



MINISTRY OF HEALTH

# Pre-exposure Prophylaxis for the Prevention of HIV Infection: A Toolkit for Providers







**Pre-exposure  
Prophylaxis for the  
Prevention of HIV  
Infection:  
A Toolkit for  
Providers**



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

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## Foreword

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

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

To obtain the full benefits of its use, PrEP must be provided under the supervision of a trained healthcare provider, 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 contra--indications to PrEP medications and offer ongoing monitoring, risk reduction and adherence support. PrEP is used only during periods increased ongoing risk of HIV infection. During follow--up, providers assess and determine whether PrEP is still necessary. The duration of PrEP use is determined by the level of risk by an individual PrEP user and the adoption and adherence to other HIV prevention interventions.

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 indications for PrEP and guidance on assessment, starting, monitoring and discontinuing PrEP. Templates of data collection tools are provided as annexures.

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 may need it across the country. I am certain, this toolkit will contribute to increasing access to PrEP for HIV prevention in Kenya.

Dr Martin Sirengo  
HEAD, NASCOP

## Acknowledgements

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A comprehensive list of contributing organizations, individuals and reviewers is provided in Appendix 5.

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## Purpose

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

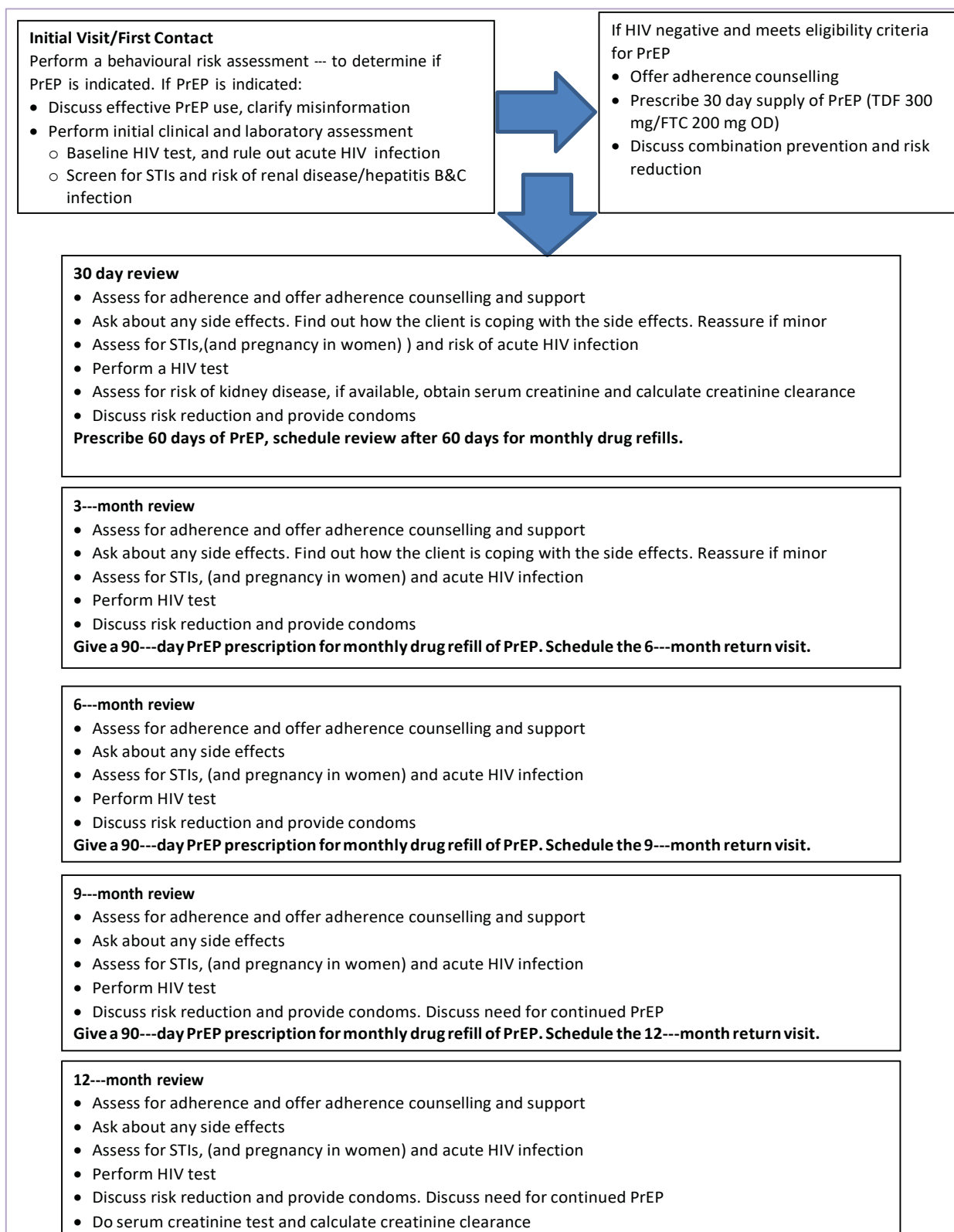
- Section 1: Provides an overview of the recommendations for use of pre-exposure prophylaxis
- Section 2: Identifying clients at ‘substantial ongoing risk of HIV infection’ who could benefit from PrEP through behavioural risk assessment.
- Section 3: Contains information on initiating PrEP including client preparation through health education and adherence counselling; initial clinical and laboratory assessment and prescribing PrEP.
- Section 4: Contains guidance on monitoring clients on ART including clinical and laboratory monitoring, risk-reduction counselling, managing adverse events during PrEP, discontinuing and restarting PrEP, PrEP in special circumstances and combination prevention interventions
- Section 5: Contains appendices with examples of initial and follow-up clinical forms, registers and frequently asked questions

## Section 1 Overview of Recommendations for Pre-exposure Prophylaxis to Prevent HIV Infection

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

What is PrEP?	PrEP is a form of HIV prevention in which a HIV negative person at high risk of HIV infection takes daily oral antiretroviral agents to prevent HIV infection.
Who can take PrEP? (indications for PrEP)	PrEP is recommended for HIV negative persons at substantial ongoing risk of HIV infection such as <ul style="list-style-type: none"> <li>In a discordant relationship, the sexual partner with HIV has not been on effective therapy for the preceding 6 months,</li> <li>Sexual partner/s of unknown HIV status and is/are at high-risk for HIV infection (has multiple sexual partners, has had STIs, engages in transactional sex, injects drugs, from high HIV burden settings)</li> <li>Engaging in transactional sex</li> <li>Recent sexually transmitted infection</li> <li>Recurrent use of post-exposure prophylaxis</li> <li>History of sex whilst under the influence of alcohol or recreational drugs as a habit</li> <li>Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status</li> <li>Injection drug use where injection equipment is shared</li> <li>Sero-discordant couples trying to conceive</li> <li>Requests for PrEP and meets any of the above eligibility criteria</li> </ul>
Contraindications to PrEP	<ul style="list-style-type: none"> <li>HIV infection (confirmed HIV positive)</li> <li>Renal impairment --- as shown by creatinine clearance &lt; 50 ml/min</li> <li>Lack of willingness to adherence to daily PrEP and associated follow-up schedule</li> <li>Adolescents &lt; 35kgs or age &lt; 15 years</li> </ul>
Initiating PrEP	PrEP is initiated only after thorough behavioural and risk assessment (to establish level of risk and willingness to use PrEP); and clinical and laboratory evaluation (to exclude HIV infection and establish safety to use PrEP). Clients should also receive adequate adherence and ongoing risk reduction counselling.
What are the recommended PrEP medications?	<p><i>Preferred</i></p> <ul style="list-style-type: none"> <li>TDF/FTC (300 mg/200 mg) as FDC once daily</li> </ul> <p><i>Alternative</i></p> <ul style="list-style-type: none"> <li>TDF 300 mg once daily</li> <li>TDF/3TC 300 mg/300 mg as FDC once daily</li> </ul> <p><i>At initiation, prescribe PrEP for only 30 days to allow for follow-up visits to assess adherence, tolerability and commitment to continue with PrEP. Subsequently, longer prescriptions may be given; however, the medicines should be issued monthly.</i></p>
What is effective PrEP use?	PrEP should be offered as part of a comprehensive, individualized prevention plan following behavioural risk assessment and adherence counselling. Combination prevention includes: <ul style="list-style-type: none"> <li>Risk reduction counselling</li> <li>Prevention and treatment of STIs</li> <li>Safer sex practices</li> <li>Substance abuse treatment</li> <li>Consistent &amp; correct condom use</li> <li>Prevention of gender-based violence (GBV)</li> <li>VMMC (where indicated)</li> <li>Adherence to PrEP --- efficacy of PrEP is dependent on adherence.</li> <li>Effective cART for HIV+ persons (Treatment as Prevention)</li> <li>After initiation PrEP will be effective after a minimum of 7 days of consistent use.</li> </ul>
Follow-up	After starting PrEP, clients require regular follow-up (initially at 1 month) then every 3 months thereafter (i.e months 1, 3, 6, 9, 12, 15, 18 etc) to monitor HIV status (every 3 months), for risk reduction counselling, adherence assessment and support, side effects. Obtain creatinine annually; or earlier/more frequently if clinically indicated.
Duration	PrEP is not meant to be a lifelong intervention. It is a method of HIV prevention during periods when a person is at greatest risk of acquiring HIV.
Discontinuation of PrEP	PrEP should be discontinued in any of the following circumstances <ul style="list-style-type: none"> <li>HIV positive</li> <li>change in risk (to low risk)</li> <li>renal adverse effect (CrCl &lt; 50 ml/min)</li> <li>sustained non-adherence</li> <li>sustained viral suppression in the HIV partner of a discordant couple</li> <li>client request to discontinue.</li> </ul>

