



**The Republic Of Uganda**

**MBALE DISTRICT YOUNG PEOPLES' PREP PRIORITY ACTION PLAN 2022-2023**

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## **1.0 INTRODUCTION TO THIS GUIDE**

### **1.1 Background**

Uganda has one of the highest HIV and AIDS disease burdens, with a prevalence of 5.5% among adults ages 15-49 years, 7.1% among females, and 3.8% among males. Approximately 1.3 million adults 15 years and older are living with HIV (UPHIA, 2020). The Joint United Nations Programme on HIV and AIDS (UNAIDS) 2020 Spectrum estimates that the HIV incidence rate is 0.95 per 1,000 persons; 570 young women ages 15–24 years acquire HIV each week in Uganda (UNAIDS 2020 spectrum estimates).

Uganda adopted the HIV combination prevention strategy consisting of structural, behavioral and biomedical interventions. The biomedical interventions include safe male circumcision (SMC), condoms, antiretroviral (ARV) drugs for prevention and treatment (prevention of vertical transmission, pre-exposure prophylaxis [PrEP] and post-exposure prophylaxis [PEP]) and harm reduction. The adoption of the combination prevention strategy contributed to key achievements, with a significant reduction in new HIV infections from 123,000 in 2015 to 53,000 in 2018 and 38,000 in 2020 (UNAIDS, 2020). Despite these achievements, new HIV infections are still unacceptably high, even with the inclusion of oral PrEP in the combination HIV prevention strategy.

PrEP is the use of ARV drugs by people who are HIV-negative to prevent HIV acquisition before potential HIV exposure. In 2021 and 2022, the World Health Organization (WHO) provided new HIV prevention guidance that includes additional options for PrEP: the dapivirine vaginal ring (hereafter referred to as the “PrEP ring” or “the ring”) and long-acting injectable PrEP. These provide yet another opportunity to expand the available options for individuals in need of HIV prevention.

The PrEP ring and long-acting injectable cabotegravir (CAB-LA) are offered as additional prevention choices for persons in need of HIV prevention as part of combination HIV prevention package. PrEP ring and CAB-LA can be used discreetly and provide an opportunity to address challenges to effective use of oral PrEP faced by clients.

These Work plan provide a framework for service providers to provide daily and event-driven (ED) oral PrEP, PrEP ring and CAB-LA.

### **Rationale for the Plan**

Uganda adopted oral PrEP in 2017 and has since rolled it out in a phased-funded approach. Since 2017, oral PrEP has been scaled up from six sites in four districts to 351 sites in over 65 districts across the country. By end of June 2022, over 250,000 clients had ever initiated oral PrEP. Despite these achievements, there have been challenges: oral PrEP uptake is at 60% among those eligible, and only 20% of those who initiated oral PrEP continue to take it. A root cause analysis (RCA) attributed these levels of uptake and continuation to the burden of daily pill taking and drug fatigue, poor access to the facilities that offer oral PrEP due to travel and transport challenges, the high mobility of some clients, forgetting to take the drug, fear of being seen taking drugs with packaging similar to that of ARVs used for treatment, lack of food, perceived low risk, lack of information, fear of side effects, poor counseling, negative attitudes of the service providers toward oral PrEP (e.g., thinking that it encourages transactional sex), and knowledge gaps (RCA, 2020). After WHO in 2021 and 2022 recommended including the PrEP ring and CAB-LA as part of HIV combination prevention, Uganda adopted these new

options for PrEP users. This decision necessitated the review and update of Uganda's Technical Guidance on PrEP for Persons in need of HIV prevention.

### **Purpose of the PrEP Action Plan**

The purpose of these Work plan is to provide a framework for service providers to deliver quality PrEP services at all levels of the health system.

### **Objectives of the PrEP Action Plan**

To provide guidance to health service providers on:

1. Mobilize community for Client screening for eligibility, offering appropriate linkage and referrals for PrEP services
2. Initiation and monitoring of clients on PrEP
3. Recording and reporting of PrEP services

### **The Review of the PrEP Action Plan**

The review of these PrEP Work plan was a consultative process spearheaded by the District HIV and AIDS Coordination committee and involving a number of stakeholders. A task force was constituted to review existing studies, policies, strategies, WHO guidance and various reports on PrEP and to develop an initial draft. Meetings to refine the draft were conducted with support implementing partners including WWM and UNASO, health development partners, technical working groups, PrEP service providers, district health teams, civil society organizations and PrEP beneficiaries.

Target Audience for the PrEP Action Plan include policy makers, funding agencies, implementers, advocates, service providers, beneficiaries and any other stakeholders involved in PrEP service delivery.

### **Guiding Principles for the District**

**Access:** Identify individuals with increased need of HIV prevention and ensure access to HIV interventions including PrEP

**Integration:** Integrate PrEP into other HIV prevention programs, including sexual and reproductive health services

**Quality of care:** Provide PrEP within a framework of quality health service provision

Public health and rights-based approach: PrEP can enable and empower individuals to have an informed choice of HIV prevention options, using a public health approach. This approach includes confidentiality, access to non-discriminatory health care, privacy, informed decision making and shared responsibility.

**Choice:** As more PrEP products become available, informed choice is an important factor to consider in client-provider interactions and decision-making, especially because clients who can choose a preferred product are more likely to use it effectively. Providing additional choices for PrEP and supporting clients to select their preferred methods offers the potential to increase uptake and effective use of PrEP.

## **USE OF PrEP**

### **Overview of PrEP**

PrEP is an important biomedical intervention element of the comprehensive Combination HIV Prevention Strategy. PrEP is the use of ARV drugs by HIV-negative individuals to reduce the risk of HIV acquisition. The level of effectiveness provided by PrEP is strongly correlated with effective use, meaning it is important for clients to use PrEP methods as prescribed. Current PrEP methods in use in Uganda do not prevent pregnancy and sexually transmitted infections (STIs) other than HIV.

