**MINISTRY OF HEALTH**

**NASCOP**

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

**[Plus other Front Matter]**

Contents

[Overview of Recommendations for Post-Exposure Prophylaxis to Prevent HIV Infection 3](#_Toc467998688)

[Schema for Managing Pre-Exposure Prophylaxis for HIV Prevention 4](#_Toc467998689)

[Initiating PrEP 5](#_Toc467998690)

[Figure x: Initiating Pre-Exposure Prophylaxis 5](#_Toc467998691)

[Table X: Clinical Features and Symptoms of Acute HIV Infection 8](#_Toc467998692)

[Table X: Initial Assessment 9](#_Toc467998693)

[Table x: Managing Clinical and Laboratory Results on Initial and Follow-up Assessment 10](#_Toc467998694)

[Table X: Initial adherence preparation and counselling 11](#_Toc467998695)

[Table x: Pre-Initiation Education Check-list 12](#_Toc467998696)

[Table X: Pre-Initiation Assessment Check-list 13](#_Toc467998697)

[Table X: Adherence support during follow-up visits 14](#_Toc467998698)

[Figure X: Follow-up after initiating PrEP 15](#_Toc467998699)

[Special Considerations 16](#_Toc467998700)

[Combination Prevention of HIV Infection 18](#_Toc467998701)

[Figure x: Combination Prevention of HIV Infection 18](#_Toc467998702)

[Appendices 1](#_Toc467998703)

[Appendix x: Pre-Exposure Prophylaxis Client's Assessment and Follow up Form 1](#_Toc467998704)

[Appendix x: Follow-up Form for PrEP Clients 3](#_Toc467998705)

# Overview of Recommendations for Post-Exposure Prophylaxis to Prevent HIV Infection

|  |  |
| --- | --- |
|  |  |
| What is PrEP? | PrEP is a form of HIV practice in which persons not infected with HIV who are at high risk of the disease take antiretroviral medication in an attempt to lower their chances of becoming infected if exposed. |
| Who can take PrEP? | PrEP is recommended for HIV negative persons at substantial ongoing risk of HIV infection such as   * Sexual partner with HIV who has not been on effective therapy for the preceding 6 months, * Sexual partner/s are of unknown HIV status and 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) * Engaging in transactional sex * Recent sexually transmitted infection * Recurrent use of post-exposure prophylaxis * History of sex whilst under the influence of alcohol or recreational drugs as a habit * Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status * Injection drug use where injection equipment is shared * Sero-discordant couples trying to conceive * Requests for PrEP |
| Contraindications to PrEP | HIV positive  Renal impairment - as shown by creatinine clearance < 60 ml/min  Lack of willingness to adhere to daily PrEP and associated follow-up schedule |
| 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 assessment (to exclude HIV infection and any establish safety to use PrEP). Clients should also receive adequate adherence counselling. |
| What are the recommended PrEP medications? | *Preferred*   * TDF/FTC (300 mg/200 mg) as FDC once daily   *Alternative*   * TDF 300 mg once daily * TDF/3TC 300 mg/300 mg as FDC once daily   *At initiation, prescribe PrEP for only 30 days to allow for follow-up visits to assess adherence, tolerance and commitment to continue with PrEP.* |
| What is effective PrEP use? | PrEP should be offered as part of a comprehensive, individualized prevention plan following behavioural risk assessment and adherence counselling. Combination prevention includes:   |  |  | | --- | --- | | * Risk reduction counselling * Safer sex practices * Consistent & correct condom use * VMMC (where indicated) | * Prevention and treatment of STIs * Substance abuse treatment * Prevention of gender-based violence (GBV) * Adherence to PrEP - efficacy of PrEP is dependent on adherence. | |
| Follow-up | After starting PrEP, clients require regular follow-up (initially at 1 month) then every 3 months thereafter (i.e months 3, 6, 9, 12, 15, 18 etc) to monitor HIV status, adherence side effects and risk reduction efforts.  PrEP is not meant to be a lifelong intervention. It is a method of prevention during periods when a person is at greatest risk of acquiring HIV. |
| Discontinuation of PrEP | PrEP should be discontinued in any of the following circumstances  ● HIV positive ● change in risk (low risk) ● renal adverse effect (CrCl < 60 ml/min) ● sustained non-adherence ● sustained viral suppression in the HIV partner of a discordant couple ● client request to discontinue. |