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

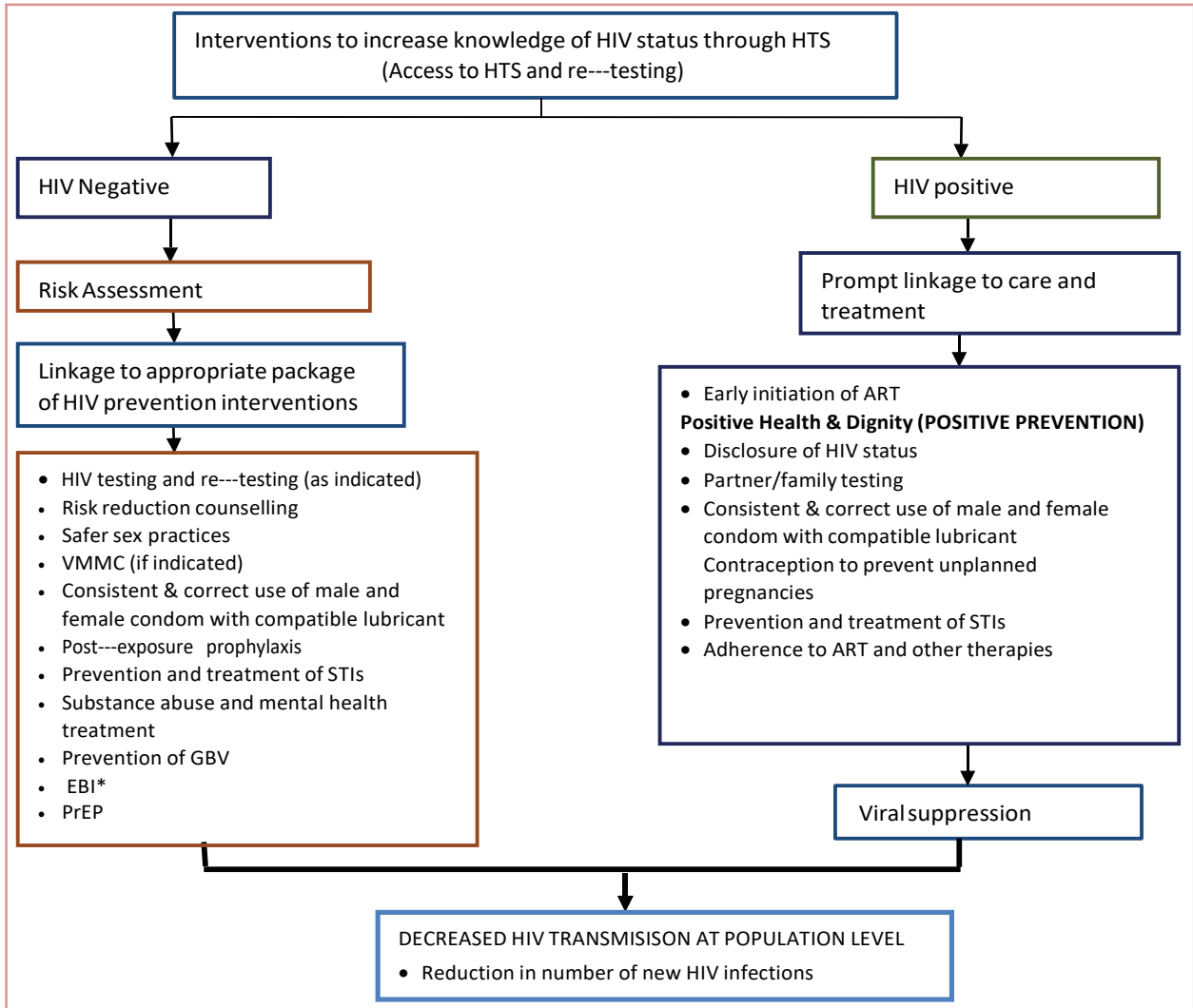


*Note: Risk and adherence assessment and support should be offered during each visit including at dispensing refill visits.*

### Combination HIV Prevention

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. Figure 1.2 summarizes steps for combination prevention for clients accessing PrEP services.

**Figure 1.2 Combination Prevention of HIV Infection**



### **\*Evidence Based Behavioural Interventions**

- a. *Health Choices I & II*: This intervention targets sexually and non--sexually active youth and youth living with HIV (10 – 13 years and 14 to 17 years). The interventions involves sessions on decision making, sex communication, negotiation and refusal skills with the aim of delaying sexual debut, promoting safer sex practice, HIV and STI risk reduction and condom use.
- b. *EBAN*: This intervention is for discordant couples and entails training the couples in assertive communication skills, overcoming barriers to negotiating for safer sex and emphasis on partner involvement in safer sex.
- c. *Sister to sister*: is delivered by female healthcare workers and peer educators targeting women 10 to 45 years of age aimed at reducing or eliminating risk behaviour and preventing HIV and STIs through self--efficacy and condom negotiation.
- d. *Shuga* : This is a multimedia intervention targeting youth (15--24 years) out of school focusing on reducing sexual concurrence, correct and consistent condom use, personal risk perception, stigma and discrimination, transactional sex, gender based violence and parent--child communication..
- e. *RESPECT*: This is a 2--session intervention for key populations and individuals at high risk focusing on risk reduction counselling.
- f. *START*: Targets released prisoners (males 18 to 29 years) returning to the community. Focuses on increasing awareness of risk of HIV and STIs and offers tools to reduce risk.
- g. *IMAGE*: This is an intervention for young girls and women of reproductive age. This intervention rides on economic empowerment initiatives to provide HIV and GBV training and risk reduction.

## Section 2 Risk Assessment and Indications for Pre---Exposure Prophylaxis

PrEP for prevention of HIV infection is **only** indicated for HIV negative individuals at **substantial ongoing** risk of HIV infection.

### Indications for Pre---exposure Prophylaxis

- An individual whose sexual partner is known to be HIV positive and: not on ART, or on ART but has not achieved viral suppression (often ART for less than 6 months), or on ART but with suspected poor adherence.
- A person whose sexual partner/s are of unknown HIV status and are at high---risk for HIV infection (multiple sexual partners, history of STIs, transactional sex, injection drug use or from high HIV burden settings)
- Engaging in transactional sex
- History of recent or current 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 needles and syringes are shared
- Sero---discordant couples trying to conceive

### Assessing for 'substantial ongoing' risk of HIV Infection

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

Before starting the sexual behavioural assessment,

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

### General Screening Questions

---

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

---

In the past 6 months,

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

#### *Screening Questions for People in Discordant Relationships*

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

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

*(Refer to the Appendix 1: Rapid Assessment Screening Tool)*

#### **Excluding Acute HIV Infection**

Inquire about the presence of fever, fatigue, myalgia, rash, headache, sore throat, cervical adenopathy, arthralgia, night sweats, or diarrhoea; with high risk exposure to HIV infection within the past month.

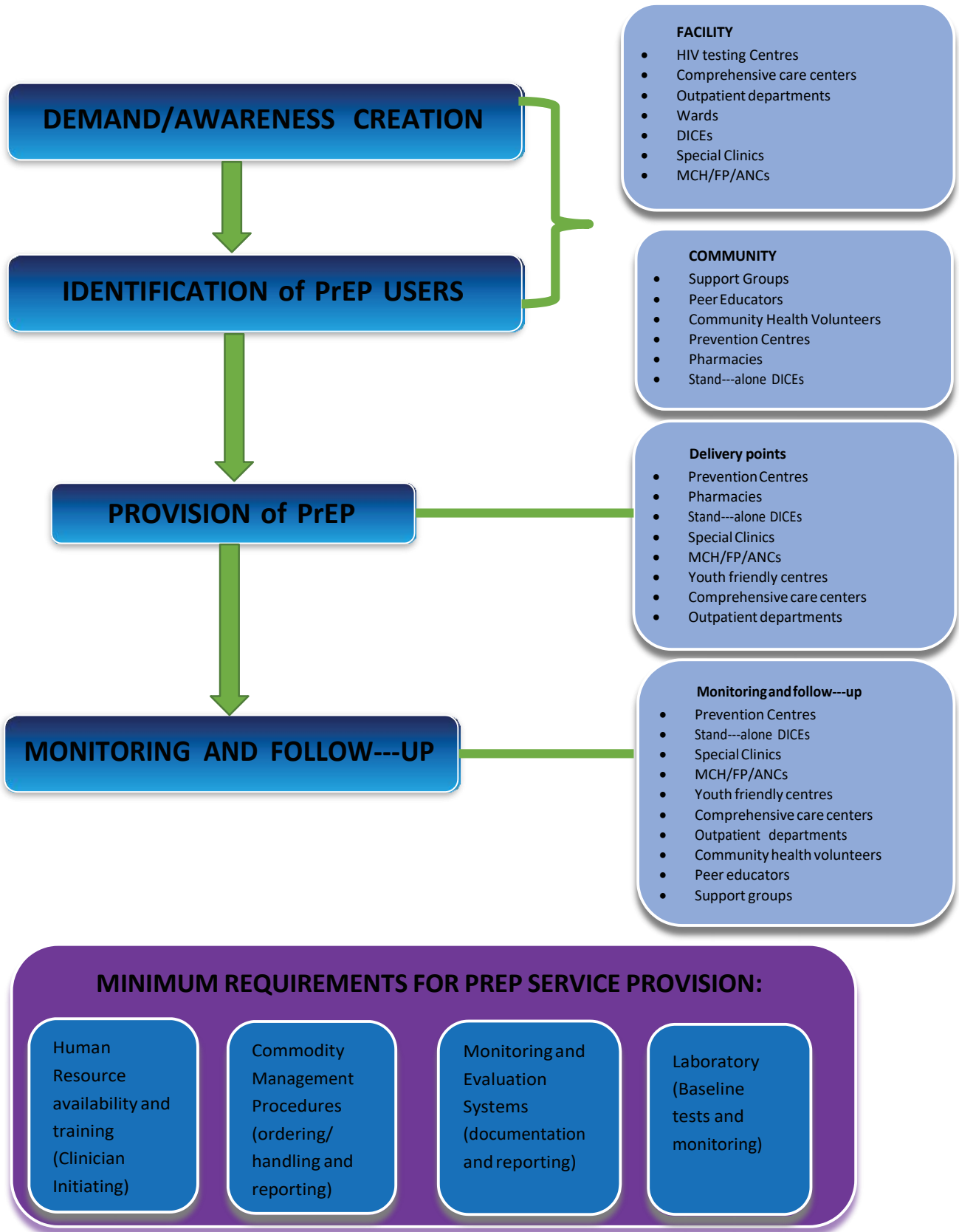
**Table 2.1 Clinical Features and Symptoms of Acute HIV Infection**

Feature	Frequency (%)
Fever	75
Fatigue	68
Muscle pain	49
Skin rash	48
Headache	45
Sore throat	40
Cervical adenopathy	39
Arthralgia	30
Night sweats	28
Diarrhoea	27