These Work plan focus on Tenofovir Disoproxil Fumarate (TDF)-based daily and ED oral PrEP, the monthly “PrEP ring” and CAB-LA.

### **Oral Daily PrEP**

Oral daily PrEP taken as a once daily combination pill of TDF + FTC or TDF+ 3TC is effective and safe for preventing HIV acquisition by HIV negative individuals at substantial risk of HIV infection.

Oral daily PrEP is offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention strategy that includes; use of condom, and condom-compatible lubricants, STI screening and management, harm reduction, risk reduction counselling, screening and management of intimate partner violence (IPV) and other gender-based violence (GBV), and effective antiretroviral treatment for partners living with HIV, among others.

### **Event-driven PrEP**

Event-driven PrEP (ED-PrEP), also called on-demand PrEP or 2+1+1, is effective in reducing the likelihood of HIV acquisition during sex for cisgender men, trans and transgender and gender diverse people Assigned Male at Birth (AMAB) who are not using estradiol-based exogenous hormones. ED-PrEP is appropriate for people AMAB who are not using estradiol-based exogenous hormones and who;

- 1) Find it more convenient to have infrequent sex (for example, fewer than two times per week on average)
- 2) Are able to plan for sex at least two hours in advance can delay sex for at least two hours

To start ED-PrEP, a double dose should be taken two to 24 hours before potential sexual exposure. Clients should be encouraged to take the loading dose as close to 24 hours before exposure as possible.

Daily or event-driven PrEP can be safely offered to persons with hepatitis B, so a wait for hepatitis B test results should not delay initiation. If tested for hepatitis B, clients who are negative can be offered hepatitis B vaccination (per national hepatitis Work plan, if available).

### **Additional Guidance for ED-PrEP Use**

Clients AMAB who are not using estradiol-based exogenous hormones may benefit from providers walking through some scenarios to support their effective use of ED-PrEP.

## **Switching between ED-PrEP and Oral Daily PrEP**

Clients AMAB who are not using estradiol-based exogenous hormones may switch between ED-PrEP and daily oral PrEP as their needs for HIV prevention evolve. Clients may decide to switch back and forth between ED-PrEP and daily oral PrEP due to changes in relationship status or sex partner(s), behavioral changes, moving to a new location, or any situation affecting the frequency and predictability of sex, or when a client's preferred PrEP option changes. For clients who are taking ED-PrEP, transitioning to daily oral PrEP may be appropriate if sex becomes more frequent and/or less predictable. There is no limit on the number of times a client can switch between ED-PrEP and daily oral PrEP. To transition from ED-PrEP to daily oral PrEP, a client should continue daily dosing indefinitely after the last exposure. Daily dosing would continue until sex becomes less frequent and more predictable again, or for as long as the client prefers the daily dosing option.

To transition, a client should continue with daily dosing oral PrEP for as long as they are still at substantial risk

## **PrEP Ring**

The PrEP ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination HIV prevention strategy. It is a flexible silicone vaginal ring that slowly releases the antiretroviral drug dapivirine, which is a non-nucleoside reverse transcriptase inhibitor, into the vaginal mucosa over the course of one month. The ring must be in place for at least 24 hours before it is maximally effective. The ring may be offered as an option for people assigned female at birth (AFAB) who wish to prevent HIV acquisition through receptive vaginal sex and are unable or do not want to use other PrEP options, or when other PrEP options are not available. The ring must be inserted correctly into the vagina and worn for one month without removal. The PrEP ring has a shelf life of five years. It should be stored at room temperature away from direct light and out of reach of children. Offering the ring in community settings would increase access to HIV prevention options, especially for those who are not currently accessing PrEP services in clinical settings.

If a client wishes to discontinue use of the ring, they can remove it. Ideally, clients who are discontinuing PrEP use will alert their providers and receive support to use other HIV prevention practices if they are still having ongoing exposure to HIV.

- 1) PrEP Ring Insertion and Removal
- 2) Inserting the PrEP Ring Clients should be given initial information, demonstration and support on ring insertion and removal, and once confident, clients can continue to use the ring on their own.

Some clients are comfortable using the ring on their own with minimal support from their first use. However, for clients who prefer support, a health care provider can help insert the ring or confirm placement. The ring is inserted by hand; there is no need to use a speculum or other tools to insert the ring. Clear visual instructions should be offered with the ring.

## **Ring insertion steps for clients**

1. Get into a position that is comfortable for inserting the ring, such as squatting, lifting one leg, or lying down. If a health care provider is assisting you, you should be in a reclining position.

2. With clean hands, squeeze the ring between the thumb and forefinger, pressing both sides of the ring together so that the ring forms a “figure 8” shape.
3. Use the other hand to open the folds of skin around the vagina.
4. Place the tip of the ring into the vaginal opening and use your fingers to push the folded ring gently up into the vagina.
5. Push the ring as far toward the lower back as possible. If the ring feels uncomfortable, it is probably not inserted far enough into the vagina. Use a finger to push it as far up into the vagina as is comfortable. \*Ring insertion should be painless. If you have any bleeding or discomfort upon insertion, contact your health care provider.

Clients can remove the ring with or without the help of a health service provider. However, for clients who prefer support, a health service provider should help remove the ring. The ring is removed by hand; there is no need to use a speculum or other tools to remove the ring. If a client is being assisted by a health service provider, they should be in a reclining position during removal. Ring removal steps for clients are listed below;

#### **Ring removal steps for clients**

1. Get into a position that is comfortable for removing the ring, such as squatting, lifting one leg, or lying down.
2. With clean hands, insert one finger into the vagina and hook it around the edge of the ring.
3. Gently pull the ring out of the vagina. \*Ring removal should be painless. If you have any bleeding or discomfort upon removal, contact your health care provider.