# Schema for Managing Pre-Exposure Prophylaxis for HIV Prevention

**Initial Visit/First Contact**

* Brief behavioural risk assessment - to determine if PrEP is indicated
* Discuss effective PrEP use, clarify misinformation
* Perform initial clinical and laboratory assessment
  + Baseline HIV test, and rule out acute HIV infection
  + Screen for STIs and risk of renal disease/hepatitis B infection
  + In females, determine if pregnant

If HIV negative and meets eligibility criteria for PrEP

* Offer adherence counselling
* Prescribe 30 day supply of PrEP (TDF 300 mg/FTC 200 mg OD)
* Discuss combination prevention and risk reduction
* Follow-up visit at 2 weeks to assess side effects

**30 day review**

* Assess for adherence and offer adherence counselling and support
* Ask about any side effects. Find out how the client is coping with the side effects. Reassure if minor
* Assess for STIs, (and pregnancy in women) and acute HIV infection
* Assess for risk of kidney disease, if available, obtain serum creatinine and calculate creatinine clearance
* Discuss risk reduction and provide condoms

**Prescribe 60 days of PrEP, schedule review after 60 days**

**3-month review**

* Assess for adherence and offer adherence counselling and support
* Ask about any side effects. Find out how the client is coping with the side effects. Reassure if minor
* Assess for STIs, (and pregnancy in women) and acute HIV infection
* Perform HIV test
* Discuss risk reduction and provide condoms

**Prescribe 90-day refill of PrEP and 6-month return visit**

**6-month review**

* Assess for adherence and offer adherence counselling and support
* Ask about any side effects
* Assess for STIs, (and pregnancy in women) and acute HIV infection
* Perform HIV test
* Discuss risk reduction and provide condoms

**Prescribe 90-day refill of PrEP and 9-month return visit**

**9-month review**

* Assess for adherence and offer adherence counselling and support
* Ask about any side effects
* Assess for STIs, (and pregnancy in women) and acute HIV infection
* Perform HIV test
* Discuss risk reduction and provide condoms. Discuss need for continued PrEP

Prescribe 90-day refill of PrEP and 12-month return visit

**12-month review**

* Assess for adherence and offer adherence counselling and support
* Ask about any side effects
* Assess for STIs, (and pregnancy in women) and acute HIV infection
* Perform HIV test
* Discuss risk reduction and provide condoms. Discuss need for continued PrEP

**Prescribe 90-day refill of PrEP**.

# Initiating PrEP

### Figure x: Initiating Pre-Exposure Prophylaxis

* Willing to take PrEP - on self-request or provider initiated

HIV Testing and Counselling

Does the client other eligibility criteria for PrEP? 1

HIV Seronegative

Evidence of pre-existing renal impairment

Link to HIV care andf treatment

Willing to take PrEP?

YES

Doe the client have symptoms of acute HIV infection? 2

NO

Defer PrEP, offer risk reduction counselling, retest after 2 weeks

* Offer risk reduction and adherence counselling
* Prescribe PrEP for one month
* Draw blood for creatinine and HBsAg (if available and not yet done)

Creatinine clearance < 60 ml/min

HIV Positive

HIV positive

* Offer risk reduction counselling
* Refer to other HIV preventive and RH services

NO

HIV Negative

NO

YES

YES

NO

YES

Creatinine clearance > 60 ml/min

* Defer PrEP,
* Offer risk reduction counselling
* Refer for further assessment and treatment of renal disease

1. **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 result
* 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

*Establishing ‘Substantial Risk’ of HIV Infection*

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

* Sexual partner is known HIV positive and: not on ART, or on ART < 6 months, or suspected poor adherence to ART, or most recent VL is detectable
* 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 who may be offered PrEP based on personal circumstances, risk and desire for additional HIV prevention. The questions are framed to elicit people’s behaviours and vulnerabilities as opposed to specific sexual practices.

|  |
| --- |
| Before starting the sexual behavioural assessment,   * Ensure adequate privacy * 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 |

*General Screening Questions*

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?”

