiretroviral drug taken by HIV negative people who are at high risk of HIV infection to reduce the risk of becoming infected.

2. **How effective is PrEP?**

   If used correctly and consistently, PrEP can reduce the risk of HIV infection by 90%. However, PrEP does not protect you against other STIs and Pregnancy thus it is recommended to be used alongside other prevention methods such as Condoms.

3. **How does PrEP prevent HIV?**

   If you have been taking PrEP correctly and consistently, it helps build a protective layer round your body cells, such that if you get exposed to HIV, for example by having unprotected sex with someone who is living with HIV or People who inject drugs, PrEP can stop the virus from establishing itself in your body.

4. **What are the benefits of PrEP?**

   If used consistently, PrEP can significantly REDUCE THE RISK OF GETTING INFECTED WITH HIV INFECTION.

   54

   The benefits include:
   - ❖ Decreased anxiety following HIV exposure
   - ❖ Promotes desired behaviour
   - ❖ Among HIV discordant couples, PrEP is a means to:
     - ✓ Reduce risk of HIV transmission
     - ✓ Meet their pregnancy desires
     - ✓ Cope with HIV sero-discordance.
     - ✓ Increased communication, disclosure and trust

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

   PrEP is used by HIV negative people who are at high risk of HIV BEFORE EXPOSURE to reduce their chances of being infected with HIV. PEP is used by HIV negative people AFTER exposure to HIV but must be taken within 72 hours of the exposure.

6. **Who can take PrEP?**

   PrEP isn't recommended for everyone. It's for people who are **HIV NEGATIVE** and are at a high risk of HIV infection. PrEP may be an option for you, if you are HIV negative and you have a sexual partner who is:
   - Known to be HIV positive and not on ARV OR
   - Is on ARV but does not take medication consistently or has not achieved viral suppression.

   Also if:
   - You have sexual partner(s) of unknown HIV status;
   - You have multiple sexual partners;

- You have frequent STIs
- You use injecting drugs;
- You are engaging in transactional sex (sex in exchange of gifts etc.);
- You have recurrent use of Post Exposure Prophylaxis (PEP);
- You are a sero-discordant couple trying to conceive (where one partner is HIV positive and not on ARV or not virally suppressed and the other is HIV negative);
- You do not use condoms or you use them inconsistently;
- You experience frequent condom bursts or you are unable to negotiate condom use with persons of unknown HIV status.

7. How should I take PrEP?

PrEP is administered in different forms; orally, injectable and insertion of vaginal ring.

- **For daily oral PrEP;**
  - one needs to take it for at least 7 DAYS BEFORE ANY EXPOSURE(applies to individuals born female, for those born male, can have protective levels as soon as 2 hours before sex but ideally 24 hours) for it to be effective. Thereafter, the pill should be taken once a day for as long as the person remains at risk of HIV infection (or as advised by a health care provider).
  - You should **not take two pills at the same time** or on the same day to make up for a missed dose.

For Event driven PrEP:

- Event driven PrEP is where oral PrEP is to be used when an isolated sexual act is planned.
- Event-Driven PrEP is recommended for all people assigned male at birth not taking exogenous estradiol-based gender affirming hormones.
- Two pills are taken between 2 and 24 hours in advance of planned sex; then, a third pill 24 hours after the first two pills and a fourth pill 48 hours after the first two pills; **2-1-1**(In case of prolonged exposure, continue taking 1 pill daily until 2 days after the last sex act).

- **For Injectable:**
  - Long Acting Cabotegravir Injection
  - Initiation injections: 600 mg Intramuscular (IM) x 2 doses given 1 month apart (the second initiation injection can be given up to 7 days before or after the date scheduled to receive injection)
  - THEN, Continuation injections: 600 mg IM every 2months.

- **For Dapivirine Vaginal ring:**
  - Dapivirine vaginal ring, 25mg, is inserted vaginally every 28 days.

8. 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 care provider for advice.

9. Am I protected from HIV if I miss PrEP?

Evidence has showed that PrEP provides the best protection from HIV if it is USED CORRECTLY AND CONSISTENTLY AS PRESCRIBED.