#### **PrEP ring to Oral PrEP ring to CAB-LA**

1. After removal of the ring, the client should take oral PrEP for at least 7 days before a potential exposure.
2. If the client is to have sex before taking oral PrEP for at least 7 days, they should:
3. Use a condom for at least 7 days after removal of the ring, \* or
4. Take oral PrEP for at least 7 days before removal of the ring.
5. The client should get a CAB-LA injection after removal of the ring and should not have unprotected sex for at least 7 days after the injection.
6. If the client is to have sex within 7 days of removing the ring and receiving a CAB-LA injection, they should:
7. Use a condom for at least 7 days after removal of the ring, \* or
8. Get a CAB-LA injection 7 days before removal of the ring.
9. If a client stops using a condom after the 7 days, they will be at increased likelihood of exposure to STIs and (for clients AFAB) pregnancy.

#### **Contraindications for PrEP Ring Use**

The ring should not be provided to people with:



1. An HIV-positive test result according to the national HIV testing algorithm
2. Known exposure to HIV in the past 72 hours (because such clients may derive more benefit from PEP if the potential for HIV exposure was high)
3. Signs of acute HIV infection (AHI) and potential exposure within the past 14 days
4. Inability to commit to effectively use the ring and attend scheduled follow-up visits
5. Allergy or hypersensitivity to active substance or other substances listed in the product information sheet

### **Long-Acting Injectable PrEP**

Long-acting injectable cabotegravir (CAB-LA) may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches.

Injectable cabotegravir is a long-acting drug which is an integrase inhibitor. It is effective in preventing HIV among people at substantial risk of acquiring HIV. It is administered in the buttock; 600mg month 1 and month 2, and then once every 8 weeks. It is contraindicated in people who are Hypersensitive to any active substances in CAB-LA. CAB-LA could be a good choice for people who value discretion, are familiar and comfortable with needles and/or have difficulty storing or taking oral PrEP.

CAB-LA is an intramuscular injection long-acting form of PrEP with the first two injections administered 4 weeks apart, followed thereafter by an injection every after 8 weeks.

### **Considerations for Provision of PrEP**

#### **Eligibility**

The following are the five eligibility elements for PrEP:

1. Seronegative: Only seronegative clients will be initiated on PrEP.
  2. No suspicion of acute HIV infection: Clients with AHI (“flu-like” symptoms AND recent exposure to HIV) will not be offered PrEP until they are proved to be HIV
  3. At substantial risk of HIV infection. PrEP will be offered to only clients who are deemed to be at substantial risk of HIV infection. They include individuals who:
    - a) Have multiple sexual partners of unknown HIV status
    - b) Engage in transactional sex including sex workers
    - c) Use or abuse drugs, substances and alcohol
    - d) Have had more than one episode of an STI within the last twelve months
    - e) HIV negative partners in a Sero-different relationship if the HIV positive partner is not on ART or when his/her viral load has not been suppressed.
    - f) Recurrent users of PEP
    - g) Individuals who engage in anal sex
    - h) Adolescent girls and Young Women (AGYW) who are at substantial risk of HIV
    - i) Pregnant women and lactating mothers at substantial risk of HIV
    - j) Key populations who are unable and unwilling to achieve consistent use of condoms People actively asking for PrEP.
1. Willingness to use PrEP as prescribed. The Client should show willingness and readiness to start and adhere to PrEP ARVs. X
  2. Free from contraindication for use of their chosen PrEP method.

**NOTE:**

The decision to take PrEP should be made voluntarily by the individual client after receiving information on the risks and benefits of PrEP use.

People who are actively seeking to use PrEP should be comprehensively assessed for eligibility and considered for other prevention services

**Steps for Initiating Clients on PrEP****Step 1: Screen for Substantial risk for HIV.**

Assess the client for need for HIV prevention using the questions below;

Does the client:

- a) Have multiple sexual partners of unknown HIV status?
- b) Engage in transactional sex, including sex work?
- c) Use or abuse/inject drugs and or substances?
- d) Use or abuse alcohol?
- e) Have a history of more than one episode of an STI within the last 12 months?
- f) Has an HIV-positive partner who is not on ART or is on ART but not virally suppressed?
- g) Have recurrent use of PEP?
- h) Engage in anal sex?
- i) Belong to a key population group and say they are unable and/or unwilling to achieve consistent use of condoms?
- j) Ask for PrEP at the visit?

**Step 2: Determine HIV Status of the Client.**

1. HIV testing and counseling should be conducted per national Work plan.
2. In the absence of the recommended national HIV testing, HIV self-testing can be used for follow-up and refills for oral PrEP and the PrEP ring. If the results are positive with HIV self-testing, repeat the HIV test using the National Testing Algorithm.
3. If the HIV status is unknown, conduct HIV testing to confirm status, and:
  - o If HIV positive, refer to a care facility
  - o If HIV negative, proceed with PrEP initiation
4. If the test result is inconclusive, defer PrEP and follow the national algorithm until a definitive HIV test result has been obtained for all clients who are not pregnant or breastfeeding. In the meantime, counsel the client on other HIV prevention options.

If the definitive results from re-testing come back positive, refer the client for ART; if the results are negative, proceed with PrEP initiation.

If the results are inconclusive again, do a DNA PCR test.

For pregnant and breastfeeding people with inconclusive HIV test results, refer to PMTCT Work plan.

For CAB-LA, the HIV test should also follow the national HIV testing algorithm.

### **Step 3: Assess for PEP Indication.**

- 1) Clients exposed to HIV within the past 72 hours: If a client reports an exposure to HIV within the past 72 hours, screen for PEP indication instead of PrEP and provide PEP according to national Work plan. Educate clients on the differences among PEP, PrEP, and ART and offer HIV exposure reduction counselling. After 28 days of PEP, a client may be transitioned from PEP to PrEP without a gap if they are HIV-negative and meet other criteria for PrEP use.