#### **Managing high risk exposure within the last 72 hrs**

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

**Figure 2.1 Entry Points for PrEP and other HIV Prevention Services**

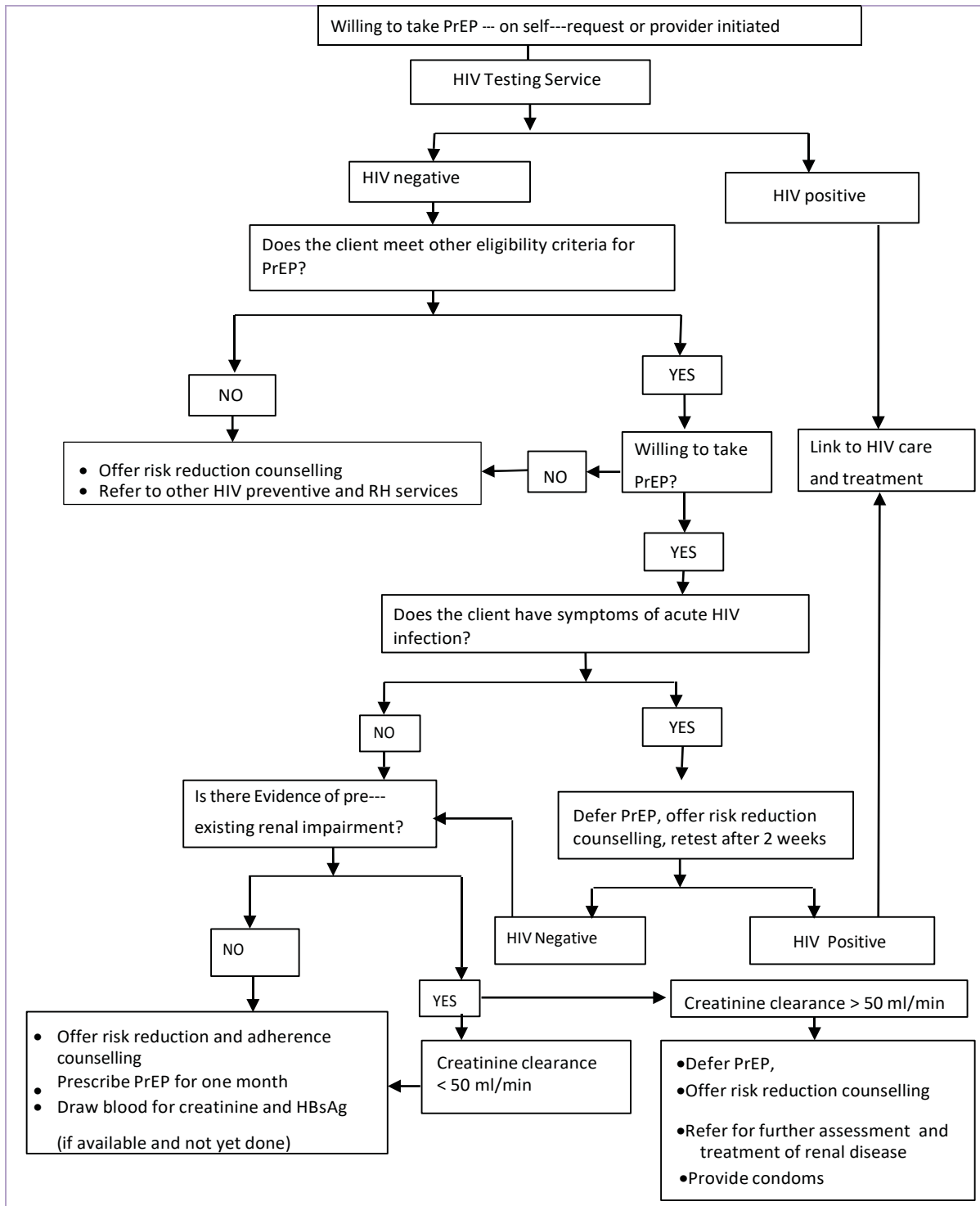




### Section 3 Initiating Pre-exposure Prophylaxis

PrEP should only be initiated after a clinical and laboratory assessment and adequate preparation through health education and adherence counselling and support. Figure 3.1 provides the overview of the requisite steps before a client is started on PrEP.

**Figure 3.1 Initiating Pre-exposure Prophylaxis**



## Eligibility for PrEP

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

- substantial on going risk of HIV infection
- no suspicion of acute HIV infection
- documented HIV negative test
- no contraindications to PrEP medications (TDF/FTC or TDF/3TC or TDF)
- willingness to use PrEP as prescribed, including regular visits to monitor HIV status, adherence and side effects

Once a decision is made that a client requires PrEP, further assessment (listed in Table 3.1 below) should be carried out to establish safety and suitability of PrEP for the individual client.

This will be documented in the Client Encounter record (Appendix 2)

**Table 3.1 Initial Assessment**

Assessment/Service	Rationale
Complete medical history and examination	<ul style="list-style-type: none"> <li>• Identify medical conditions that could affect the management of PrEP               <ul style="list-style-type: none"> <li>○ Past or current kidney disease</li> <li>○ Risk of kidney disease (diabetes mellitus, uncontrolled hypertension, chronic NSAID use)</li> <li>○ Use of other nephrotoxic agents</li> <li>○ Past or current liver disease</li> <li>○ Current or past chronic hepatitis (B or C)</li> <li>○ Acute HIV infection. If acute HIV infection is suspected, defer PrEP until HIV infection is excluded.</li> </ul> </li> </ul>
Establish eligibility to use PrEP	<ul style="list-style-type: none"> <li>• Establish willingness to adhere to PrEP and medical follow-up including HIV retesting</li> <li>• Screen for substantial risk of HIV infection</li> <li>• Document HIV status --- HIV testing using the national algorithm for HTS</li> <li>• To complete a symptom checklist to exclude acute HIV infection</li> </ul>
Baseline laboratory investigations*	<p><i>Urinalysis</i></p> <ul style="list-style-type: none"> <li>• Proteinuria is an early indicator of TDF toxicity. An initial urinalysis helps identify pre-existing proteinuria and risk of renal disease and therefore additional testing (creatinine) and closer monitoring after initiation of PrEP</li> </ul>
	<p><i>Serum creatinine and creatinine clearance</i></p> <ul style="list-style-type: none"> <li>• To identify pre-existing renal dysfunction. PrEP is contraindicated if the baseline CrCl &lt; 50 ml/min</li> </ul>
	<p><i>Hepatitis B surface antigen</i></p> <ul style="list-style-type: none"> <li>• To identify undiagnosed current hepatitis B infection. If negative, consider vaccination against hepatitis B. [Refer to the national guidelines on hepatitis prevention and treatment]</li> </ul>
	<p><i>Hepatitis C antibody (especially in people who inject drugs, PWID).</i></p> <ul style="list-style-type: none"> <li>• If positive, consider treatment for hepatitis C infection.</li> </ul>
	<p><i>Rapid Plasma Reagin</i></p> <ul style="list-style-type: none"> <li>• To diagnose and treat syphilis infection.</li> </ul>
	<p><i>Pregnancy testing</i></p> <ul style="list-style-type: none"> <li>• To guide antenatal care, contraceptive and safer conception counselling, and to assess risk of mother to child transmission. Pregnancy is not a contraindication to PrEP use.</li> </ul>
Screening for other STIs	Assess for presence of dysuria, discharge, anorectal itching or pain, rash, or ulcers. To diagnose and treat STI (syndromic or diagnostic STI testing, depending on local guidelines).

Review vaccination history	Consider vaccination for hepatitis A, human papilloma virus, tetanus and meningitis.
Brief counselling	<ul style="list-style-type: none"> <li>• Assess whether the client is at substantial risk of HIV.</li> <li>• Discuss prevention needs and provide condoms and lubricants.</li> <li>• Discuss desire for PrEP and willingness to take PrEP.</li> <li>• Develop a plan for effective PrEP use, sexual and reproductive health.</li> <li>• Assess fertility intentions and offer contraception or safer conception counselling.</li> <li>• Assess intimate partner violence and gender-based violence.</li> <li>• Assess substance use and mental health issues.</li> <li>• If proceeding to offer PrEP, offer detailed initial adherence counselling (Table 3.3)</li> </ul>

**Table 3.2 Managing Clinical and Laboratory Results on Initial and Follow-up Assessment**

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

**Table 3.3 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?	<ul style="list-style-type: none"> <li>• 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: <ul style="list-style-type: none"> <li>○ Make it a habit linked to an activity you do daily such as brushing teeth, taking a meal etc</li> <li>○ Disclose PrEP use to a partner or trusted person</li> <li>○ Use reminder devices like a cell phone alarm</li> <li>○ If available enrol into an SMS reminder system</li> </ul> </li> <li>• 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</li> <li>• 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</li> <li>• PrEP can be used safely with family planning pills or injections</li> </ul>
Starting PrEP	<ul style="list-style-type: none"> <li>• 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.</li> <li>• It takes up to 7 days of daily used 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 used of male or female condoms.</li> </ul>
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: <ul style="list-style-type: none"> <li>• Adopting safer sexual practices, such as abstinence, or using condoms during all sexual contacts;</li> <li>• Following viral suppression in a sero-discordant couple;</li> <li>• Leaving sex work;</li> <li>• Ceasing injection drug use or the sharing injection drug use equipment</li> </ul>
Protection from other STIs	PrEP does not offer protection from other STIs such as gonorrhoea, syphilis, herpes etc. Discuss with your provider if you suspect that you have an STI (genital sores or discharge). Using a condom each time you have sex will provide additional protection from HIV and other STIs
PrEP safety	<ul style="list-style-type: none"> <li>• TDF-based PrEP is generally safe and well tolerated.</li> <li>• 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.</li> <li>• A few people may not be able to use PrEP due to kidney-related side effects</li> </ul>
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

**Table 3.4 Pre---Initiation Education Check---list**

<b>Ensure that at least the following aspects during client counselling and education</b>	
<input type="checkbox"/> How PrEP works as part of combination prevention	<input type="checkbox"/> Explain the need for baseline and follow---up tests including HIV testing.
<input type="checkbox"/> Limitations of PrEP <ul style="list-style-type: none"> <li>• Link efficacy to adherence</li> <li>• PrEP reduces but does not eliminate the risk of acquiring HIV</li> <li>• PrEP does not prevent pregnancy or other STIs</li> <li>• May not be suitable in clients with renal impairment or intolerance to the PrEP medicines</li> </ul>	<input type="checkbox"/> Discuss when and how PrEP may be discontinued.
<input type="checkbox"/> PrEP use <ul style="list-style-type: none"> <li>• The medications used (show the client the pills)</li> <li>• How the medications are used (daily)</li> <li>• Number of daily doses required to achieve efficacy (7)</li> <li>• What to do when doses are missed?</li> <li>• Discontinuation of PrEP (need to continue for 28 days from last potential exposure to HIV)</li> </ul> <input type="checkbox"/> Safety and side effects and what to do in case these are experienced.	<input type="checkbox"/> What to do in case of client experiences symptoms of sero---conversion (acute HIV infection)
<input type="checkbox"/> <b>Risk reduction counselling and support</b> <ul style="list-style-type: none"> <li>• Education (risk and safer sex practices)</li> <li>• Managing mental health needs</li> <li>• Couple counselling</li> <li>• Access to, and consistent use of condoms and lubricants</li> <li>• Access to and need for frequent HIV testing</li> <li>• Early access to ART for those who test HIV positive</li> <li>• VMMC (if indicated)</li> <li>• STI screening and treatment</li> <li>• Harm reduction for PWID</li> </ul>	

**Table 3.5 Pre---Initiation Assessment Check---list**

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

**Prescribing Pre---exposure Prophylaxis**

Table 3.6 provides the recommended regimen for PrEP. The first prescription should be for 30 days to allow for scheduling for the first follow---up visit to assess adherence, tolerability and adverse effects. Subsequently, a 3---month prescription can be given. However, drug refills are done monthly.