For oral PrEP, whenyou miss one or more pillsyou are greatly reducing the ability of PrEP to provide you with full protection against HIV infection.

10. Can I share PrEP with others?

PrEP should NOT BE SHARED but only be used by the person it is prescribed for.. Anyone who wants to use PrEP should discuss their intention with a health care provider.

11. What are the side effects of PrEP?

One may experience side effects that last for a SHORT PERIOD. These may include; headache, weight loss, nausea, vomiting and abdominal discomfort. These side effects often reduce or stop after a few weeks of taking PrEP.

12. If I take PrEP, can I stop using condoms?

No, you SHOULDN'T STOP USING CONDOMS. While it significantly reduces your risk of HIV infection, PrEP does not protect you from other Sexually Transmitted Infections (STIs) such as herpes and gonorrhea or unplanned pregnancies and should be combined with other methods of prevention such as condoms and use of contraceptives is recommended.

13. Is PrEP a vaccine?

No, PrEP is NOT A VACCINE.

14. Is PrEP an Emergency Medication?

No. PrEP requires to be taken for a specific duration of time prior to HIV exposure.

15. When should I stop/discontinue taking PrEP?

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

- You become HIV positive;
- You reduce your risk of getting infected with HIV;
- Following a medical evaluation and you are found to have a kidney problem
- When you request to stop;
- When you are experiencing challenges to take your PrEP as prescribed
- When you are in a discordant relationship and your HIV positive partner has achieved sustained viral suppression. However, you can continue using PrEP if you so desire and continue using condoms consistently.

16. Where is PrEP available?

Currently PrEP is available atpublic and private health care facilities near you.

For more information call Uliza NASCOP toll free number 0726 460 000, 1190, or visit us on www.prep.nascop.org

Appendix 11: Standard Operating Procedure for DBS collection

PrEP Seroconverter Dried Blood Spot (DBS) Collection Kit Package Insert

Full standard operating procedure (SOP), job aids and training materials available at: www.gems.pitt.edu. All users of this kit MUST be familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and Other Blood-Borne Pathogens in Health Care Settings.

PURPOSE OF KIT

To collect blood by venipuncture and spot onto Dried Blood Spot (DBS) cards for assessment of HIV Drug Resistance.

BACKGROUND

Resistance to antiretroviral (ARV) drugs are a risk when an individual becomes HIV infected while using pre-exposure prophylaxis (PrEP) for HIV prevention. The collection of a DBS after seroconversion will enable the determination of the presence of HIV drug resistance mutations known to cause ARV resistance. A drug resistance test will be performed using DBS collected from this procedure.

KIT CONTENTS

Box contains 5 individual kits, each with a unique sample identifier. Please do not mix contents of kits. Please ensure that the unique identifier is used only once per blood draw.

Per Kit

- Rubber latex powder free gloves
- Alcohol or spirit swabs
- EDTA vacutainer blood collection tube
- Blood collection safety needle and cap
- Vacutainer holder
- Lancet
- Tourniquet
- Transfer pipette (plastic dropper)
- Two sealable plastic bags
- Desiccant packs
- Barcode labelled stickers (5 unique identifiers)
- Lab Requisition form
- Informed Consent forms
- DBS collection Job Aid
- Pre-addressed shipping envelope

Materials Required (but not provided)

- Disinfectant: Diluted sodium hypochlorite (1:10 v/v solution)
- Sharps container for needle and blood collection tube disposal
- Protective clothing (lab coat) (optional)

CAUTION: Performance of this procedure will expose personnel to biohazardous material. All specimens must be handled as infectious material using Universal Precautions, including:

- Wear gloves at all times and change if contaminated
- Do not eat or drink in testing areas
- Ensure all spills and contaminated material are properly decontaminated using 10% sodium hypochlorite or chlorhexidine solution
- Ensure all consumables and unused blood specimens are disposed of in accordance with local regulations

SPECIMEN INFORMATION

Specimen volume:

- Minimum volume required: one full EDTA containing tube of whole blood

Handling/storage Instructions:

- All whole blood specimens must be handled as infectious material as outlined in your laboratory's Safety Manual.
- Whole blood should be used for DBS preparation immediately or within 12 hours after collection. If not used immediately, blood tubes must be constantly gently mixed at ambient temperature until use through the use of a tube rocker or similar piece of equipment.
- Do not freeze whole blood.