### **Step 4: Assess HIV Status of Sexual Partner.**

If any sexual partner is known to be living with HIV, determine whether they are receiving ART. If the person is receiving ART, determine the duration on ART and whether they have achieved viral load suppression. If the person is not receiving ART, link them to care.

Consider PrEP for a client whose partner is HIV-positive and not on ART, has not been on ART for six months or is not adhering to the ART regimen, or has been on ART for more than six months but has not achieved viral suppression.

### **NOTE:**

A risk assessment of partner(s) is done to ascertain recurrent history of potential exposure to HIV according to the list of considerations in Step 1 above (unprotected sex with someone who is HIV positive or of unknown HIV status, experience of coercive sex, recurrent use of PEP, etc.)

### **Step 5. Assess for Contraindications to PrEP**

#### **Oral PrEP (TDF/FTC or TDF/3TC)**

**Oral PrEP should NOT be provided to people with:**

1. An HIV-positive test result according to the national HIV testing algorithm
2. Potential exposure to HIV in the past 72 hours (these clients should be offered PEP)
3. Signs of acute HIV infection (AHI) (see Box 3) AND potential exposure to HIV within the past 14 days
4. Unwillingness or inability to commit to effectively using oral PrEP
5. Allergy or hypersensitivity to an active substance or other substances listed in the product information sheet
6. Known kidney function impairment, indicated by an estimated glomerular filtration rate (eGFR) of under 60 mL/min per 1.73m<sup>2</sup> or a creatinine clearance of less than 60 mL/min. Kidney function assessment is necessary for people using TDF-based oral PrEP; however, the absence of kidney function test should not delay initiation of PrEP.

#### **PrEP Ring**

The ring should not be provided to people with:

1. An HIV-positive test result according to the national HIV testing algorithm
2. Known exposure to HIV in the past 72 hours (because such clients may derive more benefit from PEP if the potential for HIV exposure was high)

3. Signs of AHI (see Box 3) and potential exposure within the past 14 days
4. Unwillingness or inability to commit to effectively using PrEP ring
5. Allergy or hypersensitivity to an active substance or other substances listed in the product information sheet 2.7.7.3 Long-acting Injectable Cabotegravir CAB-LA should not be provided to people with:
6. Allergy or hypersensitivity to an active substance or other substances listed in the product information sheet
7. Hepatotoxicity and/or hepatitis B
8. An HIV-positive test result according to the national HIV testing algorithm
9. Potential exposure to HIV in the past 72 hours (these clients should be offered PEP)
10. Signs of AHI (Box 3) AND potential exposure within the past 14 days
11. Some co-administered anticonvulsants or anti-mycobacterials
12. Unwillingness or inability to commit to effectively using CAB PrEP
13. Allergic or hypersensitivity reaction(s) with previous use of CAB or other integrase inhibitor medications 2.8 Preparation for Initiation of PrEP

For most clients, PrEP can be initiated the same day. However, in some scenarios, as outlined below, deferred PrEP initiation is recommended. Clients must meet five criteria to begin PrEP use. They must be:

- Seronegative
- Having no suspicion of acute HIV infection:
- At substantial risk of HIV infection.
- Willing to use PrEP as prescribed.
- Free from contraindication for use of their chosen PrEP method.

## **Counseling**

Education and counseling for clients considering PrEP, or clients already on PrEP, are important to ensure clients can make informed choices and effectively use PrEP. PrEP counseling should be based on the following right to health-based principles:

- Be client-driven and person-centered, based on their needs, resources and preferences
- Be based on a foundation of respect and include an open, honest relationship between provider and client
- Recognize that behavior change can take time
- Validate and normalize client concerns and seek to affirm and encourage client efforts and not be prescriptive or judgmental
- Focus on the identification of small wins and achievable next steps in reducing potential exposures and/or making effective use easier
- Include contingency planning when common barriers are encountered
- Promote choice among available options based on user preferences and acceptability

## **Topics for Initial PrEP Counseling**

1. Sexual behaviors
2. Alcohol and drug use

3. Plan for preventing HIV and other STIs
4. Mental health
5. Prevention needs and interest in and willingness to take PrEP
6. Experience of gender-based violence, including intimate partner violence
  - a. Provide appropriate GBV and IPV response, including first-line support and referral where necessary, and support clients to identify ways to effectively use and continue PrEP. (Clients experiencing GBV, including IPV, should not be prohibited from receiving PrEP if they can effectively use it.)
  - b. Contraceptive needs
  - c. Key messages on PrEP, PEP, and specific PrEP methods, including starting, stopping and effective use of chosen method During counselling, ascertain that the client:
    - d. Is motivated to follow PrEP as prescribed
    - e. Is willing and able to adhere to PrEP dosing
    - f. Is willing and able to attend PrEP monitoring visits, including HIV counseling and testing, adherence counseling, clinical review and adverse events monitoring
    - g. Understands that the protection provided by PrEP is not complete and that PrEP must be used as part of a package of HIV prevention services (inclusive of condoms, SMC, risk reduction counseling and STI management)
    - h. Understands that PrEP is safe and effective in pregnancy and during breastfeeding
    - i. Does not have misconceptions about PrEP — identify and discuss any myths or misconceptions that may be held by the client

**NOTE:**

For clients opting to use the PrEP ring, counsel them on cervical cancer screening. Offer screening to those who accept. If they don't accept, go ahead and offer the PrEP ring.