**Table 3.6 Recommended Regimen for Pre---Exposure Prophylaxis**

<b>Preferred</b>	TDF 300 mg/FTC 200 mg once daily as FDC
<b>Alternative 1</b>	TDF 300 mg once daily
<b>Alternative 2</b>	TDF 300/FTC 300 mg once daily as FDC

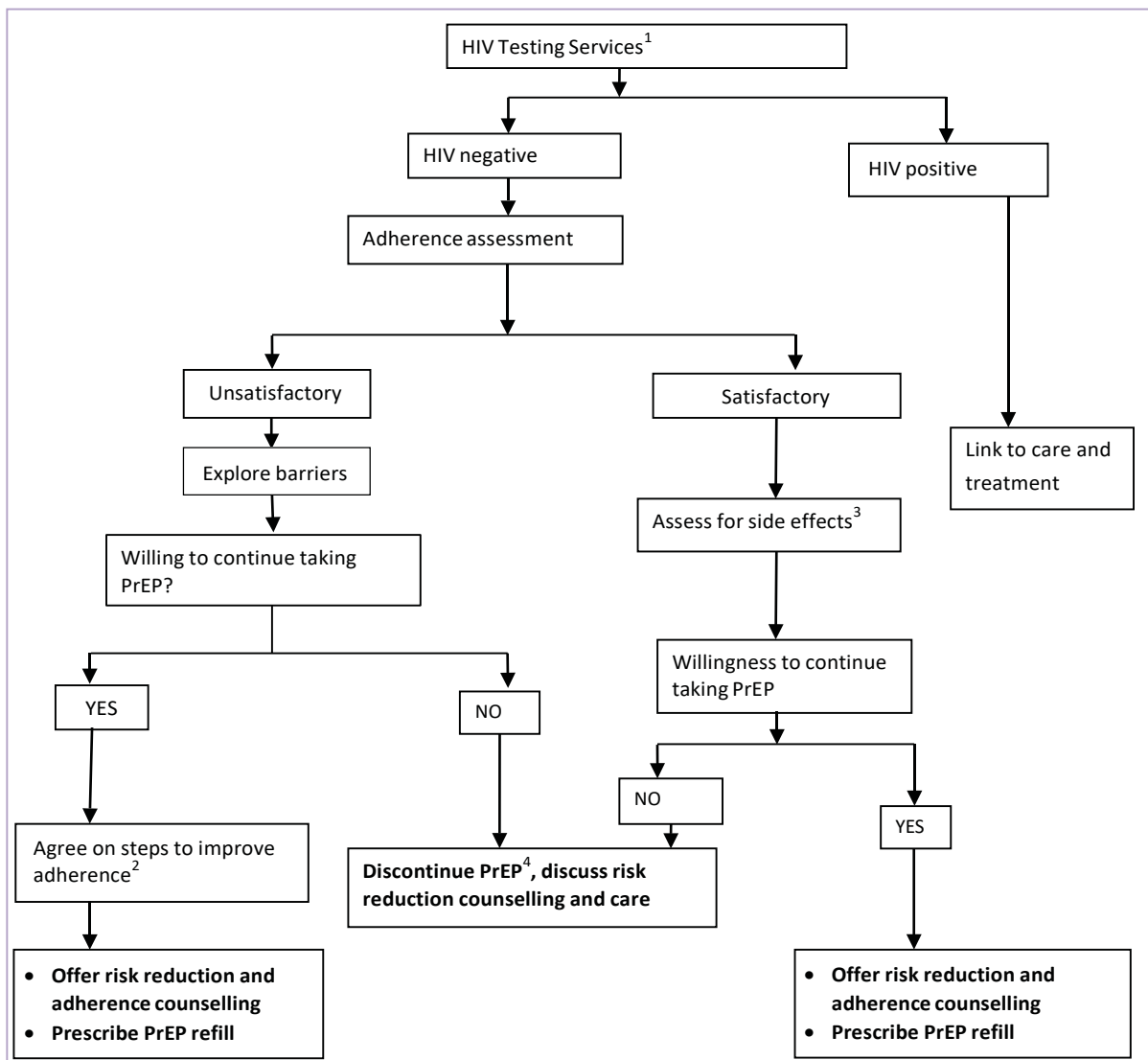
This will be documented in the Client Encounter record (Appendix 2)

## Section 4 Follow-up and Monitoring of Pre-Exposure Prophylaxis

PrEP should only be prescribed to clients who demonstrate good understanding of/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 for and manage side effects
- Exclude HIV infection
- Provide other prevention services including risk reduction counselling, condoms, STI screening and treatment, substance abuse treatment etc
- Review indications for PrEP

**Figure 4.1 Follow-up after initiating PrEP**



This will be documented in the Client Encounter record (Appendix 2) and summarised in the PrEP summary reporting tool (Appendix 3)



### **Counselling Messages for PrEP**

- PrEP is not to be taken for life unless one has on-going risk
- PrEP works when taken correctly as prescribed by the health care providers
- For discordant couples, PrEP is a bridge before the positive partner achieves complete viral suppression
- PrEP is safe in pregnancy and during breastfeeding

### **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. HIV self-testing, HIVST, (as recommended in the national HTS guidelines) may be used to further increase access to HIV testing.

#### **b. Managing suspected acute seroconversion illness**

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

#### **c. Managing Confirmed HIV Infection during PrEP**

- Counsel the patient and urgently link 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).
- Contact the regional or national TWG. It may be necessary to obtain a baseline VL and DRT to help decide on the optimal first-line ART for the patient.

### **Improving adherence to PrEP**

Approaches to improve adherence include:

- d. Encouraging the client to make it a daily habit at any most consistent most convenient time of day linked to an activity done daily such as brushing teeth, taking a meal etc
  - e. Disclosure of PrEP use to a partner or trusted person
  - f. Use of reminder devices like a cell phone alarm
  - g. SMS reminders where available and feasible
  - h. Explore and mitigate other barriers to adherence
  - i. Encourage peer support
2. Exercise caution when discontinuing PrEP in a client with HBV infection. Such clients may experience severe flare-up of hepatitis. Refer to hepatitis guidelines and consult a provider experienced in the management of hepatitis.

**Table 4.1 Adherence support during follow-up visits**

Theme	Adherence message/action
<b>Climate Setting</b>	Introduce yourself to the client, giving your name and role, ensure adequate privacy and reassure on confidentiality
<b>Assess</b>	<ul style="list-style-type: none"> <li>• Understanding and experience with adherence: dosage and timing</li> <li>• Experience with possible side effects</li> <li>• Risk reduction efforts since last visit</li> <li>• Challenges to adherence and risk reduction</li> <li>• Possible acute seroconversion illness<sup>1</sup></li> </ul>
<b>Advice</b>	<ul style="list-style-type: none"> <li>• In case of problems with adherence, explore approaches to improving adherence</li> <li>• Emphasize need for adherence and ongoing risk reduction including consistent use of condoms to prevent STIs and pregnancy.</li> <li>• For People Who Inject Drugs refer to a Needle and Syringe Exchange Program and Methadone Assisted Therapy</li> <li>• Remind clients circumstances under which PrEP can be discontinued</li> </ul>
<b>Agree</b>	<ul style="list-style-type: none"> <li>• Adherence and risk reduction goals based on degree of the client’s desire to meet these goals</li> </ul>
<b>Assist</b>	<ul style="list-style-type: none"> <li>• Provide client with any reading material, and if available access to telephone consultation</li> </ul>
<b>Arrange</b>	<ul style="list-style-type: none"> <li>• Schedule next counselling/refill appointment date</li> </ul>

**Assessing for medication side effects**

- a. *Minor side effects* --- few people may experience minor side effects like diarrhoea, nausea, decreased appetite, abdominal cramping or flatulence; dizziness or headaches. Such side-effects are usually mild and resolve without stopping PrEP. If necessary, symptomatic treatment such as anti-diarrhoeal, antiemetic or anti-flatulence medication can be prescribed for a brief period.
  
- b. *Elevated creatinine* --- where available, serum creatinine should be estimated at baseline and annually (earlier if the patient is at risk of renal disease). Self-limiting mild creatinine elevation occurs in a few individuals. Risk factors for significant creatinine elevation include:
  - Conditions such as diabetes mellitus and hypertension
  - Age > 60 years of age (in the African population, the risk increases from age >45 years)
  - Reduced CrCl (< 90 ml/min) at baseline
  - Concurrent use of nephrotoxic agents such as NSAIDs
  - If the creatinine clearance (CrCl) is < 50 ml/min, discontinue PrEP immediately and counsel on other HIV preventive measures; refer for further assessment. If the CrCl > 50 ml/min, PrEP may be restarted and creatinine re-assessed after 1 month. Exclude treatable/preventable causes of elevated creatinine such as dehydration, herbal remedies and supplements, NSAID use/abuse, other medications, uncontrolled blood pressure etc.

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

**Cockcroft–Gault equation:**

$$\text{Estimated Cr Clearance} = \text{Sex} * ((140 - \text{Age}) / (\text{Serum Creat})) * (\text{Weight} / 72)$$

**Notes:**

- For “sex”, use 1 for a male, 0.85 for a female
- Give “age” in years
- Provide “serum creatinine” in mg/dL
- Give “weight” in kilograms (should be lean body weight)

**Discontinuing PrEP**

Indications for discontinuing PrEP include;

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

PrEP use can be discontinued at least 28 days from the last high risk exposure to HIV.

**Restarting PrEP**

- A client who stops PrEP for more than 7 days and wishes to restart should be assessed for resumption of PrEP as a new client. Importantly, obtain a HIV test. If a high risk exposure occurred in the previous 7 days (i.e acute HIV infection is suspected), defer PrEP and obtain repeat HIV test after 30 days; if negative, PrEP can be prescribed if the other criteria are fulfilled.