If the individual answers ‘yes’ to any of these questions, the provider should discuss the benefits of PrEP and assess for additional vulnerabilities including:

* Unstable housing or homelessness
* Recent breakup with a sexual partner
* Recent loss of source of income
* Recent premature discontinuation of schooling or relocation from regular residence
* Habituation to psychoactive agents

*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?”

1. **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 X: Clinical Features and Symptoms of Acute HIV Infection **(Ref)**

|  |  |
| --- | --- |
| **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, provide PEP for 28 days. Obtain a rapid HIV test at 28 days, if the test result is negative, transition to PrEP immediately (if indicated, i.e. the client has substantial on going risk of HIV infection)

### Table X: Initial Assessment

|  |  |
| --- | --- |
|  |  |
| Complete medical history and examination | * Identify relative or absolute contraindications to PrEP such as   + Past or current kidney disease   + Risk of kidney disease (diabetes mellitus, uncontrolled hypertension, chronic NSAID use   + Use of other nephrotoxic agents   + Past of current liver disease   + Current or past chronic hepatitis (B or C)   + Acute HIV infection |
| Establish eligibility to use PrEP | * Screen for substantial risk of HIV infection * 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*   * To screen for renal disease in patients at risk |
| *Serum creatinine and creatinine clearance*   * To identify pre-existing estimated creatinine clearance less than 60 ml/min. |
| *Hepatitis B surface antigen*   * To identify undiagnosed current hepatitis B infection. If negative, consider vaccination against hepatitis B. |
| *Hepatitis C antibody*   * If positive, consider treatment for hepatitis C infection. |
| *Rapid Plasma Reagin*   * To diagnose and treat syphilis infection. |
| *Pregnancy testing*   * To guide antenatal care, contraceptive and safer conception counselling, and to assess risk of mother to child transmission. Pregnancy is not a contraindication for PrEP use (see section below). |
| Screening for other STIs | 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 | Depending on local guidelines, consider vaccination for hepatitis A, human papilloma virus, tetanus and meningitis. |
| Brief counselling | * To assess whether the client is at substantial risk of HIV. * To discuss prevention needs and provide condoms and lubricants. * To discuss desire for PrEP and willingness to take PrEP. * To develop a plan for effective PrEP use, sexual and reproductive health. * To assess fertility intentions and offer contraception or safer conception counselling. * To assess intimate partner violence and gender-based violence. * To assess substance use and mental health issues. * If proceeding to offer PrEP, offer detailed initial adherence counselling (Table x) |

### Table x: 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 | **GIT** - nausea, vomiting, weight loss: these are often mild, self-limiting and occur during the first 1-2 months. Provide supportive counselling, offer symptomatic treatment e.g. anti-emetics like Metoclopramide 10 mg 8 hourly for 3 to 5 days.  **Renal** - transient increase in creatinine, and rarely proteinuria and Fanconi’s syndrome (presenting as polyuria, bone pain and weakness). Measure creatinine (and calculate estimated creatinine clearance) at initiation of ART, at 1 and 4 months and annually thereafter (or whenever indicated (symptom directed)). If creatinine clearance (eGFR) < 60 mL/min; do not start PrEP, recheck after 2 weeks. Refer for evaluation of underlying renal disease. If the renal function returns to normal, reassess for PrEP and initiate/continue PrEP. When restarting PrEP, optimum protection is reached after 7 doses of PrEP.  PrEP should not be prescribed for individuals using nephrotoxic drugs like acyclovir, aminoglycosides, retinoids, instead, offer alternative HIV prevention options. |
| Pregnancy or breastfeeding | Pregnancy and breastfeeding are not contraindications to provision 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 X: Initial adherence preparation and counselling