**Key messages**

- Review results from baseline investigations and confirm that the creatinine clearance is <60mls/min.
- Commence hepatitis B vaccination if the Hep B surface antibody test is negative and if the vaccine is available.
- Provide STI treatment if needed.
- Counsel and educate the client about potential PrEP side effects and their management.
- Educate the client about the signs and symptoms of AHI and the need to return for urgent HIV testing in case of manifestation of these signs and symptoms.
- Ascertain and address barriers to adherence.

| <b>Myths and misconceptions</b>                                  | <b>How to address</b>   |
|--|---|
| You can develop resistance to ART drugs because of PrEP.         | You cannot develop resistance when you are HIV negative.  |
| If I start PrEP, I will have to take it for the rest of my life. | You can start PrEP and stop PrEP, depending on your level of risk, through discussions with your health service provider. |
| My friend is HIV-positive and takes                              | Wrong! All HIV medicines are not the same, and one has to use the right   |

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| antiretrovirals. I can take his medicines and it's the same, right? | ones for PrEP. You should consult with your health service providers to learn more about all the factors that taking PrEP entails. Additionally, you should never share drugs with anyone.  |
| Oral PrEP causes dangerous side effects.                            | The most common side effects of oral PrEP are stomach upset and loss of appetite, but these side effects usually go away within the first month. About one in 200 people using PrEP experiences kidney problems. That is why you will need to make sure you see your health service provider and have your blood screened every six months if needed. |
| PrEP promotes unsafe sex.   | NO, it doesn't! However, PrEP does not protect against other STIs and pregnancy, so it should be used in combination with other prevention methods.   |
| Can PrEP be used by LGBTQI individuals?                             | Yes. Using PrEP will reduce their chances of acquiring HIV.   |
| Can I use PrEP when I am on injectable or oral contraceptives?      | injectable or oral contraceptives?  |
| A PrEP ring can disappear into the uterus or the abdomen.           | No. The entrance to the uterus (cervix) is always closed, blocking entrance of the ring during intercourse.   |
| The ring protects me against unwanted pregnancy.                    | No, the PrEP ring doesn't protect you from unwanted pregnancies.  |
| CAB-LA injection protects me from unwanted pregnancies.             | No, CAB-LA injection does not protect you from unwanted pregnancies.  |

### Initiation of PrEP

1. Provide PrEP counseling and help client decide on their chosen PrEP method.
2. Provide risk-reduction and PrEP medication adherence counseling, as well as condoms.
3. Initiate and agree on a medication adherence plan.
4. Prescribe the chosen method:

### Initiating Oral PrEP

A once daily pill of TDF (300mg) and FTC (200mg)

Preferred A once daily pill of TDF (300mg) and 3TC (200mg) Alternative

1. Initially, provide a one-month TDF/FTC or TDF/3TC prescription (one tablet orally, daily) together with a one-month follow-up date.
2. For people AMAB not using estradiol based exogenous hormones who wish to use EDPrEP, still prescribe enough oral PrEP for daily use should they need to use it. This means initially, provide a one-month TDF/FTC or TDF/3TC prescription together with a one-month follow-up date
3. Counsel the client on the side effects of TDF/FTC or TDF/3TC. 2.9.2 Initiating PrEP ring
4. Provide instructions and/or demonstration of how to insert the ring
5. Counsel on potential side effects of the PrEP ring.
6. Initially, provide a one-month PrEP ring prescription together with a one-month follow-up date.

## **Initiating CAB-LA**

7. Provide initiation injection 1.
8. Counsel on potential side effects of CAB-LA.
9. Schedule next appointment in four weeks for initiation injection

### **NOTE:**

In the event that an individual has an incidental exposure to HIV infection before initiation of PrEP, they should be given PEP per the PEP Work plan. However, individuals who have recurrent PEP use (three or more yearly) should be prepared for and initiated on PrEP.

## **How Long It Takes for PrEP to be Effective**

1. Oral PrEP: seven days
2. Event-driven PrEP: two hours for AMAB
3. Injectable PrEP: seven days
4. PrEP ring: 24 hours

Clients should be counseled on using another HIV prevention strategy (such as condoms) between when they start PrEP and when it is expected to become fully effective.

## **Minimum Package of Services to Be Offered with PrEP**

The following minimum package of services must be provided to clients receiving PrEP in accordance with the national Work plan.

1. HIV testing services (HTS)
2. Linkage to ART services for those diagnosed with HIV; the offer of PEP and complete PEP standard of care for those with an exposure to HIV within 72 hours.
3. Syndromic STI management
4. Condoms and lubricants
5. Pregnancy screening
6. Contraception
7. TB screening
8. GBV/IPV
9. Counseling

## **PrEP Follow-up Visits**

Once on PrEP, clients should return after one month for assessment and confirmation of HIV negative test status, assessment for early side effects, and discussion of any difficulties with effective use and any other client concerns.

After the initial visit, the subsequent clinic visit should be after one month, two months, and then every three months thereafter for oral PrEP and the PrEP ring. For CAB-LA, subsequent follow-up should be after four weeks, and then every eight weeks. Some ring users may prefer to return used rings to the health service provider/service provision point. If clients choose to return used rings, those rings should be disposed of along with other medical waste, such as used gloves, in accordance with the National Infection Prevention and Control (IPC) Work plan. Needles and syringes that have been used for CAB-LA injections should also be disposed of in accordance with the IPC Work plan.

## **Essential Components of PrEP Follow-up Visits**

### **Component 1: HIV Testing and Counseling**

HIV testing and counseling should be conducted per national Work plan one month after a client starts oral PrEP or the PrEP ring and every three months thereafter. For CAB-LA, HIV testing should be conducted per national Work plan four weeks after a client's first injection and every eight weeks thereafter. This testing is conducted to inform decisions on whether to continue or discontinue PrEP.

### **Component 2: Counseling**

1. Review the patient's understanding of PrEP, tolerance to the medication and any barriers to adherence, as well as any side effects.
2. Review the patient's risk exposure profile and perform risk reduction counseling.
3. Evaluate and support PrEP adherence at each clinic visit.
4. Evaluate the patient for any symptoms of STIs at every visit and treat as needed.
5. Evaluate creatinine clearance six months after initiation, and then annually if clinically indicated.