Unacceptable Specimens:

- Blood that has coagulated or been stored at unacceptable temperatures.
- EDTA must be used as the anticoagulant. Other anticoagulants may give incorrect results.

STORAGE REQUIREMENTS

- Store kit at ambient temperature.
- Dried DBS cards may be stored at ambient temperature in a sealable plastic bag with desiccant for up to 3 days.
- Ship dried DBS cards immediately or within 3 days of collection.

QUALITY CONTROL

- Ensure blood collection tubes are within their stated expiration date.
- Note any blood collection or DBS card preparation issues or abnormalities on the data collection form.
- Use all materials and consumables only once.
- Avoid contamination of DBS cards by placing them on a clean surface and avoiding touching the defined circles where the blood will be spotted.

PROCEDURE

- After HIV infection is confirmed, the healthcare worker will send the client to the phlebotomist for collection of blood sample.
- The health care worker (phlebotomist) will open one kit from the HIV Drug Resistance box, remove contents, and affix barcode labeled stickers to:
  - Blood tube
  - Two (2) DBS collection cards
  - Laboratory Requisition form
  - Client's medical file
- Record date of sample collection on all the 5 barcoded labeled stickers
- Complete Lab Requisition Form (LRF) with client

NOTES:

- *The DBS collection is expected to be completed at the time of HIV seroconversion confirmation. However, if for some reason the sample collection is not completed on the day of seroconversion confirmation, clients will be asked to return as soon as possible to complete the procedure.*
- *If DBS collection via venipuncture is not possible, fingerprick using the clinic's SOP may be used to collect the blood on one DBS card. A lancet is provided in the kit in case fingerprick needs to be done. The following procedure outlines procedures to prepare DBS using intravenous blood collection.*

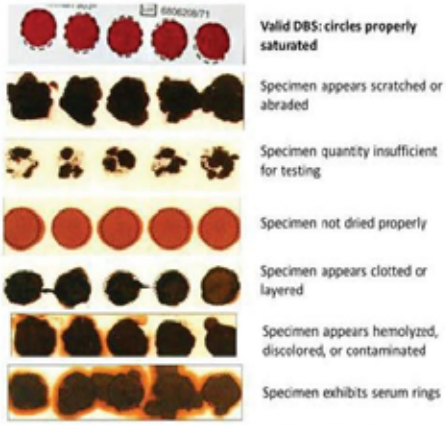
Specimen Preparation:
The health care worker should wash hands and put on gloves once hands are dry before starting procedure.

1. Prepare the client for venipuncture blood draw according to the clinic's SOP. Fill one EDTA containing blood tube with approximately 2 mL whole blood.
2. If the DBS card will not be prepared immediately following blood collection, place the tube containing blood on a moving rocker at ambient temperature in order to prevent separation and ensure constant mixing with the EDTA in the tube.

DBS Preparation:
The health care worker should wash hands and put on gloves once hands are dry before starting procedure.

1. Lay out both barcoded DBS cards onto a clean surface.
2. Gently invert the blood tube 2 to 3 times to ensure complete mixing then draw up at least 0.5 mL of blood using the transfer pipette.
3. Starting from left to right on the first DBS card, fill each circle on the first DBS card with two drops of blood by slowly depressing the bulb.
    a. Do not touch the card with the pipette tip.
    b. The drops should fall on the center of each circle.
    c. When absorbed, the blood drops should fill the entire outline of each circle.
4. Spot the second card in the same manner.
5. Once both cards have been successfully spotted with 5 spots per card, bend the flap behind each card and place the cards on a surface in a clean, dry space.
    a. The cards should be stored with blood spots facing up, and dried overnight or for at least 3 hours at ambient temperature.
    b. Protect the cards from rodents, insects and direct sunlight.
    c. Do not stack the cards on top of each other, or allow them to touch other surfaces during the drying process.
6. Dispose of all consumable materials and unused blood in accordance with local protocols and clean working areas with a 10% sodium hypochlorite or chlorhexidine solution when finished.