**For a sero-discordant couple, the indications for re-starting PrEP by the negative partner include**

- HIV positive partner stops taking ART including defaulting from treatment
- Rebound in viral load in the HIV positive partner. Assess for and support adherence, evaluate for treatment failure. Provide the full package of care and support for discordant couples (including PrEP until the partner on ART achieves viral suppression)
- Having a new sexual partner of unknown HIV status.
- Negative partner is assessed to have additional risk of HIV infection such as a new STI
- During pregnancy (for the HIV negative female partner)

**PrEP in Special Circumstances****a. Chronic 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**

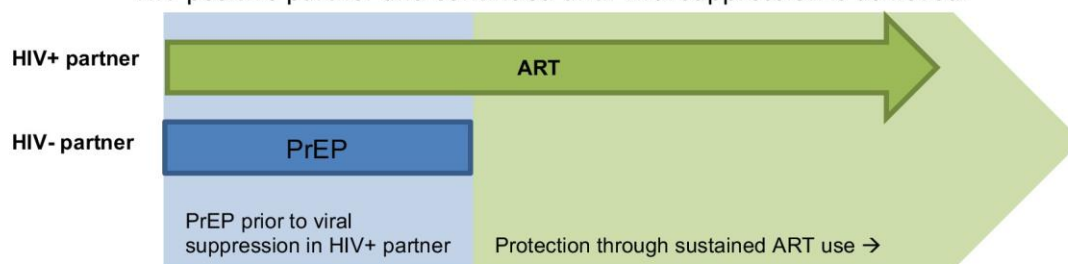
**when discontinuing TDF/FTC especially in the first 1---3 months after stopping PrEP. Monitor clinical symptoms (nausea, anorexia, jaundice, abdominal pain and dark urine); obtain ALT where available and refer to a physician for specialised assessment and treatment.**

*b. Pregnancy/Breastfeeding*

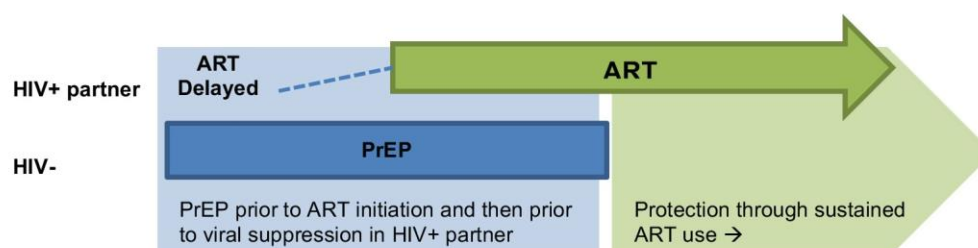
- For women at substantial ongoing risk of HIV infection who become pregnant or desire to conceive, PrEP decreases the risk of acute HIV infection during pregnancy. Acute HIV infection significantly increases the risk of mother-to-child transmission.
- There's no evidence that TDF/FTC or 3TC increase the risk of birth defects if used during any gestation of pregnancy. However, there's enough evidence to completely exclude harm.
- Assess for pregnancy intention in all women of reproductive age who are considering PrEP and provide counselling on safer conception options including the use of PrEP. Offer effective contraception unless pregnancy is desired.
- 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 continue PrEP individualized based on ongoing risk for HIV infection during pregnancy.
- Risk reduction counselling should be intensified for an uninfected individual who becomes pregnant while taking PrEP.
- Once the decision to continue PrEP is made, the client should start antenatal care immediately and followed up monthly until cessation of breastfeeding; with care coordinated between the antenatal and PrEP providers.

*c. PrEP use in discordance (the illustrations below were provided by....)*

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



- 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.



## Section 5 Appendices

### Appendix 1: Rapid Screening tool

RAST serves as a filter tool to identify clients who might be eligible for PrEP. It can be done before HIV testing and/or during HIV testing. This tool can be administered in any place including the community, CCC, MCH, etc.

It consists a set of 8 questions that assesses the behavioral risks of a client.



MINISTRY OF HEALTH  
NATIONAL AIDS & STIs CONTROL PROGRAM

#### PrEP Rapid Assessment Screening Tool (RAST)

Age: \_\_\_\_\_ Sex: \_\_\_\_\_ Date: \_\_\_\_\_

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

Negative     Positive     Unknown     Unwilling to disclose

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

Negative     Positive     Unknown

**In the past 6 months**

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

No             Yes

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

No             Yes

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

No             Yes

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

No             Yes

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

No             Yes

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

No     Yes

**Refer the client for further PrEP assessment at the health facility if:**

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

*Any Yes to the screening questions*

**Remarks**

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## Appendix 2: Clinic Encounter Record: Initiation and Follow up

The PrEP Clinical Encounter form is used for recording information of all PrEP package services offered at a health facility as part of HIV prevention.

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

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

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

**Where placed in the Facility:** It can be found in multiple places where PrEP services are offered.

Column Label	Description	Notes
Name of Facility	Enter the name of the facility where the PrEP is received from	
Delivery point	Record the service delivery point/department where the service is being offered in that health facility	
Tier	This is the facility position in service delivery per KHSPIII (2012–2017), <b>Tier 1:</b> Community, <b>Tier 2:</b> Primary Care level – Previous KEPH levels 2 and 3, <b>Tier 3:</b> County level – Previous KEPH level 4, <b>Tier 4:</b> National level – Previous KEPH levels 5 and 6	
MFL Code	Indicate the 5---digit Master Facility List Number of the health facility. This number can be found in the master facility list in <a href="http://ehealthkenya.org">ehealthkenya.org</a>	
County	Indicate the Name of the County where the health facility is located.	
Sub---county	Indicate the Name of the Sub county where the health facility is located.	
Ward	Indicate the Name of the Ward where the health facility is located.	
<b>Client Profile</b>		
Unique client record number	Record the client’s unique identifier number	
Initial visit date	Record the date when the initial visit was made	
First Name	Record the first name of the client	
Middle Name	Record the middle name of the client	
Last Name	Record the last name of the client	
Telephone number	Record the telephone number of the client	
Alien/National ID/ Passport/ Birth cert Number	Record Alien/National ID/ Passport/ Birth cert Number as provided by the client	
NHIF Number	Record NHIF number of the client.	
County of birth	Record the County in which the client was born	



Column Label	Description	Notes
Mother's Maiden name	Record the middle name for the client's mother	
Sex	Tick either Male for Female per the client's sex	
Date of Birth	Enter the date of birth of the client	If age is <19years tick appropriately if the clients attends school
Age (years)	Enter age of the client in completed years	
Marital status	Select one marital status as applicable <b>Never Married</b> <b>Cohabiting</b> <b>Married Monogamous</b> <b>Married Polygamous</b> <b>Separated/Divorced</b> <b>Widowed</b>	
Population Type	Select one marital status as applicable <b>Discordant Couple</b> <b>Fisher folk</b> (individuals who engage in fish trade) <b>General Population</b> (individuals who are not within the category of Discordant Couple, Fisher folks or Key population) Key Population (Specify: <b>MSM</b> (Men having sex with men) or <b>FSW</b> (Female sex workers) or <b>MSW</b> (Male sex workers) or PWID (People Who Inject Drugs))	
<b>Entry point and Transfer status</b>		
Referred from	Tick appropriately the entry point where the client has been referred for PrEP from <b>HBTC</b> (Home Based Testing and Counseling) <b>VCT</b> site (Voluntary Counseling and Testing site) <b>OPD</b> (Outpatient Department) <b>MCH</b> (Maternal Child Health Department) <b>TB Clinic</b> (Tuberculosis Clinic) <b>IPD</b> (In---PatientDepartment) <b>CCC</b> (Comprehensive Care Centre) <b>Peer</b> (Referred by the peer or Peer educator) <b>Outreach</b> (Referred during an outreach activity)	

Column Label	Description	Notes
	<p><b>Self---Referral</b> (A client who comes to the facility without being referred by anyone)</p> <p><b>CHV</b> (Community Health Volunteer)</p> <p><b>Other</b> (Please specify the referral point if not among the above)</p>	
<b>If Transfer In</b>		
Prep start date	Enter the date that the client was initiated on PrEP	
Regimen	Tick the PrEP regimen the client is already on	
Facility transferred from	Enter the name of the health facility where the client is transferring from	
MFL Code	Enter the MFL Code of the facility the client is transferring from	
County	Enter the name of the county of the facility the client is transferring from	
<b>Baseline Assessment</b>		
Behavioral Risk Assessment (mark all that apply)	<p>Tick appropriately for all that apply as:</p> <ul style="list-style-type: none"> <li>✓✓ Sex partner(s) is HIV+ and <ul style="list-style-type: none"> <li>• Not on ART</li> <li>• On ART &lt;6months</li> <li>• Suspected poor adherence to ART</li> <li>• Detectable HIV viral load</li> <li>• Couple is trying to conceive</li> </ul> </li> <li>✓✓ Sex partner(s) high risk &amp; HIV status is unknown</li> <li>✓✓ Has sex with &gt;1 partner</li> <li>✓✓ Ongoing IPV (Intimate Partner Violence) and GBV (Gender Based Violence)</li> <li>✓✓ Transactional sex (exchange of sex for favors or money)</li> <li>✓✓ Recent STI</li> <li>✓✓ Recurrent use of Post Exposure Prophylaxis (PEP)</li> <li>✓✓ Recurrent sex under influence of alcohol/ recreational drugs</li> <li>✓✓ Inconsistent or no condom use</li> </ul>	<p>For a client with a sex partner who is HIV positive indicate the following</p> <ul style="list-style-type: none"> <li>• CCC number or tick either N/A (if partner not enrolled into care) or CCC number/enrolment status unknown</li> <li>• Partner ART start date or Not on ART at initial visit</li> <li>• Time Known to be HIV---serodiscordant (number of Years and Months)</li> <li>• Indicate if the client had sex without condom with the sex partner in the past 30 days</li> <li>• Indicate number of living children that are HIV+</li> </ul>



Column Label	Description	Notes
	✓✓ Injection drug use with shared needles and or syringes	
<b>Complete section if partner is HIV positive</b>	<b>If the sex partner is HIV+ and any of the below are ticked continue to fill the partner's information section:</b> Not on ART, On ART <6months, Suspected poor adherence to ART, Detectable HIV viral load, couple is trying to conceive.	
HIV+ve partner CCC number	Enter the CCC number of the HIV+ partner, tick NA if the client is not enrolled in CCC or tick if CCC number or enrollment status is unknown.	
HIV+ partner ART start date	Enter the date when the HIV+ partner was initiated on ART or tick appropriately if the client is not on ART at initial visit.	
Time known to be HIV serodiscordant	Enter the time in years/ months that the partners have known their discordancy status.	
Sex without condom with HIV+ partner in past 30 days	Tick Yes if the client has had sex without a condom with a HIV+ partner in the past 30days or No if they have not.	
No of living children with HIV+ partners	Enter the number of children the client has ever had with a HIV+ve partner.	
<b>Medical Assessment and Fertility Intentions</b>		
HIV test result	Tick appropriately as Positive or Negative	
Blood pressure	Measure the blood pressure and document in the format: Systolic pressure /Diastolic blood pressure e.g. 120/80	
Weight	Indicate weight in kilograms	
Height	Indicate height in centimeters	
Signs/Symptoms of STI	Tick Yes if there are signs/ symptoms of STI or No if none.	
<b>Chronic Illness and Comorbidities / Treatment</b>		
Liver disease	Tick Yes if liver disease is diagnosed and No if it is not. Record the treatment given.	
Kidney disease	Tick Yes if kidney disease is diagnosed and No if it is not. Record the treatment given.	
1 and 2 Other	Record other chronic diseases is diagnosed and the treatment given.	
Male only: Circumcised	Tick appropriately as Yes or No	