### **Component 3: PrEP Prescription Refill**

At follow-up visits, clients should be provided with enough PrEP to avoid having to return to pick up a resupply each month. Clients who have some medication supply in reserve tend to show better effective use. This should be discussed with clients on a case-by-case basis because some clients may prefer to return to the clinic more frequently and not have to worry about discreetly storing their PrEP.

In some situations, and based on client needs and preferences, it may be appropriate to separate clinical follow-up visits from PrEP refills. For clients who may use ED-PrEP, a full refill may not be needed at each follow-up visit. At each visit, ask these clients how many full bottles of oral PrEP they have at home and provide enough bottles so that they can use oral PrEP daily should they need to.

Generally, this would mean prescribing them three minus the number of bottles the client has at home. For oral PrEP and the PrEP ring, schedule the client's next visit at least a week before their pill supply will run out based on daily use or at least a week before the client should change the last ring they have been given, at least every three months. When possible, follow-up visits should be coordinated with visits for other services to reduce the number of times a client must return to receive services. For CAB-LA, it is important that the client return on the scheduled visit date for their injection. If they cannot make it to the clinic on the scheduled date, they should go to the clinic +/- 7 days from the due date.

### **Risk-reduction Counselling**

Risk-reduction counseling is a behavioral intervention that attempts to decrease an individual's chances of acquiring HIV and other STIs. It should be implemented together with adherence counseling at all follow-up visits for clients using PrEP. Risk-reduction counseling can be provided by any trained health service provider and should address the 5 As:

1. **Assess:** Explore the context of the user's specific sexual practices. Health service providers should also be aware that clients may not always perceive their own risk or may be in denial about it. Assess which of the client's behaviors are associated with higher likelihood of HIV exposure.



2. Advise: Reflect on the client's main concerns, identify their sexual health protection needs and advise accordingly. Strategize with the client on how to manage these concerns and needs.
3. Agree on which strategies the client is willing to explore.
4. Assist: Assist and guide the client on how to implement the strategies.
5. Arrange for follow-up visits.

## **Adherence Support**

### **Oral PrEP (including daily and ED PrEP)**

Adherence to daily or ED-PrEP regimens is important in order to maintain the efficacy of this intervention. Adherence counseling and pill counting should be implemented at each clinic visit. Critically evaluate the client for possible barriers to adherence and support them client to overcome them. Discuss possible adherence reminders, such as using cell phone reminders and pill boxes, linking pill taking with a daily routine activity and having a PrEP adherence buddy.

### **PrEP Ring**

The ring must be in place for at least 24 hours before it is maximally effective. If a client wishes to discontinue the use of the ring, they can remove it. If the ring comes out within the 28-day period, it can be re-inserted after it is washed with clean water. However, if the ring falls in a dirty place, it should not be re-inserted. The client should insert another ring if available or return to the health service provider. If removed and re-inserted, the ring must be in place for at least 24 hours to reach maximum protection.

## **Community Engagement for PrEP**

### **Roles of community-based organizations:**

1. Advocacy to create awareness and demand for PrEP.
2. Providing information about PrEP, its availability and where to access it
3. Mobilizing people at substantial risk of acquiring HIV for PrEP uptake
4. Identifying how PrEP should be integrated within the existing community sexual and reproductive health services
5. Identifying and linking clients to community distribution points for PrEP
6. Distributing condoms and other HIV prevention commodities to people at substantial risk of acquiring HIV, including sex workers who should be empowered to insist on their use
7. Encouraging adherence to PrEP
8. Follow-up of clients on PrEP

### **Unscheduled PrEP Visits**

1. Determine if the reason for the visit is PrEP-related, e.g., adverse drug reactions.
2. Assess and manage the reason for the unscheduled visit according to national Work plan.
3. Provide counseling on HIV exposure reduction and effective use of PrEP.
4. Agree on a follow-up schedule.

## **Discontinuation of PrEP**

1. PrEP should be discontinued under the following circumstances:
2. Acquisition of HIV
3. Changed life situations resulting in lowered risk of HIV acquisition
4. Intolerable toxicities and side effects
5. Chronic non-adherence to the prescribed dosing regimen for PrEP
6. Personal choice
7. HIV-negative person in a stable HIV Sero different relationship when the positive partner has sustained viral load suppression. They should however continue using condoms correctly and consistently
8. Started use of contraindicated medications
9. Decision to switch to another HIV prevention strategy
10. Safety concerns, such as estimated creatinine clearance of  $<60$  mL/min or an eGFR of  $<60$  mL/min per  $1.73\text{m}^2$  (if known) for clients using oral PrEP (appropriate clients should also be counseled on using the PrEP ring, if applicable) or confirmed hepatotoxicity for clients using CAB-LA

## **Guidance on Discontinuation of PrEP**

1. Assess the client for reasons for discontinuation of PrEP. If a client is at low risk and they choose to discontinue, they should continue PrEP before stopping according to the guidance for each PrEP option. If the risk is still high, counsel, educate and advise the client to continue PrEP per the guidance for each PrEP option and offer other HIV prevention options.
2. Perform an HIV test according to the national HIV testing algorithm.
3. If a client tests HIV positive, ensure linkage to care and treatment. If the test is negative, establish linkage to risk reduction support services.
4. Clients with hepatitis B who are stopping oral PrEP should be referred to relevant management/treatment services because stopping oral PrEP may have implications for the management of hepatitis B infection.