Examples of valid and invalid dried blood spots



Source: GE Healthcare Life Sciences. 2010. *Simple spot check.* GE Document 28984392

DBS Storage and Shipping:

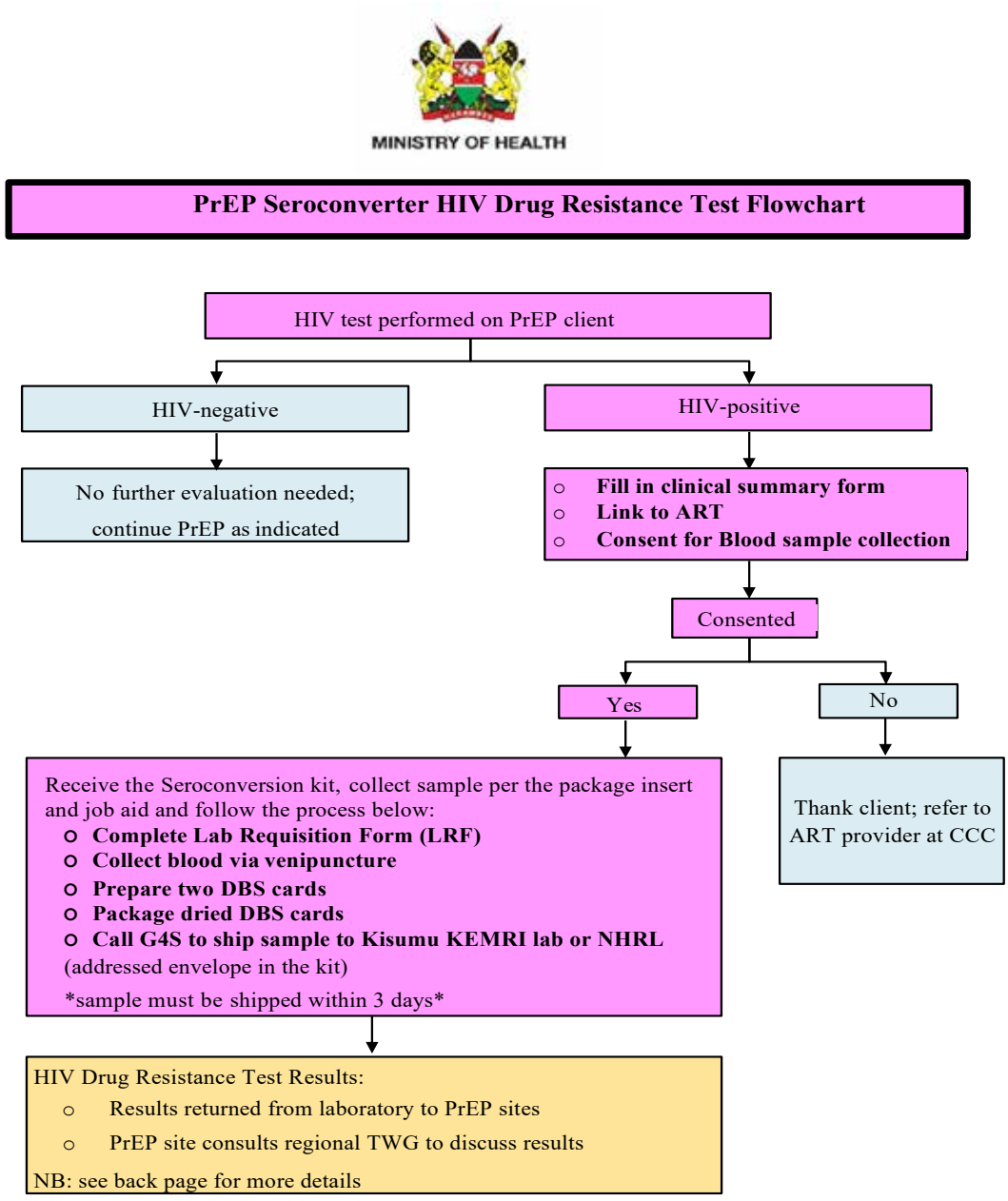
1. Once the cards are dry fold the flap over each DBS card and place both cards in the gas-impermeable, sealable plastic bag.
2. Add a desiccant pack to the sealable plastic bag to remove excess moisture.
3. Place the sealable bag containing the DBS cards and the lab requisition form into the pre-addressed shipment envelope provided in the kit.
4. Immediately notify the courier company (G4S) for pick-up of the package for transportation to Kisumu KEMRI laboratory. The account number will be indicated on the package envelope and will cover the cost of the transportation.
5. The sample must be shipped to the laboratory as soon as possible and no later than 3 days of sample collection. Temporarily store DBS cards at room temperature in a dark place (drawer) in a secured location before shipment.
6. If for any reason, direct shipment is not feasible within 3 days, contact the GEMS Coordinator (contact information listed below) and alternate instructions will be provided
    a. Note: Ship DBS cards as non-dangerous goods (they are exempt biological specimens according to ICAO and IATA).