|  |  |
| --- | --- |
| **Theme** | **Adherence Message/action** |
| Setting the stage | 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 using 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? (Effectiveness) | 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. |
| How is PrEP used? | * PrEP is provided as tablets. You should take one tablet daily (at any most convenient time of day).To ensure you do not forget take PrEP each day:   + Make it a daily habit linked to an activity you do daily like brushing teeth, taking a meal etc   + Disclose PrEP use to a partner or trusted person   + Use reminder devices like a cell phone alarm   + Discuss with your provider how you can enrol onto an SMS reminder system * If you forget to take a tablet, take it as soon as you remember. Occasionally, you may take 2 tablets in a day, but you should never exceed more than 2 tablets per 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 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. |
| 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 not having no sexual contact, or using condoms for all sexual contacts; following an effective course of ART for more than 6 months if a serodiscordant couple; leaving sex work; ceasing injection drug use or the sharing injection drug use equipment |
| Protection from other STIs | PrEP does not offer protection from other STIs such as gonorrhoea, syphilis, herpes etc. Discuss with your provider if you suspect that you have an STI (genital sores or discharge). Using a condom each time you have sex will provide additional protection from HIV and other STIs |
| 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 can be used in pregnancy and during breast feeding. |
| PrEP safety | PrEP use is safe. A 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. 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 |
| 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. |
| Client concerns | Clarify misconceptions, address any client concerns |

### Table x: Pre-Initiation Education Check-list

|  |  |
| --- | --- |
| **Item** | **Item** |
| How PrEP works as part of combination prevention | Explain the need for baseline and follow-up tests including HIV testing. |
| Limitations of PrEP   * Link efficacy to adherence * PrEP reduces but does not eliminate the risk of acquiring HIV * PrEP does not prevent pregnancies and STIs | Discuss when and how PrEP may be discontinued. |
| PrEP use   * The medications used (show the client the pills) * How the medications are used (daily) * Number of daily doses required to achieve efficacy (7) * What to do when doses are missed? * Discontinuation of PrEP (need to continue for 28 days from last potential exposure to HIV)   Side effects and what to do in case these are experienced. | * What to do in case of client experiences symptoms of seroconversion (acute HV infection) |
| Long-term use and safety of PrEP | **Risk reduction counselling and Support**   * Education (risk and safer sex practices) * Managing mental health needs * Couple counselling * Access to, and consistent use of condoms and lubricants * Access to and need for frequent HIV testing * Early access to ART * VMMC * STI screening and treatment * Harm reduction for PWID |

### Table X: Pre-Initiation Assessment Check-list

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **Y/N** | **Item** | **Y/N** |
| HIV testing and counselling, HIV-negative |  | STI screening and treatment |  |
| Symptoms of acute viral infection in last 6 weeks |  | For Women |  |
| Pregnancy test |  |
| Pregnancy and pregnancy intention |  |
| * Is the client currently using any contraception? |  |
| * If not, is she interested in using long-term hormonal contraception in addition to condoms? |  |
| * Is the client trying to conceive? |  |
| * Is the client pregnant or breastfeeding? |  |
| Behaviour risk assessment |  | Plans for accessing PrEP |  |
| Substance use and mental health screening |  | Serum creatinine and creatinine clearance >60 mL/min |  |
| Partner information |  | HBsAg |  |
| Pre-initiation education and understanding of PrEP |  | HCV serology |  |
| Readiness and willingness to adhere to prescribed PrEP and follow-up schedule |  | Medication history |  |

### Table X: Adherence support during follow-up visits

|  |  |
| --- | --- |
| **Theme** | **Adherence message/action** |
| **Setting the stage** | Introduce yourself to the client, giving your name and role, ensure adequate privacy and reassure in confidentiality |
| **Assess** | Understanding and experience with adherence: dosage and timing  Experience with possible side effects  Risk reduction efforts since last visit  Challenges to adherence and risk reduction  Possible acute seroconversion illness1 |
| **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  Remind clients circumstances under which PrEP can be discontinued |
| **Agree** | Adherence and risk reduction goals based on degree of the client’s desire to meet these goals |
| **Assist** | Provide client with any reading material, and if available access to telephone consultation |
| **Arrange** | Schedule next counselling/refill appointment date |

**Managing suspected acute seroconversion illness**

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

### Figure X: Follow-up after initiating PrEP

HIV Testing and Counselling1

Adherence assessment

HIV seronegative

**Discontinue PrEP**4**, discuss risk reduction counselling and care**

Assess for side effects3

Willing to continue taking PrEP?