## **Discontinuation of Daily Oral PrEP**

1. Assess the client for reasons for discontinuation of PrEP.
2. If a client is at low risk, and they choose to discontinue, they should continue PrEP for at least seven days after last HIV exposure before stopping.
3. If a client is non-adherent or still has a likelihood of exposure to HIV, counsel them on other prevention options.
4. Perform an HIV test according to the national HIV testing algorithm.
5. For clients with chronic hepatitis B who stop TDF-based oral PrEP, regular monitoring to detect relapse and management of hepatitis B are important. Clients taking TDF for treatment of hepatitis B who wish to stop oral PrEP can be switched to a TDF-only regimen.

## **Discontinuation of Event-driven PrEP**

Clients discontinuing ED PrEP should take PrEP for two days after the last sexual encounter. Perform the HIV test according to the National Testing Algorithm.

### **Discontinuation of PrEP ring**

If a client wishes to discontinue use of the ring, they can remove it. The ring can be reinserted after removal until the 28-day period has expired; however, levels of dapivirine in the vagina drop quickly after ring removal, and therefore removal is not recommended during the 28-day period. Because of the quick drop in levels of dapivirine in the vagina after ring removal, the need for other HIV prevention measures should be reinforced after removal if potential exposure to HIV continues.

If removed and reinserted, the ring must be in place for at least 24 hours to reach maximum protection. It is not known how long the ring must remain in place after a potential exposure to be maximally effective. Ideally, clients who are discontinuing PrEP use should be encouraged to discuss discontinuation and be supported by providers to use other HIV prevention practices, if needed.

### **Discontinuation of Long-acting CAB-LA**

1. Continuation of oral PrEP after discontinuation of CAB-LA will depend on the reason for stopping and the risk of HIV exposure after stopping CAB-LA. If the reason for stopping is reduced/no risk, then there is no need for continuity with oral PrEP.
2. If there is re-emergence of risk or ongoing risk or intolerance, continue with oral PrEP or another prevention option. If a client tests HIV positive, ensure linkage to care and treatment. If a client is HIV negative, establish linkage to risk-reduction support services.

If a client decides to stop using CAB-LA, they may stop receiving injections. The amount of cabotegravir in the blood remains at effective levels for at least eight weeks after the final injection. The time after the last CAB-LA injection when cabotegravir remains in the body but at levels that may not prevent HIV is known as the “tail period.” The “tail period” can last for up to a year, but this time frame varies for people based on sex assigned at birth.<sup>1</sup> Data on HIV acquisition during the tail period are limited. For those who do acquire HIV during this time, delayed diagnosis of HIV may be possible and could result in HIV drug resistance, meaning that medicines used to treat HIV may be less effective or not work at all. As with all PrEP methods, if a client discontinues CAB-LA, they should use another PrEP method or HIV prevention strategy during the tail period if exposure to HIV is possible.

If a client has a potential exposure to HIV during the tail period while not using an HIV prevention strategy, they should speak to a health care provider as soon as possible because PEP may be appropriate and ideally should be started as soon as possible within 72 hours of potential exposure.

#### **NOTE:**

On discontinuing PrEP, document the following in the PrEP register:

1. Reasons for PrEP discontinuation
2. Recent medication adherence
3. Reported sexual behavior in past three months
4. Duration on PrEP
5. Date of start and discontinuation, as well as any gaps in treatment
6. Advise the client to return for an HIV test one month after discontinuation.

## **Management of Side Effects and Adverse Drug Reactions**

Side effects should be managed symptomatically, and counseling should be offered. Any side effects should be recorded in client records regardless of severity (refer to Table 6). In some cases, side effects may cause a client to discontinue PrEP use. If PrEP is discontinued, record the outcome in the PrEP register. Side effects and potential adverse drug reactions for each method are found in the overviews of each method above.

## **Pregnancy and Breastfeeding**

Given the increased likelihood of HIV acquisition during pregnancy and the postnatal period, as well as reassuring safety data, oral PrEP use is a reasonable option for people who are pregnant or breastfeeding. There is no safety-related rationale for disallowing or discontinuing oral PrEP use during pregnancy and breastfeeding.

Data are limited on the use of CAB-LA during pregnancy and breastfeeding. Dolutegravir, a medication in the same drug class as cabotegravir, was found safe to use during pregnancy, and the very limited data available from a small number of women who became pregnant in clinical trials suggest CAB-LA may be safe during pregnancy and breastfeeding. There are no data on whether cabotegravir is present in human milk, impacts human milk production, or affects breastfeeding infants among clients using CAB-LA.

Due to the potential for adverse reactions and residual concentrations of cabotegravir in systemic circulation for 12 months or longer after CAB-LA injections are discontinued, clients who are or may become pregnant or are breastfeeding, especially during the tail period, should be counseled on the risks and benefits of using CAB-LA. Research is ongoing.

## **Community service delivery models for PrEP**

The community service delivery model will entail three approaches: through peers, drop-in centers (DIC) and the PrEP Hub system.

The peer-led approach: The peer educators will mobilize clients for PrEP services in their hotspots. Through targeted outreach, the trained health workers will educate and screen clients for PrEP and initiate clients on PrEP. PrEP refills can be provided by peers where necessary, except for CAB-LA refills.

Community drop-in centers approach: The DIC team (coordinator/staff/peers) will mobilize clients on the DIC's scheduled PrEP days. A trained health worker from a supervising health facility or a co-located clinic will provide PrEP services (health education and PrEP screening, initiation and refill) for the clients at the DIC. These outreach services should be integrated with other RH services for PrEP clients.

The community PrEP Hub system approach/Community Drug Distribution point (CDDP): The health facility will prepare and pack the required medicines, commodities and supplies for PrEP refills for the different communities. A health worker will make a list of expected refills, schedule days to visit communities and communicate that schedule to the focal resource of each community (e.g., VHT, peers) who will organize the clients. Clients will be offered PrEP refills, risk reduction counseling, HIV testing, and STI treatment and management at a specified time in a scheduled period. The health worker will

proceed to each community as planned to offer PrEP services. These outreach services should be integrated with other reproductive health services for the PrEP clients.

## YOUNG PEOPLE'S PrEP ACTION PLAN

| Particulars                                     | Issue/Recommendation   | Action taken  | Responsible person       | Budget<br>"000" |
|---|--|---|--------------------------|-----------------|
| Accessibility of PrEP to the community?         | Build the capacity of the communities to demand and utilize the PrEP services in the community | <ul style="list-style-type: none"> <li>Promote awareness about PrEP targeting all categories of the communities at risk</li> <li>Communication of information should be uniform and not contradictory</li> <li>Communicate consistently about PrEP including its side effects in order to promote uptake.                             <ul style="list-style-type: none"> <li>Through radios</li> <li>Schools</li> <li>Community meetings</li> <li>Social media</li> </ul> </li> </ul> | DHO/FP/CAO<br>/Partners  | 20,000          |
| School messages to learners (talking compounds) | Review and improve the IEC Material especially for Schools                                     | Integrate and update HIV and PrEP IEC materials in school community   | DEO/DFP/DHO/<br>Partners | 5,000           |
| Access to PrEP                                  | Strengthening Referral mechanism for PrEP services   | a) Refer people at risk to access PrEP services in government health facilities.<br>b) Awareness creation on free of charge of services in all government health facilities.<br>c) Profile and rationalize other PrEP service points or organizations providing similar services in order to improve referrals.   | DHO/DFP/Partners         | 10,000          |
| Engaging the local leaders in promotion         | Community Awareness creation   | To support in delivering messages to most at risk   | DFP/DHO                  | 15,000          |

|  |  |   |                |        |
|--|--|---|----------------|--------|
| of PrEP uptake   |  | community members   |                |        |
|  | Meaningful involvement of Young persons in the Demand and accessibility of PrEP services                         | Engage young people into Peer – to – peer model in PrEP service delivery in order to eliminate stigma and discrimination. | DHO/DFP/BAYLOR | 20,000 |
|  | Young people accessibility of PrEP services  | Provide conducive and safe environment for young people to access PrEP services at facilities.                            | DHO/DFP/BAYLOR | 2,000  |
| Identify and build a mass of PrEP champions amongst young people | Build the capacity of young people in PrEP services  | Train young peers to support the peers demand and access HIV and AIDS services  | DHO/DFP/BAYLOR | 25,000 |
| Monitoring and evaluation  | Support supervision of PrEP services in the District   | Monitor and support supervise PrEP services at different services points  | DHO/DFP/BAYLOR | 9,000  |
| Identification the hotspots                                      | Hotspot mapping  | Involve the peers in hotspot mapping  | DHO/DFP/BAYLOR | 10,000 |
| Target young people in colleges and universities                 | Identify and build capacity for University peers to support fellow peers in demand and accessibility of services | Training of peers   | DHO/DFP/BAYLOR | 30,000 |
| Orientation of senior women and men teachers                     | Identify the senior women and men teachers   | Training of the senior women and men teachers on PrEP   | DHO/DFP/BAYLOR | 35,000 |
| Engage the VHTs to support the young                             | Identify the VHT who can support the young people  | Train the VHTs on PrEP to support Young people  | DHO/DFP/BAYLOR | 20,000 |

|   |   |   |                |        |
|---|---|---|----------------|--------|
| people to access PrEP services                          | to demand and access PrEP services                                    |   |                |        |
| HIV and AIDS School Clubs                               | Re-Introduce the HIV and AIDS Youth Clubs in School                   | Build capacity of School clubs on PrEP                    | DHO/DFP/BAYLOR | 15,000 |
| Shiyiri Intsu Yamasaba Cultural Institution             | Engage the Inzu Ya Masaaba cultural institution to popularize Shyirir | Train the young people on PrEP                            | DHO/DFP/BAYLOR | 30,000 |
| Engage the young political leaders with in the District | Identify role model young people                                      | Build their capacity on PrEP                              | DHO/DFP/BAYLOR | 30,000 |
| Target DICs for PrEP services.                          | Identify the DICs which can provide the PrEP services                 | Involve the peers at DIC in the service delivery          | DHO/DFP/BAYLOR | 5,000  |
| Involve the Expert clients in PrEP service delivery     | Identify the young people using PrEP                                  | Peers support the fellow peers to access and use PrEP     | DHO/DFP/BAYLOR | 8,000  |
| Use of Technology and application on social media       | Identify the experts who can support access the platforms             | Design and upload messages for the young people on PrEP   | DHO/DFP/BAYLOR | 10,000 |
| DHAC to monitor the implementation of PrEP services     | Monitoring and evolution of PrEP services                             | Support supervision of HIV and AIDS implementing partners | DHO/DFP/BAYLOR | 15,000 |
| Target Recreation services for delivering PrEP services | Identify and target youth sports activities to popularize PrEP        | Programme to deliver PrEP services at youth sports events | DHO/DFP/BAYLOR | 20,000 |
| Economic empowerment of                                 | Identify the young people who have capacity to                        | Train the young people in business enterprises            | DHO/DFP/BAYLOR | 40,000 |



|                                      |  |   |                |                |
|--------------------------------------|--|---|----------------|----------------|
| young people                         | participate in Economic activities.                              |   |                |                |
| Meaningful engagement of the parents | Identify Parent champions on PrEP                                | Train the parent champions on PrEP                    | DHO/DFP/BAYLOR | 10,000         |
| Enginemen of the religious Leaders   | Identify the religious leaders and involve them in PrEP services | Identify and train religious ladders on PrEP services | DHO/DFP/BAYLOR | 20,000         |
| Budget Line by the                   | Activate the AIDS structures                                     | Deliberate allocation of 0.1%                         | DHO/DFP/BAYLOR | 10,000         |
| <b>Total</b>                         |  |   |                | <b>414,000</b> |