For additional DR boxes or supplies, or any queries related to DBS collection techniques or resistance testing, contact the National Laboratories (NHRL) or GEMS Coordinators as indicated:

NHRL Laboratory, Nairobi
Tel: 0720520190
Email: abuyadorcus@gmail.com

GEMS Coordinator, Nairobi
Tel: 0748786924
Email: everline.bosek@gmail.com

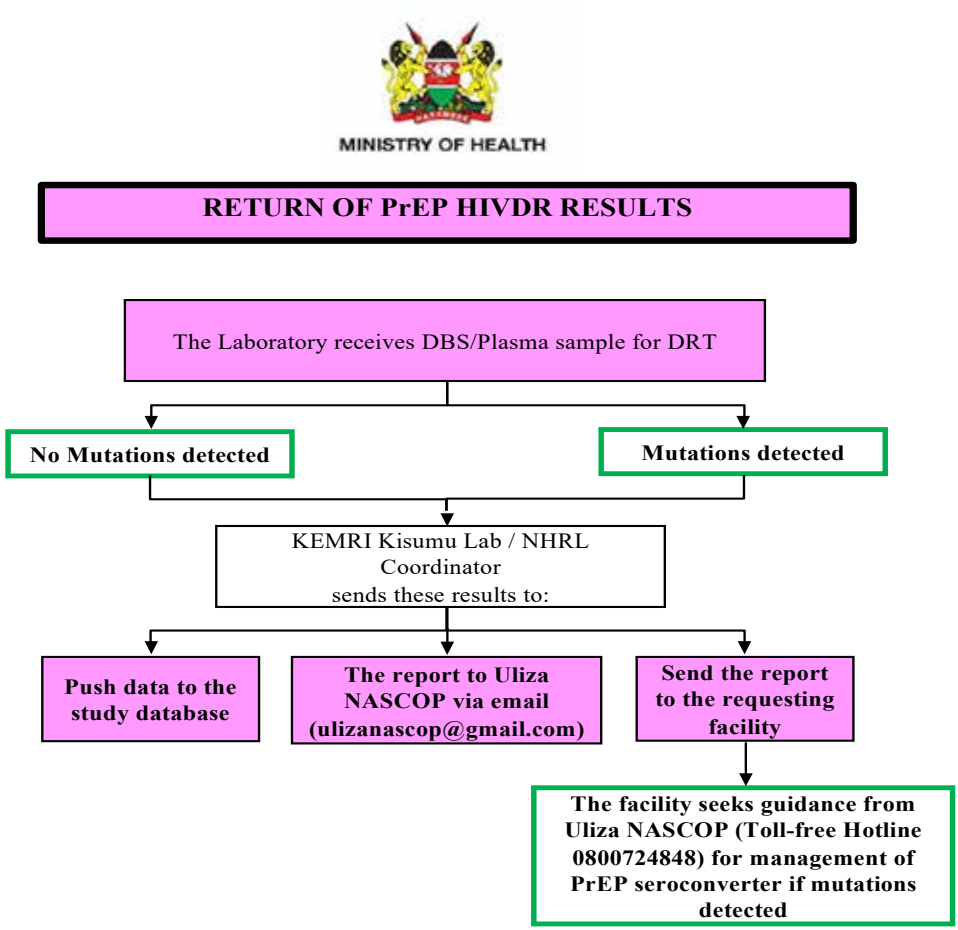
Appendix 12: DRT Laboratory Flowchart for DBS