Satisfactory

Willingness to continue taking PrEP

Unsatisfactory

Agree on steps to improve adherence2

* **Offer risk reduction and adherence counselling**
* **Prescribe PrEP refill**
* **Offer risk reduction and adherence counselling**
* **Prescribe PrEP refill**

HIV positive

Explore barriers

NO

YES

NO

YES

Link to care and treatment

1. **HIV Testing**

Offer HTC as per the national HTS Guidelines. HIV sero-status should be established and documented at the initiation of PreP, at 1 month and every 3 months thereafter.

1. **Improving adherence to PrEP**

Approaches to improve adherence include:

* 1. Encouraging the client to make it a daily habit linked to an activity done daily such as brushing teeth, taking a meal etc
  2. Disclosure of PrEP use to a partner or trusted person
  3. Use of reminder devices like a cell phone alarm
  4. SMS reminders

1. **Assessing for medication side effects**
   1. *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.
   2. *Elevated creatinine* - where available, serum creatinine should be estimated at baseline and 6-monthly while using PrEP. Self-limiting mild creatinine elevation occurs in a few individuals. Risk factors for significant creatinine elevation include:
      * co-morbid conditions such as diabetes mellitus and uncontrolled hypertension.
      * Age> 45 years of age
      * Reduced CrCl (< 90 ml/min) at baseline
      * Concurrent use of nephrotoxic agents such as NSAIDs
   * If the creatinine clearance (CrCl) is < 60 ml/min, discontinue PrEP immediately, repeat creatinine after 2-4 weeks.
   * If the CrCl > 60 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.

**Cockcroft–Gault equation:**

***Estimated Cr Clearance = Sex \* ((140 - Age) / (SerumCreat)) \* (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)

1. **Discontinuing PrEP**

Indications for discontinuing PrEP include;

* + The client becoming HIV positive
  + Change in risk status (low risk)
  + Renal dysfunction with sustained creatinine clearance below 60mL/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, if the exposure was in the last 7 days. Clients discontinuing PrEP for reasons other than a HIV positive test or renal intolerance should receive counselling on risk reduction strategies and education in safely restarting PrEP should they feel ready to do so.

1. Managing sus

# Special Considerations

***Chronic HBV infection:*** TDF and FTC (as used for PrEP)are also effective in the treatment of HBV infection. HIV infection is not a contraindication to PrEP use. However, due to the risk of hepatitis flare-up in the next 1-3 months, exercise caution when discontinuing TDF/FTC. Consider referring such clients to physicians experienced in managing HBV infection (such as MOPC in the public sector).

**Pregnancy/Breastfeeding:** Pregnancy and breastfeeding are not contraindications to PrEP. Risk reduction counselling should be intensified for an uninfected individual who becomes pregnant while taking PrEP. PrEP should be continued due to the increased risk of HIV infection during pregnancy. The client should receive standard antenatal care and be followed up monthly and after cessation of breastfeeding.

# Combination Prevention of HIV Infection

PrEP should not be offered in isolation, but instead as part of a package of evidence-informed combination prevention suited to individual client risk profile and preferences, local disease HIV transmission dynamics and cultural practices and attitudes.

### Figure x: Combination Prevention of HIV Infection

HIV Negative

Prompt linkage to care and treatment

HIV positive

Adherence to ART

Linkage to appropriate package of HIV prevention interventions

* Risk reduction counselling
* Safer sex practices
* VMMC
* Consistent & correct condom use
* Prevention and treatment of STIs
* Substance use treatment
* Prevention of GBV
* PrEP

Risk Assessment

Interventions to increase knowledge of HIV status through HIV Testing

Viral suppression

DECREASED HIV TRANSMISISON AT POPULATION LEVEL

* Reduction in number of new HIV infections

Positive Health & Dignity (POSITIVE PREVENTION)

* Disclosure of HIV status
* Partner/family testing
* Consistent & correct condom use
* Contraception to prevent unplanned pregnancies
* Prevention and treatment of STIs
* Adherence to ART and other therapies