Column Label	Description	Notes
<i>Female only:</i>		
Last LMP date	Record the date of the last menstrual period	
Pregnant(planned/unplanned)	Tick Yes or No as appropriate. Tick if the pregnancy is planned or unplanned	
Breastfeeding	Tick Yes if breastfeeding or No if not	
On Family planning	Tick Yes if client is on FP and No if not on FP.	
FP Method	Record the FP method the client is on <b>C</b> = Condoms <b>H</b> = hysterectomy <b>TL</b> = Tubal ligation/female sterilization <b>FA</b> = Fertility awareness method/periodic abstinence <b>D</b> = Diaphragm/cervical cap <b>LAM</b> = Lactational Amenorrhea Method <b>IUD</b> = Intra uterine device <b>IMP</b> = Implant <b>INJ</b> = Injectable <b>OC</b> = oral contraceptive pills <b>ECP</b> = Emergency contraceptive pills dispensed <b>V</b> = Vasectomy (partner's) <b>UND</b> = Undecided	
Plan to have children (select one)	Tick appropriately as Trying to conceive, Future, No or Don't know.	
Clinical notes	This space is provided for the clinician to make any additional notes relevant to the client.	
<b>PrEP Initiation:</b> Lab results (investigations should not delay prep initiation. To be recorded when available)		
<b>Test / Result / additional steps</b>		
Hepatitis B	Tick if the test result is Positive, Negative or Not done. If negative tick Yes if vaccine is given and No if vaccine not given	
Hepatitis C	Tick if the test result is Positive, Negative or Not done.	
Serum creatinine	Record the result in the space provided or tick appropriately if Not done	If creatinine is out of range or CrCl <50ML/min refer for further assessment
Previous PrEP use	Tick Yes or No as appropriate	

Column Label	Description	Notes
Willing to start / Continue PrEP	Tick Yes or No as appropriate. If the client is not willing to start PrEP, tick the reasons as applicable.	
Signs and symptoms of Acute HIV	Tick Yes or No as appropriate	If HIV test result is negative and Signs and symptoms of Acute HIV, Medically Ineligible to start PrEP and Contraindications for TDF---FTC or TDF---3TC have been checked as NO, the client is eligible for PrEP.
Medically Ineligible to start PrEP	Tick Yes or No as appropriate	
Contraindications for TDF---FTC or TDF---3TC or TDF	Tick Yes or No as appropriate	
Prescribed PrEP at initial visit	Tick Yes or No as appropriate	
Regimen	Tick the PrEP regimen that the client is being initiated on	
No of months	Enter the number of months the PrEP dose is prescribed for	
Date of Initiation	Enter the date the client is initiated on PrEP	
Next appointment date	Enter the date of next appointment given	
Clinician initials	Enter the clinician initials in the space provided.	
<b>Follow Up Page</b>		
Unique client record number	Record the client's unique identifier number	
Name of the client	Record the three names of the client	
Visit type (Scheduled/unscheduled):	In the check boxes provided, indicate using a tick specifying the type of visit. If client makes a visit on their appointment date, tick scheduled, If client visits the clinic on any other date other than their appointment date, tick in the unscheduled check box	
<b>Medical Assessment &amp; Fertility intentions</b>		
Clinical notes	This section will be used by the clinicians to capture additional notes that will has not been captured in any other section and will help in assessment of the client	
<b>Summary of findings</b>		
Blood Pressure	Measure the blood pressure and document in the format: Systolic pressure /Diastolic blood pressure e.g. 120/80	
Weight:	Indicate weight in kilograms Eg 50kg	

Column Label	Description	Notes
Sign/symptoms for STI	Indicate either Yes or No if the client presents any signs and symptoms of STIs	
Signs/symptoms of acute HIV	Indicate either Yes or No if the client presents any signs and symptoms of acute HIV	
If male, circumcised since last visit	For male clients, Indicate: <b>Yes:</b> if the client was circumcised since the last visit, <b>No:</b> if the client has not been circumcised since the last visit <b>N/A :</b> for clients who are already circumcised	
Possible adverse drug reaction	Fill this section if the client has had an adverse drug reaction (ADR) related to PrEP medication. Indicate the specific adverse drug reaction <b>Severity: Indicate Mild, Moderate or Severe</b> <b>Action:</b> This should be filled for patients who are found with an adverse event when an action is taken. Indicate action to manage the adverse event as : <b>Stop = Stopped drug</b> <b>Regimen=</b> Switched regimen <b>Other =</b> Other action, Enter details in clinical notes <i>The tools allow documentation of 2 ADR, additional reactions should be documented in the clinical notes section</i>	
<b>Chronic illness and co---morbidityies</b>		
Liver disease	Indicate Yes for any symptoms of liver disease, otherwise indicate No.	
Kidney disease	Indicate Yes for any symptoms of kidney disease, otherwise indicate No.	
Other descriptions (1 &2)	This will document any other illness that the client presents with	
Treatment	In the event the client has a comorbidity, enter the medication dispensed	
Plan to have children	Indicate whether the client is planning to have children: Check	

Column Label	Description	Notes
	<p><b>Trying to conceive:</b> The client is trying to have a baby at the time of the visit</p> <p><b>Future:</b> The client is planning to have children in future</p> <p><b>No:</b> The client is not planning to have children at the time of the visit</p> <p><b>Don't know:</b> The client is not decided if they have planning to have children during the visit</p> <p><b>Client/partner is pregnant:</b> The client or partner is expectant</p>	
<b>Last LMP date</b>	Record the date of the last menstrual period	
<b>Pregnant</b>	Tick Yes or No as appropriate.	
<b>Breast feeding</b>	Indicate Yes if the client is breastfeeding at the time of the visit, otherwise No.	
<b>On family planning</b>	<p>Indicate:</p> <p><b>None:</b> If the client is not using any modern family planning method</p> <p><b>Method:</b> Specify the family planning method that</p> <p>Record the FP method the client is on</p> <p><b>C</b> = Condoms</p> <p><b>H</b> = hysterectomy</p> <p><b>TL</b> = Tubal ligation/female sterilization</p> <p><b>FA</b> = Fertility awareness method/periodic abstinence</p> <p><b>D</b> = Diaphragm/cervical cap</p> <p><b>LAM</b> = Lactational Amenorrhea Method</p> <p><b>IUD</b> = Intra uterine device</p> <p><b>IMP</b> = Implant</p> <p><b>INJ</b> = Injectable</p> <p><b>OC</b> = oral contraceptive pills</p> <p><b>ECP</b> = Emergency contraceptive pills dispensed</p> <p><b>V</b> = Vasectomy (partner's)</p> <p><b>UND</b> = Undecided</p>	
<b>If ended pregnancy since last visit</b>	<p>Outcome date: Enter the date that the pregnancy ended</p> <p><b>Outcomes:</b></p> <p><b>Term live:</b> The pregnancy reached term and the baby is alive</p> <p><b>Pre---term live:</b> Baby born before full term and is alive</p>	

Column Label	Description	Notes
	<p><b>Induced abortion:</b> is the intentional termination of a pregnancy before the fetus can live independently.</p> <p><b>Loss:</b> Miscarriage or still birth</p> <p><b>Birth defects:</b> Indicate:</p> <p style="padding-left: 20px;"><b>Yes:</b> if a baby is born with any defects</p> <p style="padding-left: 20px;"><b>No:</b> If baby is not born with any defects</p> <p style="padding-left: 20px;"><b>Don't know:</b> If the client is not aware if the baby has any defects</p>	
<b>Behavior Risk Assessment</b>	<ul style="list-style-type: none"> <li>✓✓ Sex partner(s) is HIV+ and <ul style="list-style-type: none"> <li>• Not on ART</li> <li>• On ART &lt;6months</li> <li>• Suspected poor adherence to ART</li> <li>• Detectable HIV viral load</li> <li>• Couple is trying to conceive</li> </ul> </li> <li>✓✓ Sex partner(s) high risk &amp; HIV status is unknown</li> <li>✓✓ Has sex with &gt;1 partner</li> <li>✓✓ Ongoing IPV (Intimate Partner Violence) and GBV (Gender Based Violence)</li> <li>✓✓ Transactional sex (exchange of sex for favors or money)</li> <li>✓✓ Recent STI</li> <li>✓✓ Recurrent use of Post Exposure Prophylaxis (PEP)</li> <li>✓✓ Recurrent sex under influence of alcohol/ recreational drugs</li> <li>✓✓ Inconsistent or no condom use</li> </ul> <p>Injection drug use with shared needles and or syringes</p>	
<b>Follow Up Laboratory Investigations</b>		
HIV Test	Tick the HIV status of the client as per the test result on the specific clinic visit. If <b>positive</b> , blood sample	If <b>Not Done</b> , the reasons why should be given

Column Label	Description	Notes
	from the client should be collected for drug resistance test.	
Serum creatinine	Indicate the serum creatinine results from the lab in $\mu\text{mol/L}$ .	
If creatinine done, CrCl $\geq$ 50mL/min	Tick Yes if CrCl $\geq$ 50mL/min and No if CrCl $<$ 50mL/min	
Other	Indicate any other lab tests carried out on this visit, their results and units	
<b>PrEP</b>		
Self---assessment of adherence since last visit	Tick as per the client's self---report since the last visit Satisfactory or unsatisfactory. NA--- if the client did not pick up PrEP at last visit	
If Unsatisfactory	Tick all the reasons that apply if the client's assessment is poor or bad from the checklist provided Including any other that is not provided in the checklist.	
Adherence Counselling done	Tick <b>Yes</b> if the client received adherence counselling and <b>No</b> if the client did not receive adherence counselling	
PrEP status	Tick Continue, Restart or discontinue per what the client is taking	
Prescribed PrEP Today Yes/No	Tick Yes if the client has been prescribed PrEP or No if the client has not been prescribed for PrEP	
If <b>Yes</b> , regimen and duration	Tick one of the three PrEP regimens the client received on this visit Indicate the duration in months for the given regimen of PrEP	
If <b>No</b> , reasons	Tick all the reasons that apply if the client did not received PrEP from the checklist provided; including any other that is not provided in the checklist	
Condoms issued	Tick <b>Yes</b> if the client received condoms on this visit or <b>No</b> if the client did not receive condoms	
Next appointment date	Indicate date of the next appointment in the format dd/mm/yyyy	
Clinicians initials	Indicate the initials of the attending clinician	



File no: \_\_\_\_\_

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

Name of facility: \_\_\_\_\_ Delivery Point: \_\_\_\_\_ Tier: \_\_\_\_\_ MFL code: \_\_\_\_\_  
County: \_\_\_\_\_ Sub county: \_\_\_\_\_ Ward: \_\_\_\_\_

#### Client Profile

Unique client record number: \_\_\_\_\_ Initial visit date:

Name: First \_\_\_\_\_ Middle \_\_\_\_\_ Last \_\_\_\_\_ Telephone no: \_\_\_\_\_

Alien/National ID/passport/Birth Cert No: \_\_\_\_\_ NHIF No: \_\_\_\_\_ County of Birth \_\_\_\_\_ Mother Maiden Name \_\_\_\_\_

Sex:  Male  Female Date of birth: dd mm yyyy Age (years): \_\_\_\_\_ If age <19, attends school:  Yes  No

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

Population Type:  Discordant couple  Fisher Folk  Gen Population  Key Population (Specify) \_\_\_\_\_  MSM  MSW  FSW  PWID