Abbreviations:
ART - Antiretroviral Treatment;
DBS - Dried Blood Spot;
LRF - Lab requisition form;
PrEP - Pre-exposure Prophylaxis

Version 2.0 October 2022

Appendix 13: Return of DR results flowchart



- ✓ All the DRT results (synthesized) will be sent to the requesting Health facilities for patient management and completeness of patient records
- ✓ Ensures that the report gets to the patient irrespective of where they are linked to care

Appendix 14: DR Lab Request Form

MINISTRY OF HEALTH

NATIONAL AIDS AND STI CONTROL PROGRAMME

LABORATORY REQUISITON FORM FOR PrEP SEROCONVERTORS

Name of Facility		**MFL Code**	
Client PrEP barcode no. (*do not write name*)		**Date of Request:**	
Sample Type	**DBS** ☐ **Plasma** ☐		
Blood collection Date		**Time**	
DBS / Plasma Preparation Date		**Time**	
Client Details	**Year of Birth:** _____ **Gender:** _____ **PrEP initiation Date:** _____ **Date PrEP bottle was last collected:** _____ **Date PrEP was last taken:** _____ **Date of first HIV positive test:** _____ **Date of last HIV negative test:** _____		
Clinician's Name		**Test Requested:** Viral Load ☐ DRT ☐	
Facility Contacts	**Tel:**	**Email:**	

High-risk assessment criteria for reason on PrEP:

Discordant couple ☐ **Adolescent/Young women** ☐ **MSM** ☐ **FSW** ☐

Sex with unknown partner ☐

Other (specify) ☐

Is sexual Partner HIV positive: Yes ☐ **No** ☐ **Don't know** ☐

If partner HIV positive, what ARV regimen is the partner currently taking:

☐ **Don't know** ☐

Adherence Evaluation: Per client report, was the client adherent to PrEP?

☐ **Good, missed 0-3 doses in past month**
☐ **Fair, missed 4-5 doses in past month**
☐ **Bad, missed 6-7 doses (or more) in part month**

Version 1.0 June 2018

Appendix 15: List of Contributors and Reviewers

NAME	ORGANISATION
Dr. Rose Wafula	NASCOP
Dr. Jonah Onentiah	NASCOP
Dr. Norah Talam	HJF MRI/Walter Reed Project
Ruth Kamau	NASCOP
Jane Onteri	NASCOP
Abraham Sumukwo	CASCO BARINGO
Eric Mutua	NASCOP
Moses Otieno	NASCOP
Paul Ndambuki	NASCOP
Jafred Mwangi	NASCOP
Patricia Jeckonia	LVCT
Jane Nderi	LVCT
Sheila M. Baraza	NASCOP
Brandwell Mwangi	CHAI
John Mungai	CHAI
Loreen Ngarai	NASCOP
Violet Otindo	NASCOP
Ken Mawira	HJF MRI/Walter Reed Project
Nelius Ruiru	LVCT
Lucy Ondicho	MOH
Harrison Ayallo	PSK
Ogola Christabel	NHRL
Cecilia Ndua	NASCOP
Benard Adidi	BLAST
Roseline Warutere	NASCOP
Bosley Motaroki	NPHL
Dr. Muthoni Karanja	DOD Agency
Samson Anangwe	HJF MRI/Walter Reed Project
Dr. Obat Edmon	USAID
John Kinyanjui	Nyeri County
Temwa Chirembo	UNAIDS
Grace Mwangi	NASCOP
Dorcas Kipkoech	NASCOP
Joseph Makau	CIHEB
Dr. Hellen Muttai	CDC
Laureen Wafula	NASCOP
Jonathan Mwangi	CDC
Leonard Soo	USAID

Notes

Notes

Notes

Notes

Notes

NASCOP

National AIDS and STI
Control Programm