# Appendices

### Appendix x: Pre-Exposure Prophylaxis Client's Assessment and Follow up Form

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PRE-EXPOSURE PROPHYLAXIS CLIENT'S ASSESSMENT AND FOLLOW UP FORM** | | | | | | | | | | |
| **CLIENT PROFILE** | | | |  | **PRE-EXPOSURE PROPHYLAXIS (PrEP)** | | | | | |
| **Client Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | |  | ***Risk factors assessment (If yes in any, within 6 months)*** | | | | | |
| **Unique ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Height:** | \_\_\_\_\_\_\_ | (Cm) |  | Sexual partner known of +ve HIV status | | | | ¨ Yes ¨ No |  |
| **Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Age:** | \_\_\_\_\_\_\_ | (Years) |  | Sexual partner unknown HIV status | | | | ¨ Yes ¨ No |  |
| **Site Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Weight:** | \_\_\_\_\_\_\_ | (Kgs) |  | Engaging in transactional sex (money or gifts/food) | | | | ¨ Yes ¨ No |  |
| **Safe Space:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Tel Contact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |  | History of recent STI | | | | ¨ Yes ¨ No |  |
| **Date of enrolment: (DD/MM/YYYY)** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |  | Recurrent use of PEP | | | | ¨ Yes ¨ No |  |
| **Ward:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |  |  |  | History of sex under influence of alcohol or drugs | | | | ¨ Yes ¨ No | |
| **MEDICAL HISTORY** | | | |  |
| **History of any of the following** (*Indicate* ***YES or NO*** *against each of the following*) | | | |  | Inconsistent or no condom use | | | | ¨ Yes ¨ No |  |
|  | Injection drug use where needled and syringes are shared | | | | ¨ Yes ¨ No |  |
| Liver disease | | ¨ Yes ¨ No |  |  | Sero-discordant couples planning to conceive | | | | ¨ Yes ¨ No | |
| Renal disease | | ¨ Yes ¨ No |  |  |
| Pregnant | | ¨ Yes ¨ No |  |  | Having multiple sex partners | | | | ¨ Yes ¨ No |  |
| Breastfeeding | | ¨ Yes ¨ No |  |  | Ongoing GBV/IPV | | | | ¨ Yes ¨ No |  |
| Any malignancy expected to require further treatment | | ¨ Yes ¨ No |  |  | **CRITERIA FOR PrEP INITIATION-If Yes to all** | | | | | |
| Any malignancy expected to require further treatment | | ¨ Yes ¨ No |  |  | Confirmed HIV negative | | | | ¨ Yes ¨ No |  |
| Uncontrolled hypertension or Diabetes | | ¨ Yes ¨ No |  |  | Does not have a current or recent illness consistent with acute HIV infection | | | | ¨ Yes ¨ No | |
| ***Currently receiving any of the therapies below?*** *(Indicate* ***YES*** *or* ***NO*** *against each of the following)* | | | |  |
| Drugs that decrease renal function | | ¨ Yes ¨ No |  |  | Willing to take prep and attend follow-up evaluations | | | | ¨ Yes ¨ No | |
| Anti-retroviral therapy (including HIV post-exposure prophylaxis (PEP) | | ¨ Yes ¨ No |  |  |
| **BASELINE LABORATORY INVESTIGATIONS** (*Insert results in the space provided*) | | | |  | No contraindication for use of TDF +/-FTC/3TC | | | | ¨ Yes ¨ No |  |
| Creatinine clearance | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | ***(ml/min)*** |  | ***Consent*** | ¨ Yes ¨ No |  |  |  |  |
| Hepatitis B (HBsAg) | ¨ Negative ¨ Positive | | |  |  |  |  |  |  |  |
| Other Tests (please specify) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  | ***Eligible for PrEP*** |  | ¨ Yes ¨ No |  |  |  |
| **Comments:** | | | |  | ***Enroled for PrEP*** |  | ¨ Yes ¨ No |  | *Date: \_\_\_\_\_\_\_\_\_\_\_* | |
| *Version: August 2016* | | | | | | | | | | |