#### Entry Point & Transfer Status

Referred from (select one):  
DHBTC DVCT site DOPD DMCH DTB clinic DIPD DCCC  
DPeer DOutreach DSelf-referral community Dother: \_\_\_\_\_  
If transferred in:  
PrEP start date: dd mm yyyy Regimen: DTDF-FTC DTDF DTDF-3TC  
Facility transferred from: \_\_\_\_\_ MFL code: \_\_\_\_\_ County: \_\_\_\_\_

#### Baseline Assessment

##### Behaviour risk assessment

Mark all that apply:

Sex partner(s) is HIV+ and (mark all that apply)

Not on ART (If yes to any)

On ART <6 months

Suspected poor adherence to ART

Detectable HIV viral load

Partner is trying to conceive

Sex partner(s) high risk & HIV status is unknown

Has sex with >1 partner

Ongoing IPV/GBV

Transactional sex

Recent STI

Recurrent use of post-exposure prophylaxis (PEP)

Recurrent sex under influence of alcohol/recreational drugs

Inconsistent or no condom use

Injection drug use with shared needles and/or syringes

Complete section if sex partner is HIV+

HIV+ partner CCC number: \_\_\_\_\_ / \_\_\_\_\_

or DNA (not enrolled at a CCC)

or DCCC number/enrollment status unknown

HIV+ partner ART start date:

or  Not on ART at initial visit

Time known to be HIV-serodiscordant: \_\_\_\_\_ years + \_\_\_\_\_ months

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

Number of living children with HIV+ partner: \_\_\_\_\_

##### Medical assessment & fertility intentions

HIV test results:  Positive  Negative

Blood pressure (mmHg): \_\_\_\_\_ / \_\_\_\_\_

Weight (kg): \_\_\_\_\_ Height (cm): \_\_\_\_\_

Signs/symptoms of STI:  Yes; Use codes provided: \_\_\_\_\_  No

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:

#### PrEP initiation

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

Test	Result	Additional steps
Hepatitis B (HBsAg)	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Not done	If negative, vaccine series initiated: <input type="radio"/> Yes <input type="radio"/> No
Hepatitis C	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Not done	
Serum creatinine	_____ (µmol/L) or <input type="radio"/> Not done	If done, CrCl (ml/min): _____ If creatinine is out of range, or CrCl < 50 mL/min, refer for further assessment.

Previous PrEP use:  Yes  No Condom Issued:  Yes  No  
Willing to start PrEP:  Yes  No Adherence Counseling Done:  Yes  No  
If not willing, reason (mark all that apply):  None  Side effects  Cost  Lack of information  Lack of motivation  Lack of support  Other: \_\_\_\_\_  
Signs/symptoms of acute HIV:  Yes  No Prescribed PrEP at initial visit:  Yes  No  
Medically ineligible to start PrEP:  Yes  No Eligible for PrEP: \_\_\_\_\_ Regimen: DTDF-FTC DTDF DTDF-3TC  
Contraindications for TDF-FTC FTDF-3TC/FTDF:  Yes  No # of months: \_\_\_\_\_  
Date of initiation: \_\_\_\_\_

Next appointment date: dd/mm/yyyy Clinician initials: \_\_\_\_\_



**Follow Up Visit**

Unique client record number \_\_\_\_\_ Name of client: \_\_\_\_\_

Visit date: \_\_\_\_\_

Visit type:  scheduled  unscheduled  
Clinical notes

**Summary of findings**

Blood pressure \_\_\_\_\_ / \_\_\_\_\_ mm Hg

Weight \_\_\_\_\_ kg

Signs/symptoms of STI(s) \_\_\_\_\_ Dyes  No  Use codes: \_\_\_\_\_

Signs/symptoms of acute HIV \_\_\_\_\_ Dyes  No

If male, circumcised since last visit \_\_\_\_\_ n yes  n no  na (already circumcised)

Possible adverse drug reaction \_\_\_\_\_

Severity  mild  moderate  severe

Action (mark all that apply)  stop  switched req  men  Other \_\_\_\_\_

Chronic illnesses & comorbidities \_\_\_\_\_ Treatment \_\_\_\_\_

Liver disease \_\_\_\_\_ n yes  n No

Kidney disease \_\_\_\_\_ n yes  n No

Plan to have children  
If female LMP \_\_\_\_\_

Pregnant

1 Yes  No

Breastfeeding  
If ended pregnancy since last visit

Outcome date

On family planning

none or methods indicate the code

Outcome  Term live  Preterm live  Induced abortion  Missed

Birth defect(s)  yes  no  don't know

**Mark all that apply**

Sex partner(s) is HIV+ and  Sex partner(s) at high risk for HIV & HIV status unknown  Recurrent use of PEP

not on ART  Has sex with >1 partner  Recurrent sex under influence of alcohol/recreational drugs

1 month ART use  Ongoing IPV/GBV  Inconsistent or no condom use

poor adherence to ART  Transactional sex  IDU with shared needles/syringes

detectable HIV viral load  Recent STI

couple is trying to conceive

HIV test  positive  negative  not done  If positive, collect sample for drug resistance, and link to CCC (add CCC number)

Serum creatinine for PrEP  normal  abnormal  not done  If creatinine is out of range, or CrCl < 50 mL/min, refer for further assessment

If creatinine done, CrCl 50 mL/min  Dyes  No

Other \_\_\_\_\_

(write in test, results & units (if applicable))

Self-assessment of adherence since last visit  Good  Fair  sad  NA (did not pick up PrEP at last visit)

If unsatisfactory, reason(s) (mark all that apply)  forgot  lost/out of pile;  separated from HIV+ partner  no perceived risk  side effects  sick

not knowledgeable  pill burden  shared with others  none  other \_\_\_\_\_

Adherence Counseling done  yes  no  Condoms issued  Dyes  No

PrEP status  continue  restart  discontinue

Prescribed PrEP today  Dyes  No

If yes, regimen and duration \_\_\_\_\_ regimen  TDF-FTC  TDF  TDF-3TC number of months \_\_\_\_\_

If discontinued, reason(s) (mark all that apply)  HIV test is positive  low risk of HIV  renal dysfunction  OTC request  not adherent to PrEP

viral suppression of HIV+ partner  too many HIV tests  Other \_\_\_\_\_

Next appointment date: \_\_\_\_\_

Clinician Initials: \_\_\_\_\_

**Adherence:**  
Good: Missed 0-3 doses per week in the past 1 month  
Fair: Missed 4-5 doses per week in the past 1 month  
Bad: Missed 6-7 doses per week in the past 1 month  
Serum creatinine clearance =  $\frac{\text{Sex} \cdot (140 - \text{Age})}{72} \cdot (\text{Serum Creatinine})$   
Notes:  
For (e), use 1 for a male, 0.85 for a female  
Give age in years  
PrEP dose = serum creatinine (mg/dL)  
Give weight in kilograms (should be lean body weight)

**FP Methods:**  
C = Condom  
TL = Tied Ligament Sterilization  
EA = Female awareness method  
D = Diaphragm/cervical cap  
LAM = Lactational Amenorrhea Method  
IUD = Intrauterine device  
IMP = Implant  
INT = Injectable  
OC = Oral contraceptive pill  
ECP = Emergency contraceptive pills dispensed  
V = Voluntary (partner's)

**SII Diagnosis:**  
Genital Ulcer Disease (GUO), Vaginitis, Cervicitis, Vaginal Discharge (VG),  
Cervical Intraepithelial Neoplasia (CIN),  
Pelvic Inflammatory Disease (PID),  
Urethral Discharge (UD),  
Anal Discharge (AD),  
Chlamydia (ChM)



### Appendix 3: PrEP Register

This is the primary source of reported data in PrEP. It captures demographic details of the client, lab investigations and use of PrEP including adherence. It also captures details of all HIV tests done to the PrEP clients to enable identification of clients who seroconvert while on treatment.

#### Understanding the PrEP Register

Instructions below will help understand all variables (columns used to collect information) in the PrEP Register. As you are looking at the instructions refer to a copy of the register provided to you.

Variable Field Name	Column Label	Description of variable
Serial Number	(a)	Indicate Serial number as 1,2,3 .....
Date of visit	(b)	Indicate the date of the visit for that client
Name in Full	(c)	Write three names of client as First, middle and last respectively
Client Unique ID	(d)	Record the client's unique ID as it is from the clinical encounter card
Sex	(e)	Indicate the biological sex of the client (Male or Female)
Date of birth	(f)	Indicate date of birth in format DD/MM/YYYY
Age in completed years	(g)	Indicate the accurate age of the client
Population Type	(h)	Use the codes provided:
		1. Discordant couple
		2. Fisher folk
		3. General population
		4. Key population
5. Other		
Assessed	(i)	Record yes if client has been assessed for HIV risk using the clinical encounter form and No if not assessed for HIV risk using the clinical encounter form
Eligible	(j)	Record yes if client is eligible for PrEP and No if the client is not eligible
Date PrEP initiation	(k)	Indicate date in format DD/MM/YYYY
Reason for PrEP eligibility at entry point	(l)	Record the number as captured in the register
		1. Sexual partner of Known HIV+ status
		2. Engaging in transaction sex
		3. History of recent STI
		4. Recurrent use of PEP
		5. History of sex under use of drugs/alcohol
		6. Inconsistent or no condom use
		7. Injection drug use with shared needles or syringes
		8. sero---discordant couples trying to conceive
		9. Having multiple sex partners
10. Ongoing GBV/ IPV, NA if not eligible for PrEP		

Variable Field Name	Column Label	Description of variable
HTS	(m)	Record appropriately as either negative, Positive or Not done.
STI screened (YES/NO) / Result (STI Diagnosis)	(n)	Enter Yes or No in the upper cell.
		In the lower cell indicate 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),		
Others (O)		
Creatinine clearance done/ Test Results (In ml/min)	(o)	Record YES if creatinine is done and NO if not done in the upper cell and the result in ml/min in the lower cell.
HBVsAg	(p)	Record the result Record appropriately as either negative, Positive or Not done.
Is the client at risk of HIV infection? (Yes/No)	(q)	Record Yes for clients at risk of HIV from behavior risk assessment, No if the client is not at risk and NA if the client test HIV positive
If yes, insert the reason for HIV risk (Use Codes)	(r)	Enter: HIV Risk Factors
		1. Sexual partner of Known HIV+ status
		2. Engaging in transaction sex
		3. History of recent STI
		4. Recurrent use of PEP
		5. History of sex under use of drugs/alcohol
		6. Inconsistent or no condom use
		7. Injection drug use with shared needles or syringes
		8. sero---discordant couples trying to conceive
		9. Having multiple sex partners
10. Ongoing GBV/ IPV		
Adherence	(s)	Record as either satisfactory or unsatisfactory. Use ND (Not Done) if not initially on PrEP
Received Adherence Counselling	(t)	Enter Yes or No
PrEP Status	(u)	Record correctly depending on the status of the client as Newly Initiated, Continue, Discontinued Restart.
If discontinued Provide reasons	(v)	Use the codes provided:
		1. HIV test is positive

Variable Field Name	Column Label	Description of variable
		2. Low risk of HIV
		3. Renal dysfunction
		4. Client request
		5. Non---adherence (NA
		6. Viral suppression of HIV+ partner
		7. Too many HIV tests
		8. Others
Yearly Creatinine Done / Test result	(w)	Record Yes or No in the upper cell. In the lower cell indicate the result as P= positive or N= Negative. Enter ND if it is not done
HBVsAG test	(x)	Record the result Record appropriately as either negative, Positive or Not done.
For those who turn HIV Positive while on PrEP	(y)	Record Yes for linkage to CCC and NO for not linked to CCC in the upper cell.
Linkage to CCC(Yes/No)		In the lower cell enter CCC number for HIV positive clients linked to CCC
Remarks	(z)	Any other information that could be beneficial to the client

No. of visits	Frequency	Time	Duration	Visit	Counseling		Skill building		Self-efficacy	Knowledge	Attitudes	Behavior
					Pre-test	Post-test	Pre-test	Post-test				
1				1	1							
2				2								
3				3								
4				4								
5				5								
6				6								
7				7								
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## Appendix 4: PrEP Summary Reporting Tool

This the main Monthly summary reporting tool for PrEP services. 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 Register.

### Understanding the PrEP Summary Reporting Tool

Instructions below will and help understand all indicators reported in PrEP as well as the data elements in those indicators.

Data Element	Data Element Description
<b>Number assessed for HIV risk</b> Assessed_15---19 (M) Assessed_15---19 (F) Assessed_20---24 (M) Assessed_20---24 (F) Assessed_25---29(M) Assessed_25---29 (F) Assessed_30+ (M) Assessed_30+ (F)	This data element refers to the count of clients by age and sex, who have been assessed for HIV risk using the PrEP client clinical record by a clinician
<b>Number eligibility for PrEP</b> Eligible_15---19 (M) Eligible_15---19 (F) Eligible_20---24 (M) Eligible_20---24 (F) Eligible_25---29 (M) Eligible_25---29 (F) Eligible_30+ (M) Eligible_30+ (F)	This is a count of all clients by age and sex, who have been assessed and found to be eligible for Pre---exposure prophylaxis. This includes any persons who had started pre---exposure prophylaxis in the past and stopped receiving the medicines but has been found eligible to initiate PrEP again
<b>Number initiated on PrEP (New)</b> New_15---19 (M) New_15---19 (F) New_20---24 (M) New_20---24 (F) New_25---29 (M) New_25---29 (F) New_30+ (M) New_30+ (F)	This is a count of all clients by age and sex, who have been initiated on pre---exposure prophylaxis during the reporting month after meeting the eligibility criteria for PrEP.
<b>Number continuing PrEP (Refill)</b> Refill_15---19 (M) Refill_15---19 (F) Refill_20---24 (M) Refill_20---24 (F) Refill_25---29 (M) Refill_25---29 (F) Refill_30+ (M) Refill_30+ (F)	This is a count of all clients on PrEP by sex and age, who have come for a refill of PrEP drugs during the reporting period.
<b>Number restarting PrEP (Restart)</b> Restart_15---19 (M)	This is a count of all clients by sex and age, who have had stopped using PrEP and they are re---initiated in the reporting month

Data Element	Data Element Description
Restart I_15---19 (F) Restart _20---24 (M) Restart I_20---24 (F) Restart _25---29 (M) Restart I_25---29 (F) Restart _30+ (M) Restart _30+ (F)	
<b>Number currently on PrEP (New+ Refill+ Restart)</b> Current_15---19 (M) Current_15---19 (F) Current_20---24 (M) Current_20---24 (F) Current_25---29 (M) Current_25---29 (F) Current_30+ (M) Current_30+ (F)	This is an aggregate count of all clients who are currently receiving Pre---Exposure Prophylaxis. This includes clients newly started on PrEP in the current month, clients who come for their PrEP refills in the reporting month and those who restart using PrEP in the reporting month
<b>Number tested Positive while on PrEP</b> Pos_15---19 (M) Pos_15---19 (F) Pos_20---24 (M) Pos_20---24 (F) Pos_25---29 (M) Pos_25---29(F) Pos_30+ (M) Pos_30+ (F)	These are clients who seroconverted while on PrEP
<b>Number diagnosed with STI</b> STI_15---19 (M) STI_15---19 (F) STI_20---24 (M) STI_20---24 (F) STI_25---29 (M) STI_25---29(F) STI_30+ (M) STI_30+ (F)	This are clients on PrEP who have been diagnosed to have STI during the reporting month
<b>Discontinued PrEP</b> Dis_15---19(M) Dis_15---19 (F) Dis_20---24(M) Dis_20---24 (F) Dis_25---29 (M) Dis_25---29(F) Dis_30+ (M) Dis_30+ (F)	This is the count of all clients who have stopped receiving PrEP during the reporting period.



**NATIONAL AIDS & STI PROGRAMME  
PrEP Summary Reporting Tool**

Site Name/Facility: \_\_\_\_\_

MFL-Code: \_\_\_\_\_

Sub-County: \_\_\_\_\_

County: \_\_\_\_\_

Reporting Month: \_\_\_\_\_

Year: \_\_\_\_\_

<b>1. Number Assessed For HIV risk</b>		<b>6. Number currently on PrEP ( New + Refill+ Restart)</b>	
1.1 Males 15 - 19 Years		6.1 Males 15 - 19 Years	
1.2 Females 15- 19 Years		6.2 Females 15 - 19 Years	
1.3 Males 20 - 24 Years		6.3 Males 20 - 24 Years	
1.4 Females 20 - 24 Years		6.4 Females 20 - 24 Years	
1.5 Males 25 - 29 Years		6.5 Males 25 - 29 Years	
1.6 Females 25-29 Years		6.6 Females 25 - 29 Years	
1.7 Males 30 Years and older		6.7 Males 30 Years and older	
1.8 Females 30 Years and older		6.8 Females 30 Years and older	
<b>Total</b>		<b>Total</b>	
<b>2. Number Eligible for PrEP</b>		<b>7. Number tested HIV positive while on PrEP</b>	
2.1 Males 15 - 19 Years		7.1 Males 15- 19 Years	
2.2 Females 15- 19 Years		7.2 Females 15 - 19 Years	
2.3 Males 20 - 24 Years		7.3 Males 20 - 24 Years	
2.4 Females 20 - 24 Years		7.4 Females 20 - 24 Years	
2.5 Males 25 - 29 Years		7.5 Males 25 - 29 Years	
2.6 Females 25 - 29 Years		7.6 Females 25 - 29 Years	
2.7 Males 30 Years and older		7.7 Males 30 Years and older	
2.8 Females 30 Years and older		7.8 Females 30 Years and older	
<b>Total</b>		<b>Total</b>	
<b>3. Number initiated (New) on PrEP</b>		<b>8. Number diagnosed with STI</b>	
3.1 Males 15 - 19 Years		8.1 Males 15 - 19 Years	
3.2 Females 15- 19 Years		8.2 Females 15 - 19 Years	
3.3 Males 20 - 24 Years		8.3 Males 20-24 Years	
3.4 Females 20 - 24 Years		8.4 Females 20 - 24 Years	
3.5 Males 25 - 29 Years		8.5 Males 25 - 29 Years	
3.6 Females 25 - 29 Years		8.6 Females 25 - 29 Years	
3.7 Males 30 Years and older		8.7 Males 30 Years and older	
3.8 Females 30 Years and older		8.8 Females 30 Years and older	
<b>Total</b>		<b>Total</b>	
<b>4. Number continuing (Refills) on PrEP</b>		<b>9. Number discontinued PrEP</b>	
4.1 Males 15 - 19 Years		9.1 Males 15- 19 Years	
4.2 Females 15- 19 Years		9.2 Females 15- 19 Years	
4.3 Males 20 - 24 Years		9.3 Males 20 - 24 Years	
4.4 Females 20 - 24 Years		9.4 Females 20 - 24 Years	
4.5 Males 25 - 29 Years		9.5 Males 25 - 29 Years	
4.6 Females 25 - 29 Years		9.6 Females 25 - 29 Years	
4.7 Males 30 Years and older		9.7 Males 30 Years and older	
4.8 Females 30 Years and older		9.8 Females 30 Years and older	
<b>Total</b>		<b>Total</b>	
<b>5. Number Restarting PrEP</b>			
5.1 Males 15 - 19 Years			
5.2 Females 15- 19 Years			
5.3 Males 20 - 24 Years			
5.4 Females 20 - 24 Years			
5.5 Males 25 - 29 Years			
5.6 Females 25 - 29 Years			
5.7 Males 30 Years and older			
5.8 Females 30 Years and older			
<b>Total</b>			

## Appendix 5: Frequently Asked Questions about Pre-Exposure Prophylaxis

### What is PrEP?

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

### How is PrEP different from regular ARV drugs?

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

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

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

### How does PrEP work?

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

### What are the benefits of PrEP?

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

PrEP offers

- Decreased anxiety
- Increased communication, disclosure, trust
- Increased self-efficacy

Among HIV discordant couples, PrEP is a means to

- Reduce risk of HIV transmission
- Meet their fertility desires
- Cope with HIV sero-discordance.

### When can I use PrEP?

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

- Has a sexual partner who is known HIV positive and either: not on ART, has not been on ART for 6 months, Suspected of poor adherence to ART, or who has not achieved viral suppression.
- Sexual partner(s) are of unknown HIV status and are at high-risk for HIV infection i.e. has multiple sexual partners, has had STIs, engages in transactional sex, injects drugs
- Engaging in transactional sex (sex in exchange of gifts etc.)
- History of recent sexually transmitted infection
- Recurrent use of post-exposure prophylaxis (PEP)
- History of sex while under the influence of alcohol or recreational drugs as a habit
- Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status
- Injecting drug use where needles and syringes are shared
- A discordant couples (where one partner is infected with HIV and the other is not) who are trying to conceive

### Can I use PrEP with other medicines?

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

When should I not use PrEP?

- You should not use PrEP if:
  - If you are HIV positive
  - If you do not know their HIV status
  - If you cannot use your PrEP pill daily
  - If you have been advised by a health care provider not to use PrEP

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

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

What are the side effects of PrEP?

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

How should I take PrEP Pills?

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

Can I still use condoms when taking PrEP?

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

Does PrEP contribute to increase in risky sexual behavior?

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

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

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

Can I share PrEP with others?

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

How long can I take PrEP?

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

Can I use PrEP along with other medicines?

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

When should I stop/discontinue taking PrEP?

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

- HIV positive
- If you reduce your risk for getting infected with HIV

- If the health care provider informs you that your kidney (Renal) function is low after doing some test
- If you request to stop
- If you are not adhering to the drugs well
- If you are in a discordant relationship and your HIV positive partner has achieved sustained viral suppression. But you should continue to consistently use condom

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

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

**Can One Develop Resistance to PrEP**

Resistance occurs sometimes when antiretroviral agents are used for treatment.

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

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

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

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