### Appendix x: Follow-up Form for PrEP Clients

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CONTINUATION FORM FOR PrEP CLIENTS** | | | | | | | | | | |
| **Date of enrolment: (DD/MM/YYYY)** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | **Unique ID** | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| ***Data Element*** | ***Individual Client Visitation Details*** | | | | | | | | | |
| **Date of visit (DD/MM/YY)** | **Month 1** | **Month 2** | **Month 3** | **Month 6** | **Month 9** | **Month 12** | **Month 15** | **Month 18** | **Month 21** | **Month 24** |
| **/ /** | **/ /** | **/ /** | **/ /** | **/ /** | **/ /** | **/ /** | **/ /** | **/ /** | **/ /** |
| **Weight (Kg)** |  |  |  |  |  |  |  |  |  |  |
| **Blood pressure** |  |  |  |  |  |  |  |  |  |  |
| **Received adherance counseling (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **Is the client adherent? (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **If no, what is the reason for non-adherence?** *(Use provided codes below)* |  |  |  |  |  |  |  |  |  |  |
| **Does the client have symptoms of adverse drug reaction (ADR)? (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **If yes, what details of ADR** (Use codes/*Write the details)* |  |  |  |  |  |  |  |  |  |  |
| **Symptoms of sexually transmitted infection (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **If yes to above question, insert name of the STI** *(Use Codes below)* |  |  |  |  |  |  |  |  |  |  |
| **Treatment for STI issued (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **Is the client Pregnant? (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **If yes, what is the expected date of delivery?** |  |  |  |  |  |  |  |  |  |  |
| **Is the client Breast feeding? (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **Is the client at risk of HIV infection? (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **If yes, insert the reason for HIV risk** |  |  |  |  |  |  |  |  |  |  |
| **HTS Result (Negative/Positive)** |  |  |  |  |  |  |  |  |  |  |
| **Received information on condom use? (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **Received Condom? (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **Does the client want to continue taking PrEP? (Y/N)** |  |  |  |  |  |  |  |  |  |  |
| **Conclusion:  Continue or Discontinue?** |  |  |  |  |  |  |  |  |  |  |
| **If Discontinue, state the reason** *(Use codes below)* |  |  |  |  |  |  |  |  |  |  |
| **Date of return:** |  |  |  |  |  |  |  |  |  |  |
| **Clinician Initials** |  |  |  |  |  |  |  |  |  |  |
| **Codes:** |  |  |  |  |  |  |  |  |  |  |
| ***Reasons for Non-Adherence/Discontinuation:*** *Non-adherence (NA), Client is no longer at Risk (NR), Client's Choice not to take PrEP (CC), Adverse Drug Reaction (ADR), Stigma (S), Client on Other Medication (OM), Intimate Partner Violence (IPV) , Transfer Out (TO), Others (O)* | | | | | | | | | | |
| ***Adverse Drug Reaction (ADR)****: Lactic Acidosis (LA), Severe Hepatomegaly (SH), Acute Exercerbation of HBV infection (HBV), Acute Renal Failure (ARF), Lipodistrophy (L)* | | | | | | | | | | |
| ***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)* | | | | | | | | | | |

**Appendix x**

|  |  |  |  |
| --- | --- | --- | --- |
| **PrEP SUMMARY REPORTING TOOL** | | | |
| **County: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | |
| **Site Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | |
| **Ward: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |  |
| **Reporting Month: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | |
| **Indicator** | **Age** | | **Total** |
| **15-19 years** | **20-24 years** |
| Number Eligible for PrEP |  |  |  |
| Number Enrolled for PrEP |  |  |  |
| Number Refilled with PrEP drugs |  |  |  |
| Number Stopped PrEP |  |  |  |
| Number Restart on PrEP |  |  |  |
| Number Tested for HIV |  |  |  |
| Number Tested Negative |  |  |  |
| Number Tested Positive |  |  |  |
| Number Screened for STI |  |  |  |
| Number Pregnant |  |  |  |
| Number Breastfeeding |  |  |  |
| Number received Adherence Assessment |  |  |  |
| Number of condoms Dispensed |  |  |  |
| **Remarks:** | | | |
|
| **Name of person reporting: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | **Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |