



Republic of Zambia  
Ministry of Health

# HIV Pre & Post- Exposure Prophylaxis Guidelines



December 2023



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## List of Acronyms

3TC	Lamivudine
AAPF	ARV Active Pharmacovigilance Form
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AFAB	Assigned Female At Birth
AIDS	Acquired Immuno-Deficiency Syndrome
ALT	Alanine Transaminase
ARV	Antiretroviral
CAB	Cabotegravir
CBV	Community-Based Volunteer
DTG	Dolutegravir
ED	Event-driven [PrEP]
FTC	Emtricitabine
GBV	Gender-Based Violence
HCD	Human-Centered Design
HCP	Healthcare Provider
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Test
HTS	HIV Testing Services
IPV	Intimate Partner Violence
ISR	Injection Site Reaction
LA	Long-acting [injectable]
M&E	Monitoring and Evaluation
MNCH	Maternal, New Born and Child Health
OPD	Out-Patient Department
PEP	Post Exposure Prophylaxis
PR	Public Relations
PrEP	Pre-Exposure Prophylaxis
SBC	Social and Behaviour Change
SCMS	Supply Chain Management System
STI	Sexually Transmitted Infection
TAF	Tenofovir alafenamide
TDF	Tenofovir Disoproxil Fumarate
TWG	Technical Working Group
VMMC	Voluntary Medical Male Circumcision
YFS	Youth-Friendly Spaces
ZEA	Zambia Ending AIDS



## Acknowledgements



The "2023 Post-Exposure Prophylaxis and Pre-Exposure Prophylaxis Implementation Guidelines" is a collaborative effort led by the MoH Directorate of Public Health and Research. It incorporates expertise from health facilities, NGOs, and CBOs, and funding from international partners and donors. This document aims to provide Ministry of Health guidance on the implementation of PEP and PrEP to prevent HIV transmission and improve overall health outcomes. This comprehensive approach reflects the commitment of all involved in combating HIV and enhancing public health. The Ministry of Health would like to extend its appreciation and thanks in particular to the following organizations:

National HIV/AIDS/STI/TB Council (NAC)

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR)

Centre for Infectious Disease Research in Zambia (CIDRZ)

Centers for Disease Control and Prevention (CDC)

Clinton Health Access Initiative (CHAI)

Family Health International (FHI 360) - Maximizing Options to Advance Informed Choices for HIV Prevention (MOSAIC)

United States Agency for International Development (USAID)

USAID Action to Epidemic Control of HIV (USAID ACTION-HIV)

University of Maryland (UMB)

World Health Organization (WHO)

*Special thanks to the editorial committee:*

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**USAID-Zambia Accessible Markets for Health (ZAM Health) Project**

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## Guiding Principles

It is important to adopt an evidence-based public health, human rights, and people- and community-centred approach when offering Pre-Exposure Prophylaxis (PrEP) for HIV prevention. Such an approach is aligned with principles of universal health coverage, gender equity and health-related rights, including accessibility, availability, acceptability, and quality of combination HIV prevention services for people who could benefit from PrEP.

1. Evidence-based public health, human rights, and people- and community-centred approach will guide the prevention of both oral and injectable Pre-Exposure Prophylaxis
2. Integration: We are recommending the integration of PREP service delivery into various primary care service delivery points such as OPD, STI clinic, antenatal clinic, TB clinics, VMMC and men's clinics
3. Combination HIV prevention: In this guideline, we are prioritizing the provision of combination HIV prevention as opposed to PREP alone
4. Precision based delivery: We will scale up provision of PREP in areas with new HIV infections
5. Inclusiveness: An inclusive and people-centered approach that recognizes different prevention options that individuals may choose at different stages of their lives
6. Community led program leadership, service delivery and monitoring: Communities such as key and priority populations lead, deliver and monitor HIV prevention services to improve acceptance and retention in HIV prevention, care and treatment services
7. Most vulnerable populations responsive approach: A key population and vulnerable populations responsive approach that caters for MSM, FSW, PWIDS, prisoners, transgender, adolescent girls and young women (AGYW) and adolescent boys and young men (ABYM) is one of the guiding principles of this guideline. This recognizes the different needs of key and vulnerable populations in accessing HIV information and SRHR related services
8. Multi-sectoral approach: A multisectoral approach and partnership that builds on HIV being the responsibility of all sectors and constituencies

As an additional biomedical HIV prevention option, PrEP should not displace other effective and well-established HIV prevention interventions such as comprehensive condom programming and harm reduction for people who use drugs, but rather should be integrated into existing health services. Many people who would benefit from PrEP belong to key populations who often face greater legal, financial, and social barriers to accessing health services overall.

Placing the people and communities who could benefit from PrEP at the centre of programme planning allows services to be adapted to their preferences and sexual and reproductive health needs while maximizing impact and health system efficiency.

**The decision to use PrEP should always be made by the individual, ensuring they have complete, correct information and provision of choice based on National guidelines.**



## Chapter 1: Communication and Social Mobilization

### 1.1. Pre-Exposure Prophylaxis (PrEP) Re-Positioning

HIV prevention methods for HIV-negative people are available in Zambia, which are safe, effective, and easy to use to maintain one's HIV-negative status. The target audience should:

- **Know:** that there are multiple ways to prevent HIV with various forms of PrEP to suit the needs and preferences of different people that are at substantial risk of contracting HIV
- **Think:** that they are in control of protecting themselves in a way that is safe, empowering, and discreet
- **Do:** Go to a designated service delivery point of their choice to be assessed for eligibility, and once on PrEP, adhere to the medical guidelines for as long as they are at risk of contracting HIV

For PrEP to have a sustainable health impact, relevant attitudes, knowledge, social norms, and beliefs must be shaped at individual, community, and policy levels. People must understand the benefits of PrEP and believe these outweigh any possible negatives. In addition, they must have relevant practical and emotional reasons to use PrEP products consistently and correctly.

### 1.2. 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. Choice is critical for all populations – providing additional choices for PrEP and supporting clients to select their preferred methods offers the potential to increase uptake and adherence.

Zambia has been implementing oral PrEP since 2018 therefore, the introduction of new products, such as long acting injectables should strengthen the existing programme and use the learnings to develop an effective strategy for layering new products. Key messages on choice include:

- Multiple HIV prevention methods are necessary to meet the needs of clients that are at substantial risk of HIV infection
- The choice of prevention method or combination prevention should be appropriate and meet the needs and preferences of the client to ensure adherence to the method
- The client can change their choice of HIV prevention method if their earlier choice is no longer convenient or appropriate for their lifestyle
- The client should understand the method and mode of use for effectiveness

### 1.3. Advocacy, Communication and Social Mobilisation Approaches

Please refer to the Zambia Ending Campaign Implementation Handbook and Injectable PrEP SBC toolkit for detailed guidance on advocacy, communication and social mobilisation approaches to support PrEP uptake. It outlines key strategies that will be utilized to target communities in creating awareness and acceptability for the uptake and continued use of PEP and PrEP.



Outlined communication approaches will support providers' knowledge, client risk perception, and motivation to seek PEP and PrEP services as well as challenge myths, misconceptions, and negative gender norms. Though suggested audiences and messages are listed, organisations can focus on other at-risk audiences and craft messages and behavioural approaches. Messages, tactics, and social mobilisation approaches must be appropriate for the audience.

### 1.3.1. Key Counseling Considerations

#### Introduction

The purpose of this section is to outline counseling strategies. Counseling, which is a critical element of combination HIV prevention, is an integral part of PrEP service provision. Hence, PrEP is both a biomedical and bio-behavioural intervention. Counseling can include important information on PrEP use, coping with side effects and adherence, sexual health, relationship issues, drug and alcohol matters, and screening and support for gender-based violence. Since adherence is a critical predictor of the effectiveness of PrEP, counseling is an important opportunity to offer key messages around adherence to PrEP users.<sup>1</sup>

Counseling may be provided by nursing staff or trained counsellors. In some settings, peer educators – who come from the same community as people receiving PrEP services – will be employed to provide counseling and support. Training, ongoing support, mentorship and refresher training will need to be planned and provided to the people offering counseling services to PrEP clients.

### 1.3.2. PrEP Counseling Guiding Principles

Counseling should follow PrEP Counseling Guiding Principles:

- **Be sensitive, inclusive, and non-judgmental:** *Recognize that behaviour change is difficult and human beings are not perfect*
- **Be presented as a personal choice:** *Counseling should support the client in making a personal choice based on their needs and desires*
- **Problem-solve and foster motivation:** *Offer choices and tangible solutions; identify small wins and achievable next steps in reducing risk*
- **Be client-driven and based on their needs, resources, and preferences:** *counseling should be interactive and tailored to the client's counseling needs and lifestyle*
- **Be brief:** *10–15-minute check-ins about the experience with PrEP and sexual health protection plans are most effective; longer (~30 minutes) sessions may be necessary at the first PrEP consultation or specific issues*
- *Be fact-based or evidence/data-backed*

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<sup>1</sup> WHO. 2017. Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 8: Site planning. Geneva: World Health Organization.



Table 1: PrEP Counseling Checklist

√	What to discuss	How to discuss it
	<b>Assess client risk profile.</b>	Develop a clear picture of the client's risk profile and lifestyle; ensure they understand how their lifestyle impacts their risk profile.
	<b>Combination prevention choices</b>	PrEP is an additional prevention option. It should be used in combination with other prevention tools, like condoms, PEP, healthy lifestyles, partner reduction, treatment for STIs, Voluntary medical male circumcision, and ART for partners living with HIV. <b>REMEMBER: counseling should highlight that, ideally, PrEP should be used with condoms</b>
	<b>Condom negotiation</b>	Some clients, especially sex workers, adolescent girls and young women, may not be able to enforce condom use. Provide guidance on how to advocate for condom use by the partner safely. Condoms provide protection against STIs, HIV and unintended pregnancy.
	<b>STIs</b>	Oral/injectable PrEP does not protect against STIs. Regular testing for STIs is encouraged, regardless of PrEP use. <b>REMEMBER: STIs may increase the risk of HIV acquisition</b>
	<b>Contraception/ Fertility goals</b>	PrEP is not a contraceptive. Oral and CAB-PrEP are safe to use with all contraceptive methods. Consult with a physician to guide how to proceed if the client becomes pregnant.
	<b>Effectiveness of PrEP</b>	When used as prescribed, oral PrEP is more than 90% effective at preventing HIV acquisition, and CAB-PrEP is highly effective. Oral PrEP becomes effective seven days after correct use. When choosing a PrEP method, it is essential to consider which method(s) will work best for you to prevent HIV during the types of exposures you anticipate, among other factors. Daily oral PrEP reduces your chances of getting HIV during all types of exposures to HIV; injectable PrEP works for sexual exposures and, as a systemic product, may also cover injection-related exposures.
	<b>Adherence (daily)*</b>	For oral PrEP to be effective, the pill must be taken every day. Adherence counseling is critical for full HIV protection. Adherence to the injection schedule is important for effective use of Injectable PrEP. Adherence counseling is critical for full HIV protection <b>*More detail is provided in the Adherence/ Oral/ Injectable PrEP sections</b>
	<b>Side effects*</b>	Some people get mild side effects when they start PrEP, but they generally go away after a few weeks. The most common oral PrEP side effects include nausea, headache, tiredness, diarrhoea, depression, abnormal dreams, vomiting, rash, problems sleeping, and changes in appetite. The most common Injectable CAB-PrEP side effects include nausea, headache, tiredness, diarrhoea and injection site reactions. See the Oral/Injectable PrEP section in the Side Effects section.



√	What to discuss	How to discuss it
	<b>Switching between HIV prevention methods</b>	<p>It is okay to start one PrEP method now and decide later that you want to use another PrEP method or another HIV prevention strategy. Many people switch between methods as their needs change.</p> <p><b>Important: Refer to the clinical section for detailed guidance about switching between methods.</b></p>
	<b>Intimate partner violence (IPV)</b>	<p>People who have abusive or controlling partners may find it more difficult to take care of their sexual health and to adhere to PrEP. Ask about the client's relationships, and for clients experiencing abuse, provide first-line support to IPV for clients that disclose experiencing violence, and offer referrals when required.</p> <p><b>*Important: If you are not trained to provide a first-line response to IPV, do not inquire about IPV so as not to cause unintentional harm. Where violence is suspected, refer the client to a provider trained in IPV inquiry and providing first-line response.</b></p>
	<b>Talking to your partner, family, friends, etc.</b>	<p>Deciding whether to tell anyone about your PrEP use is an entirely personal decision. Some people find it helpful to ask friends or family for support and to provide reminders to take the pill daily or adhere to an injection schedule. Discuss with the client whether and how they would like to discuss PrEP with loved ones and how to overcome any potential barriers to gaining their support.</p>
	<b>Visit schedule</b>	<p>Explain the visit schedule for PrEP use. For oral PrEP, the client must return for follow-up visits in the first month and every three months.</p> <p>For Injectable CAB-PrEP, the client must return one month after the first initiation injection for injection two and then every two months after that for follow-up injections.</p>
	<b>PrEP is not for life.</b>	<p>The client: You should take PrEP or use another HIV prevention strategy for as long as the client you feel you may be exposed to HIV. Some people need to take PrEP only during certain times in their lives, while others have an ongoing need to use PrEP.</p>
	<b>Injectable PrEP Discontinuation</b>	<p>Injectable PrEP remains in the body after discontinuing injections for as long as one year but at a low level that cannot protect against HIV. Clients should use another HIV prevention method if they are still at risk of acquiring HIV.</p>
	<b>PrEP and other medications</b>	<p>The drugs in some PrEP methods may interact with other medications you may take. Are you taking any medications?</p> <p>Depending on the PrEP method the client is interested in or using, refer to the relevant "[PrEP method] and Other Drug Interactions" section.</p>



Table 2: Frequently Asked Questions for Injectable PrEP

√	What to discuss	How to discuss it
	<b>How does Injectable PrEP work?</b>	<p>Discuss with the client that the medicine is injected into the muscle on one side of their buttocks, and over the following days and weeks, the medicine will make its way into their blood and throughout the rest of their body where it can protect them.</p> <p>The client will be protected from HIV after seven days. During the first week, the client will need to use other HIV prevention methods, like condoms.</p> <p>To stay protected, the client must return in one month, on [date], so they can give them more CAB-LA. After that, they need to come back every two months to stay protected from HIV.</p>
	<b>How long does it take for injectable PrEP to be effective?</b>	<p>The client will be protected from HIV after seven days. During the first week, the client will need to use other HIV prevention methods, like condoms.</p> <p>To stay protected, the client must return in one month, on [date], so they can give them more CAB-LA. After that, they must return every two months to stay protected.</p>
	<b>HIV resistance risk</b>	<p>After the client has an injection today, they must be on time for their next dose. This is because, over time, the amount of medicine in the client's body reduces. When the client gets their next injection on time, they will keep enough medicine in their body to stay protected, lasting two months.</p>
	<b>Importance of receiving follow-up injections on time</b>	<p>If the client misses any appointments, they will slowly become less protected. If the client were to get HIV when Injectable PrEP is still in their body, the HIV virus may try to find a way to change itself so that medicines like injectable PrEP will no longer work against it.</p> <p>HIV has a better chance of changing itself when injectable PrEP levels are low, which is why returning on time is so important. If the client were to get HIV and it was to change itself successfully, it could make treating HIV more difficult.</p> <p>The medicines we usually use could be less effective, so that different medications could be needed.</p>
	<b>Side Effects</b>	<p>Tell the client that it is normal to experience some side effects after the injection and that, for most people, these are minor discomforts and not bad enough to stop using injectable PrEP.</p> <p>Some clients might experience some normal soreness around the place where they were injected, which can last for a few days, while others might notice swelling and might feel bumps under the skin and have a bruise or redness. All of this is normal and nothing to worry about. To feel better, the client could take a pain reliever available at the pharmacy without a prescription and put ice or heat on the area.</p> <p>The client may also experience headaches, upset stomach, and feel feverish or more tired than usual. These side effects usually go away on their own as your body gets used to the drug, and after that, you should feel fine.</p>



√	What to discuss	How to discuss it
	<b>Drug-drug Interactions</b>	Discuss with the client that Injectable PrEP does interact with a few other medicines. If the client starts any new medicines while taking injectable PrEP, they must ask about it or tell a provider they are taking injectable PrEP in case they need to choose a different medication. It's very rare, but some clients who have taken injectable PrEP have found they feel very sad or depressed. If those are feelings that the client is already dealing with now, talk about them with them.
	<b>When to seek help</b>	<p>Discuss with the client If any of the following things happen, are severe, or don't go away, they should return to see a provider immediately:</p> <ul style="list-style-type: none"> <li>· If the client has a rash on their body AND blisters or sores in their mouth</li> <li>· If the client has shortness of breath—trouble catching their breath</li> <li>· If the client's whites of their eyes start to look yellow</li> <li>· If the client becomes very nauseated and starts vomiting</li> <li>· If the client has thoughts about killing themselves</li> <li>· If the client feels very sad or depressed, and it gets worse or doesn't go away</li> </ul>
	<b>Stopping Injectable PrEP</b>	<p>Please discuss with the client that after their final injection, Injectable PrEP would continue to protect them from HIV for up to two months, but after that, they'd gradually lose their protection. Because this medicine is long-acting, it stays in their body for about a year after their last injection.</p> <p>If the client were to become infected with HIV when the injectable PrEP medicine is still in their body, the HIV virus would try to find a way to change itself so that injectable PrEP and other medicines like it do not work as well against the virus. That could make treating HIV in the future more difficult. The medicines that would usually be used to keep them healthy might not work as well, and they would have to choose other medicines instead.</p> <p>The client needs to stay protected against HIV in the year after they get their last injectable PrEP injection. Some clients might use a pill form of PrEP, and others are very careful to use condoms every time they have sex during that time, but they will have to visit the clinic every three months for that year after they stop using injectable PrEP.</p>





## Chapter 2: HIV Testing Services for PrEP

HIV Testing Services (HTS) are the entry point to HIV prevention and treatment interventions. In Zambia there are two HTS Models; one for the health facilities and one for the community. All HTS should adhere to the 5Cs; consent, counseling, confidentiality, correct results, connection.

Table 3. Showing HTS Models

Facility Based HTS Model	Community Based HTS Model
Provider Initiated Testing Counseling	National HTS
Index Testing	Index testing
HIV Self Testing	HIV Self Testing
Client-initiated HIV Testing and counseling	Client-initiated HIV Testing and counseling
Diagnostic HIV Testing Counseling	HTS Integrated Campaigns
Mandatory HIV Testing and Counseling	Social Network Testing Strategy
Couple Counseling	Couple Counseling

### 2.1. Testing Modalities for PrEP

HIV testing and counseling is a critical element of combination HIV prevention and is an integral part of PrEP service provision. The first step is to screen all clients for HIV risk using the HIV screening tool. Those who screen at high risk for HIV acquisition are offered HTS. Those who accept and consent are tested for HIV. Those who test positive for HIV are linked to HIV care services while those who test negative for HIV are assessed for PrEP eligibility. For clients who tested negative for HIV and who are eligible for PrEP, the next step is to screen for HIV exposure to determine if they may have been exposed to HIV in the past 72 hours. Such individuals may be better protected against HIV with Post-Exposure Prophylaxis (PEP) instead of pre-exposure prophylaxis (PrEP).

If an individual is confirmed HIV-negative with a serological test, and they have not been exposed to HIV in the last 72 hours, they can continue through the PrEP initiation visit and may be eligible to start PrEP, either oral or injectable.

Recent global evidence has demonstrated the high sensitivity of Nucleic Acid Testing (NAT) when compared to rapid and serological testing. Optimally, NAT testing should be considered to reduce the high probability of drug resistance for clients who have their initiation or reinjection appointments by more than 7 days, or at the discretion of the provider, for clients that are established. However, until NAT becomes widely available and accessible in Zambia, rapid and serological testing will be utilized, in line with current national guidance on HIV counseling and testing.



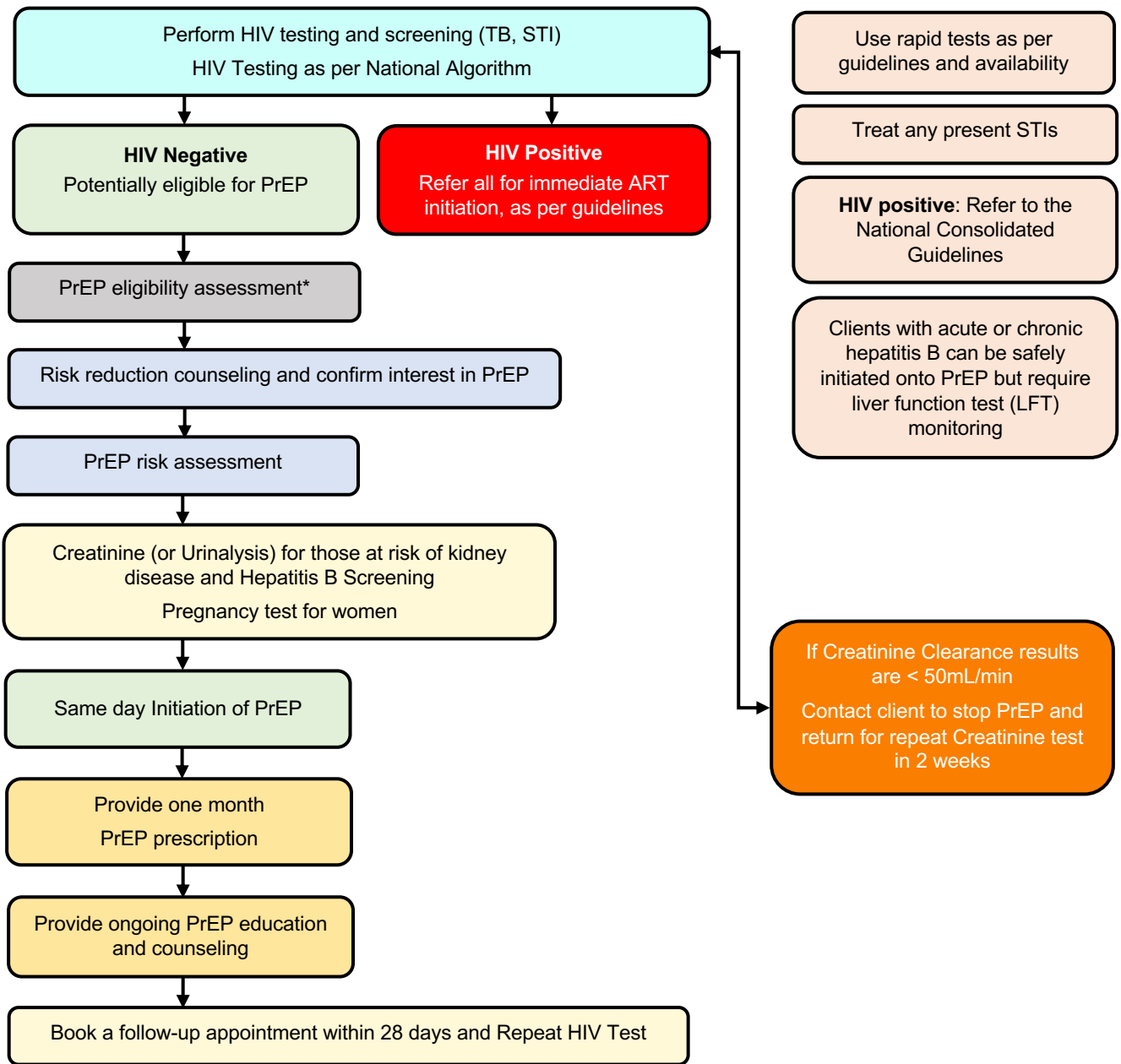


Figure 1: Oral and Injectable PrEP Flow Chart

Next, prospective PrEP clients should be assessed for Acute HIV Infection (AHI) signs or symptoms currently present and risk of HIV infection in the past 2 weeks. Signs/symptoms of AHI are non-specific, meaning they may be related to other illnesses, and not HIV (e.g., fever; swollen lymph nodes; rash; headache; sore throat; aches and pains; mouth sores). Clients with current or recent (past 2 weeks) AHI signs/symptoms, should be asked whether they may have been exposed to HIV in the past 2 weeks (e.g., sex that resulted in the client acquiring a sexually transmitted infection). For clients with AHI signs/symptoms and corresponding risk, clinicians need to make a judgement call as to whether a client may be experiencing AHI, based upon the number and severity of signs/symptoms and details about the exposure(s).



If the individual is HIV [positive the client must **not** be initiated on PrEP but it should immediately be initiated on or referred for ART. However, if the test result is inconclusive, defer PrEP and follow the national guidelines until a definitive HIV test result has been obtained.

HIV self-testing complements existing HIV testing strategies for continuing oral PrEP, supporting the differentiated PrEP service delivery approaches.

Distribution of HIVST to hard-to-reach populations should be used as an opportunity for PrEP sensitization. For individuals on PrEP who are less likely to access facility-based testing services, HIVST provides additional testing choice and allows for continuation of oral PrEP while reducing clinic follow-up visits.

HIVST can be used for continuation of oral PrEP at follow-up visits within 3 Months. Regular interactions between providers and clients are important to ensure PrEP users have adequate counseling and can raise any issues or concerns with providers. Clear and concise messages are critical, including:

- Following a reactive HIVST, PrEP users should not discontinue PrEP but should immediately seek a standard testing algorithm by a trained provider. Note HIVST performance during PrEP may be unreliable, therefore standard testing should be used whenever possible
- Regular HIV testing is important while taking PrEP to identify HIV infection as soon as possible

#### **Key Message**

A self-reported HIV-negative test is not sufficient for PrEP initiation. An HIV confirmation test should be done by a trained health Provider



## Chapter 3: Post-Exposure Prophylaxis (PEP)

World Health Organization (WHO) recommends the use of Post-Exposure Prophylaxis (PEP) by individuals potentially exposed to HIV for the prevention of HIV. Evidence supporting the use of antiretrovirals (ARVs) for HIV PEP dates to 1990, but it remains an underutilized part of HIV combination prevention. In addition to playing a vital role in HIV prevention on its own, PEP can act as bridge from potential exposure to uptake of other HIV prevention strategies, including Pre-Exposure Prophylaxis (PrEP).

PEP is a short-term (28-day) course of combination antiretroviral medicines, ideally a fully suppressive 3-drug regimen. PEP is taken to reduce the likelihood of HIV acquisition after potential exposure, either occupationally or nonoccupationally—for instance, through sex, sharing injection equipment, or needle stick injuries. It should be obtained and started within 72 hours (about 3 days) of potential exposure.

Table 4: Potential Exposure Risk Categorization

Risk Category	ART	Duration
No risk: intact skin	Not recommended	
Medium risk: Invasive injury, no blood visible on needle	Preferred: TDF or TAF + XTC + DTG Alternative: TDF or TAF + XTC + DRV-r TDF or TAF + XTC + LPV-r AZT + 3TC + DTG (children ≥ 3kg, where available) TAF + FTC + DTG (children ≥ 25kg)	28 days
High risk: large volume of blood/fluid, known HIV-infected patient, large bore needle, deep extensive injury		
Penetrative sexual abuse		

Clients on PEP should have an HIV test before starting PEP, 6 weeks and at 3 months. While on PEP, the client should be reviewed and offered appropriate laboratory investigations

### 3.1. Assessing for PEP Initiation

#### HOW:

1. Assess whether a client had an exposure to HIV in the past 72 hours
2. If a client reports an exposure to HIV in the past 72 hours, the client should be screened for eligibility for PEP instead of PrEP and provided PEP or linked to PEP services
3. After 28 days of PEP, the client may be directly transitioned from PEP to PrEP without a gap, if still HIV negative and if the client otherwise meets the criteria for PrEP use

**WHY:** Bidirectional referrals (from PEP services to PrEP services and vice versa), as well as integrated PEP and PrEP services wherein an individual provider or providers at a single location can prescribe or dispense both PEP and PrEP, can increase access to comprehensive HIV prevention.



### 3.2. Assessing for PrEP use in clients returning after full course of PEP

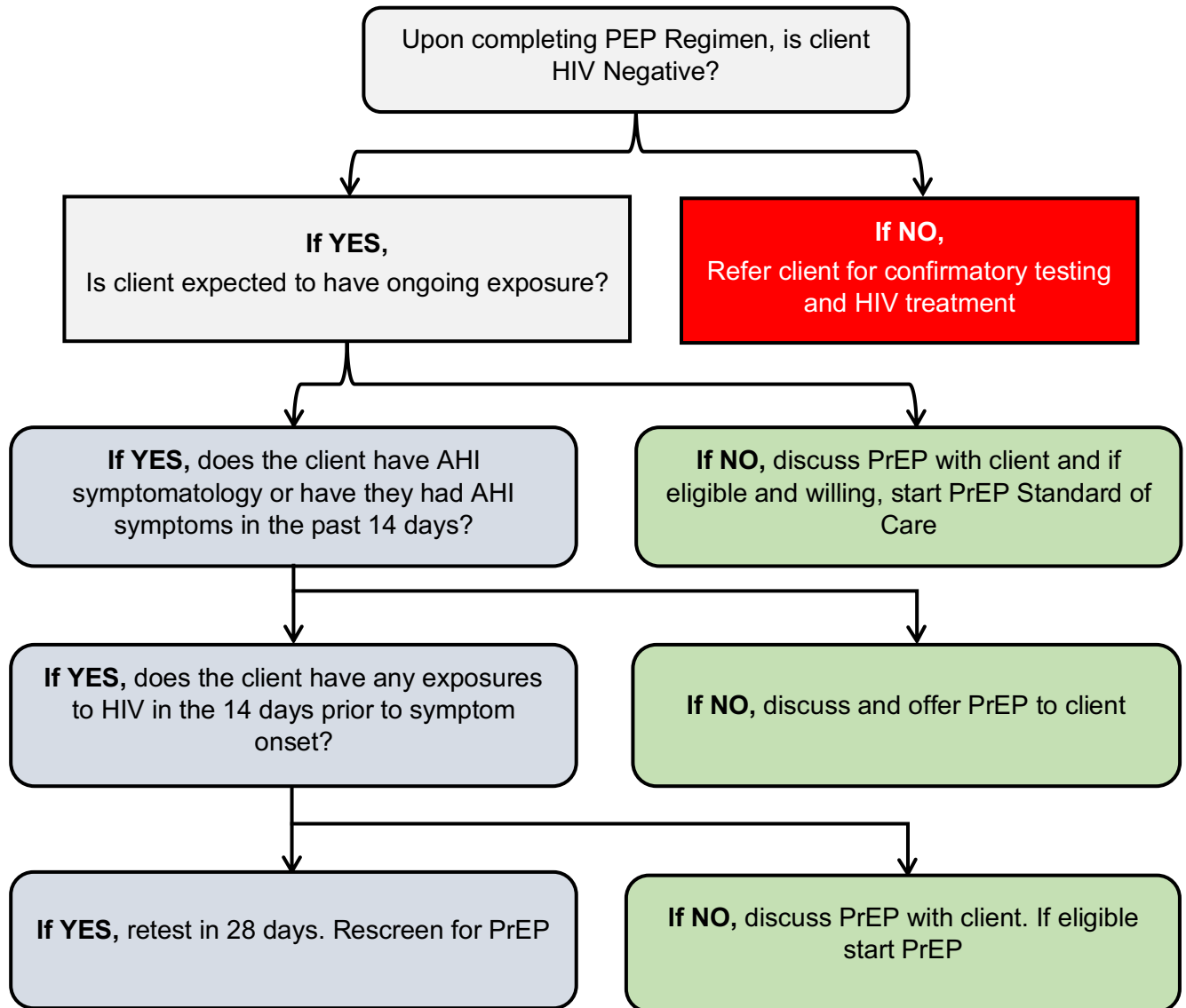


Figure 2: Algorithm for Assessing PrEP use in Clients after Full Course of PEP



### 3.3. PEP to PrEP Transition

Post-Exposure Prophylaxis (PEP) is when HIV negative individuals take antiretroviral (ARV) drugs after potential HIV exposure, ideally within 72 hours. With PEP, ARVs are taken daily and continued for 28 days. The preferred ARV regimen for adults and adolescents is TDF+3TC (or FTC) with Dolutegravir (DTG) as the third drug.

Clients with possible exposure to HIV in the previous 72 hours should have an HIV test and offered PEP without delay. Providers should provide information about PrEP and PEP to PrEP transition to individuals offered PEP.

Individuals who have completed PEP can be immediately transitioned to PrEP with a negative HIV test result, provided they do not have any contraindications to the PrEP product chosen. This is preferable in the case of individuals with ongoing exposure to HIV. Individuals transitioning from PEP to PrEP can be managed similarly to other individuals on PrEP and additional barrier methods should be used to enhance protection during transition period.

Individuals using PrEP but who are concerned about a recent HIV exposure (for example, not taking oral PrEP according to the prescribed regimen, or due to discontinuing PrEP) can transition to PEP as soon as possible after potential HIV exposure and ideally within 72 hours.

#### **Key Message**

Switching between PEP and PrEP: WHO recommends offering PrEP to individuals after the completion of PEP if they are HIV negative and potential exposure to HIV is expected to continue after PEP completion



## Chapter 4: Pre-Exposure Prophylaxis (PrEP)

### 4.1. PrEP Initiation Visit

For most clients, PrEP can be initiated the same day. For clients choosing oral PrEP, there will be one initiation visit. For clients choosing CAB-LA, there will be two initiation visits scheduled 30 days apart for initiation injection 1 and 2, respectively. However, in some scenarios, as outlined below, deferred PrEP initiation is recommended. Clients must meet four criteria to begin PrEP use. They must be:

- HIV negative
- Not indicated for PEP or suspected of having AHI
- Requesting PrEP or indicated for PrEP use
- Free from contraindications for use of their chosen PrEP method

The four essential components of PrEP initiation visits are:

1. HIV testing and counseling
2. assessments
3. PrEP counseling
4. PrEP prescription
5. Other prevention strategies

#### 4.1.1. Assessment for PrEP Clients

Table 5: Risk Assessment Checklist & Basic Information about PrEP

Risk Assessment Checklist	PrEP Education Session Checklist
<ul style="list-style-type: none"><li>• Condom use history</li><li>• Number of partners (known and unknown HIV status)</li><li>• STI diagnosis history</li><li>• PrEP use history</li><li>• Desire for family planning</li><li>• Transactional sex history</li><li>• Current use of drugs/alcohol</li><li>• Intimate partner violence</li><li>• Client and partner's preferences for HIV prevention strategies</li></ul>	<ul style="list-style-type: none"><li>• Basic PrEP information</li><li>• Safe-use and risk-reduction counseling</li><li>• Possible side effects, treatment options</li><li>• Baseline and regular tests, schedule for monitoring</li><li>• PrEP follow up visits and continuation</li><li>• Long-term safety</li><li>• When and how to stop taking PrEP</li><li>• Symptoms of possible sero-conversion</li><li>• Benefits/risks in case of pregnancy or breastfeeding</li></ul>



#### 4.1.2. Assessing for Acute HIV Infection

- Clients suspected of having Acute HIV Infection (AHI): If a client has signs and symptoms of acute HIV infection (see Box 1) AND possible exposure to HIV in the 14 days prior to symptom onset, it is possible that the client's symptoms may be due to AHI because a prevention method was not being used or used ineffectively around time of potential exposure to HIV
- Given the client's timing of potential exposure(s), provider and client should weigh the risks and benefits of delaying PrEP initiation and retesting client per national algorithm 28 days from potential exposure, or earlier if there is HIV testing available that can reliably detect HIV

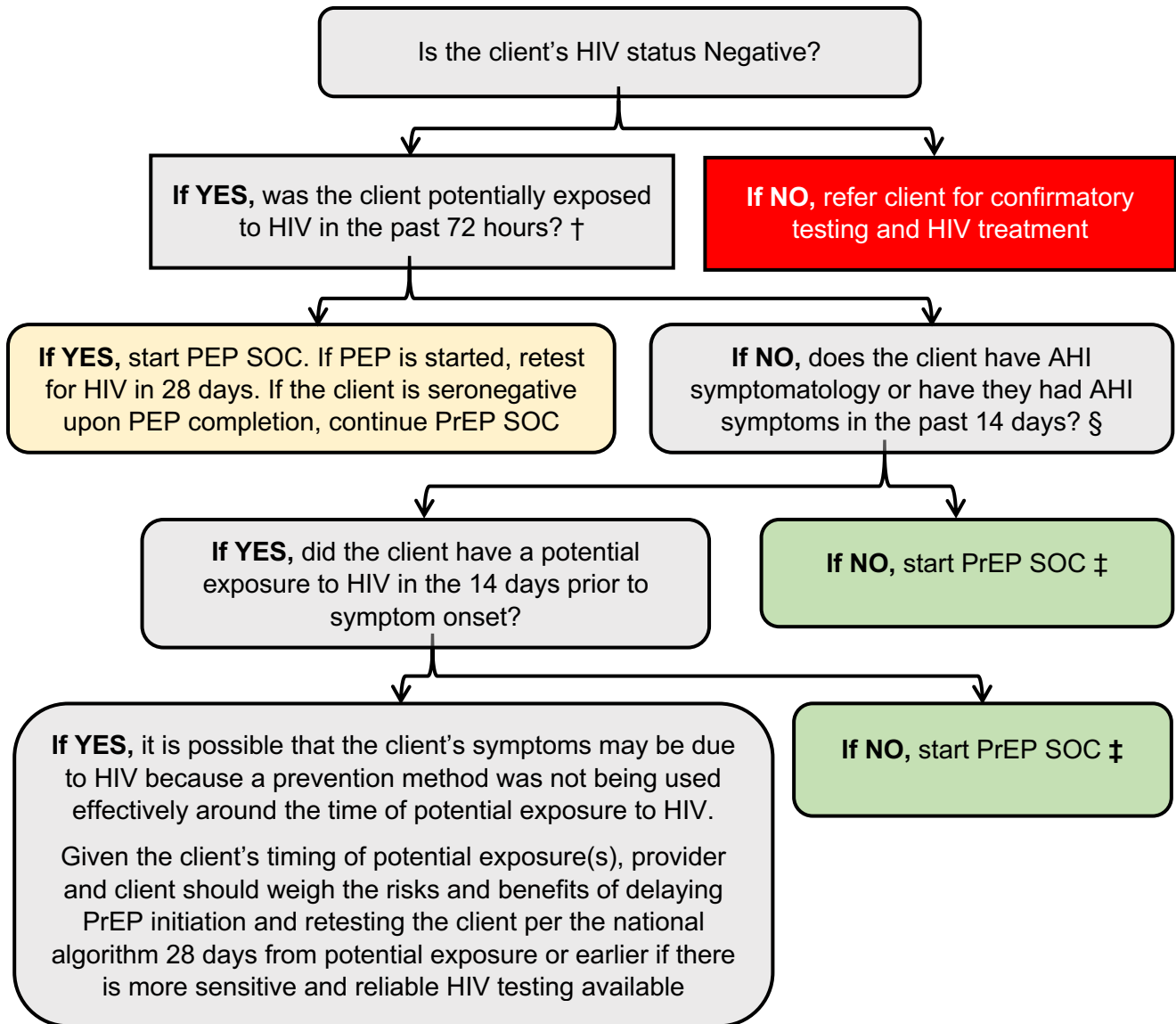
Clients should be provided with HIV exposure reduction counseling, such use of barrier methods as well as STI Screening, diagnosis, and management, if available. If the client has an HIV-negative result after retesting and the client meets other criteria for PrEP use, the client can start PrEP.

##### Box 1: Signs of Acute HIV Infection

- Fever
- Swollen lymph glands
- Skin rash
- Sore throat
- Aches and pains
- Mouth sores







† Answering “NO” to this question means no potential past exposure to HIV at all or potential HIV exposure that was 73+ hours ago

§ Two-thirds of people will have symptoms of AHI within 2-4 weeks of HIV acquisition (Letizia et al., 2022). Signs and symptoms mimicking AHI (i.e., sore throat, fever, sweats, swollen glands, mouth ulcers, headache, rash, and muscle aches) are commonly due to illnesses other than HIV; providers need to use discretion to determine whether the symptomatology is consistent with HIV or may be explained by an alternative cause

‡ In order to make an informed choice prior to starting PrEP, the client should be aware that available HIV testing may not have been able to detect HIV even if present. The client should also be aware that while they do not have symptoms of AHI, they could be pre-symptomatic or be part of the one-third of individuals who do not develop symptoms of AHI within 2-4 weeks of acquiring HIV

SOC = Standard of Care

Figure 3: PrEP Initiation – HIV Exposure and AHI Assessment



#### 4.1.3. Screening for Intimate Partner Violence (IPV)

The Zambia National Clinical handbook for caring for women who experience sexual gender-based violence in accordance with World Health Organization recommendations, which outline minimum requirements that must be met before providers can ask about gender-based violence recommends the following requirements to be met before providers can inquire about violence.

1. A protocol/standard operating procedure for asking about violence
2. A standard set of questions where providers can document responses
3. Providers who are trained to ask about GBV
4. Providers who are trained to provide first-line support for violence (LIVES) or beyond
5. A private, confidential setting
6. A referral or service linkage process

In addition to training on asking about violence and providing first-line support, PrEP service providers should also complete gender-sensitive training to support their skills and understanding on;

1. Types, consequences, and patterns of gender-based violence
2. Links between inequitable gender norms, power dynamics, and violence
3. Relationship between gender-based violence and PrEP initiation and continuation
4. Needs of clients when they experience violence and barriers to accessing violence response services
5. Relationship between gender-based violence and PrEP initiation and continuation
6. Opportunities to critically reflect on one's beliefs, assumptions, potential biases, and emotional responses that affect interactions with PrEP clients and with clients who have experienced violence



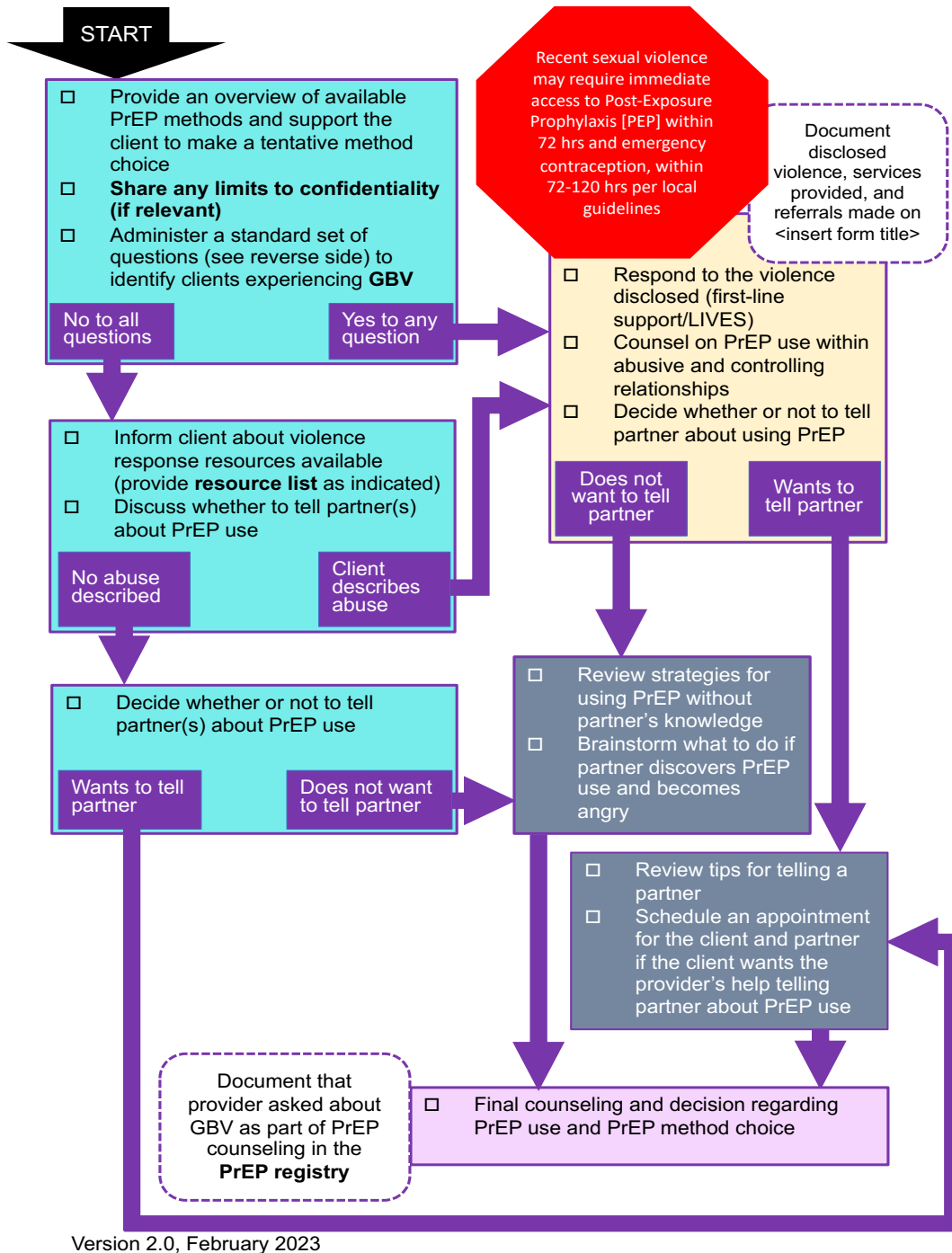


Figure 4: Provider Job Aid for Discussing IPV and PrEP Use

If sexual violence within the past 72 hours was reported, PrEP should not be given, and the client should be offered PEP when eligible and refer to other GBV services. On completion of PEP, schedule an appointment to assess PrEP eligibility.

<sup>1</sup> Standard Operating Procedures for Addressing Partner Relationships and Gender-Based Violence in Pre-Exposure Prophylaxis (PrEP) Services. January 2023. [https://www.prepwatch.org/wp-content/uploads/2023/03/CHARISMA-MOSAIC\\_SOP\\_Relationships\\_GBV\\_PrEP.pdf](https://www.prepwatch.org/wp-content/uploads/2023/03/CHARISMA-MOSAIC_SOP_Relationships_GBV_PrEP.pdf)



PrEP use in some instances may trigger IPV if a partner is unsupportive or suspicious of its use, and experience or fear of IPV may hinder PrEP uptake and adherence. However, no service should be denied a client because they did or did not disclose violence. Survivors of IPV may be at risk of HIV acquisition and may still benefit from PrEP. Providers should counsel clients on the risks and benefits of PrEP in the context of IPV using the following strategies:<sup>2</sup>

- Discuss how to use PrEP safely in the context of the client's relationship
- Brainstorm potential challenges and solutions to using PrEP
- Discuss whether and how to disclose PrEP use to a partner
- Discuss strategies for discreetly using PrEP and keeping it a secret from the partner. This may involve exploring injectable options of PrEP such as CAB-LA may be more discreet than oral
  - Identify reasons the client wishes to use PrEP and validate those reasons

Although Injectable PrEP (CAB-LA) may be an option for clients concerned about IPV due to its discreet nature, clients who wish to keep CAB-LA use private should be counselled on the possibility of visible injection site reactions and be assisted with a plan to implement should this occur. If the service provider and client cannot create a plan for safe PrEP use, other HIV prevention strategies should be explored.

#### 4.1.4. Assessing for PrEP Eligibility

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

- Test HIV Negative on serological Rapid Test
- Interested in PrEP and willing to be adherent
- No suspicion of acute HIV infection
- Able to attend regular follow-ups and HIV testing

At substantial risk for HIV infection, defined as engaging in one or more of the following activities within the last six months:

- Vaginal/high risk sexual intercourse without condoms with more than one partner  
Having sexual intercourse with a partner of unknown HIV status
- Sexually active with a partner who is known to be HIV positive or at substantial risk of being HIV positive
- Sexually active with an HIV-positive partner who is not on effective treatment (defined as on ART for < 6 months or not virally suppressed)
- History of STI (based on lab test, syndromic STI treatment, self-report)
- History of Post-Exposure Prophylaxis (PEP) use
- Sharing injection material or equipment

**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.



## PrEP Screening Algorithm

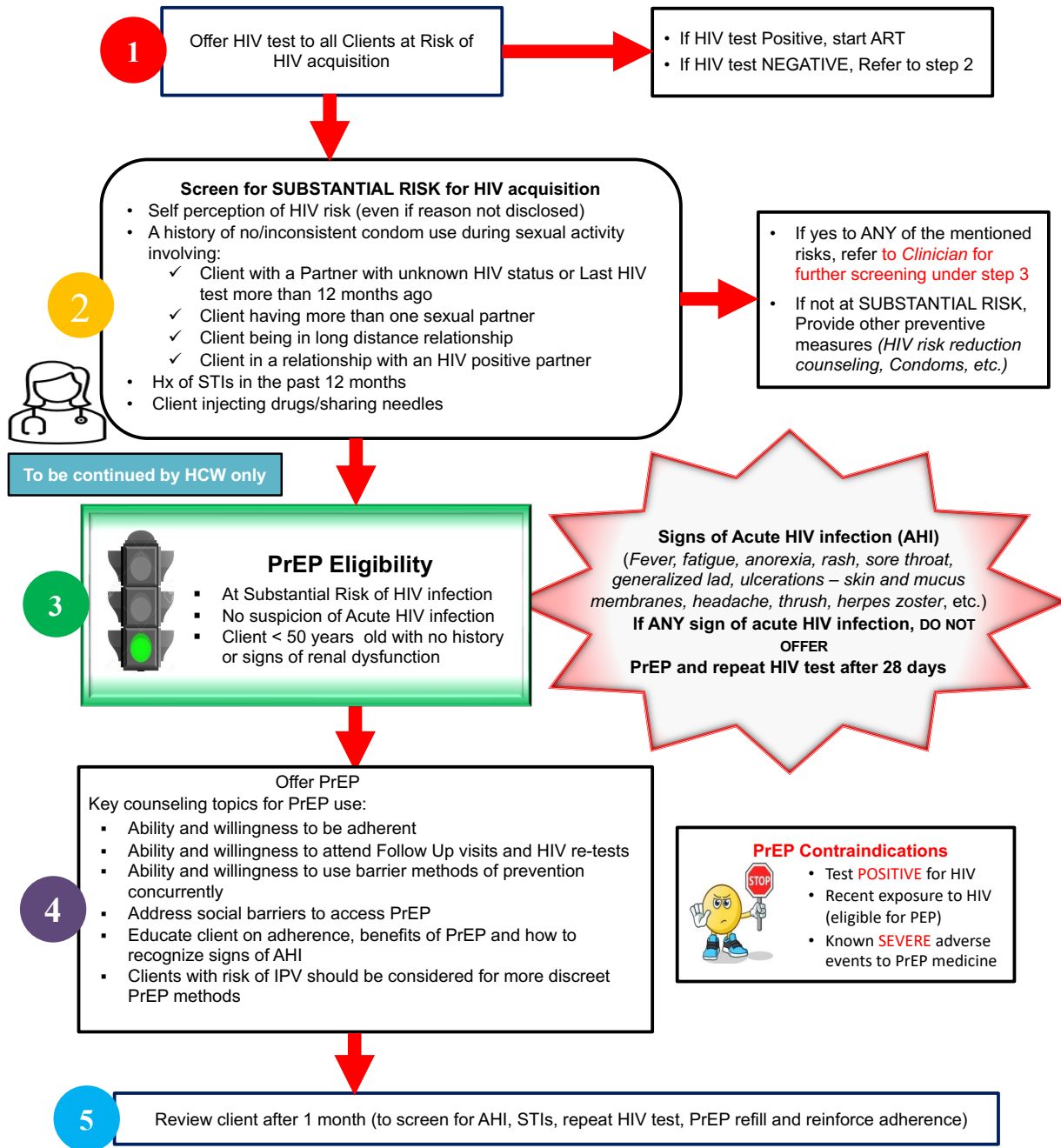


Figure 5: PrEP Screening Algorithm



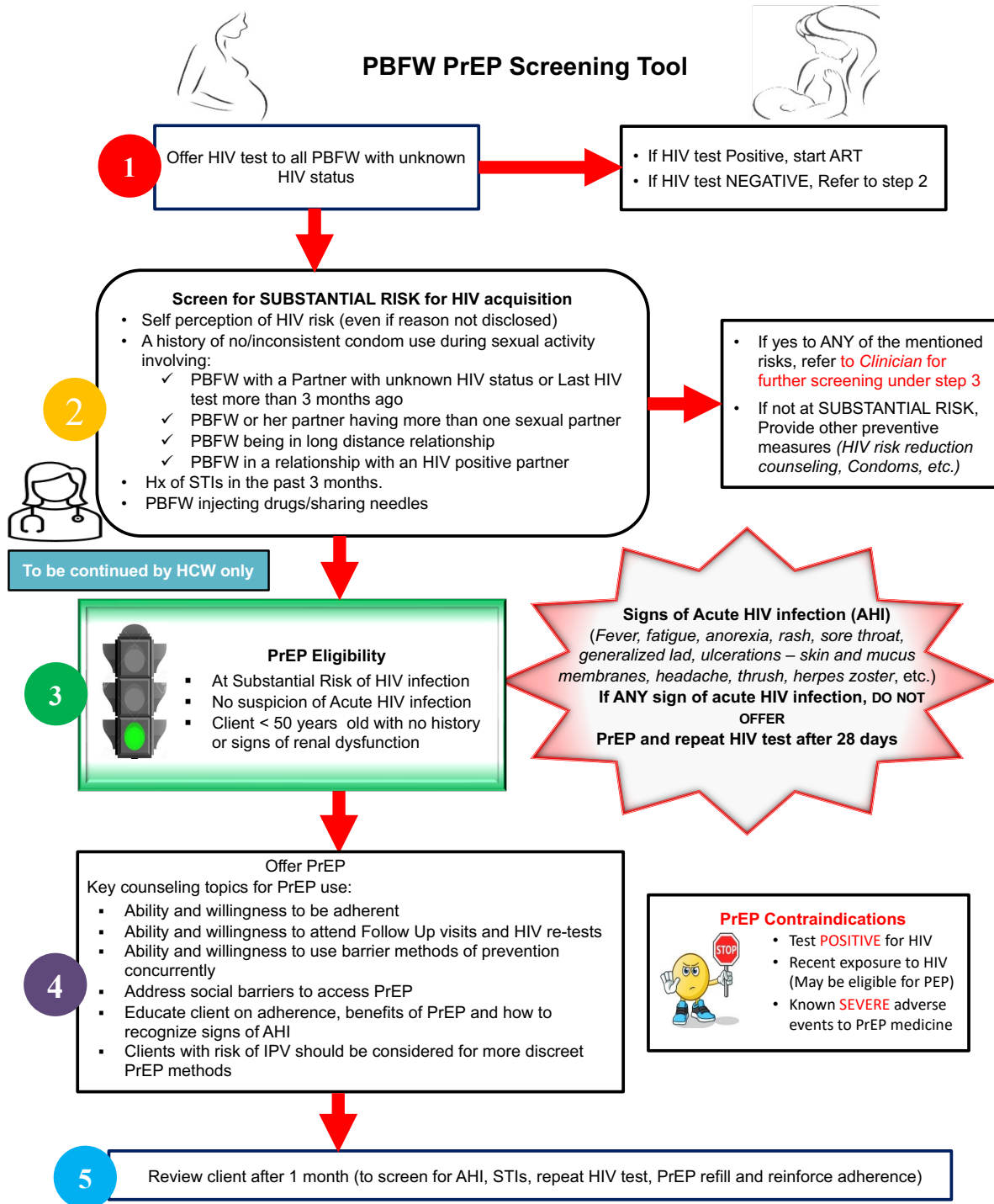


Figure 6: PrEP Screening Algorithm for PBFW



## 4.2. Oral Pre-Exposure Prophylaxis

Oral PrEP may be offered as a daily regimen to prevent HIV acquisition during all potential exposures for all populations. In Zambia, either Tenofovir TDF 300mg/FTC 200mg or TDF 300mg/Lamivudine (3TC) 300mg can be used for oral PrEP. The current preferred drug for oral PrEP is [TDF/FTC or TDF/3TC].

For everyone else, including those using oral PrEP to prevent HIV from nonsexual exposures, only a daily regimen may be offered. Details on starting and stopping oral PrEP for different populations are provided in [Table 6](#) below. Clients starting oral PrEP should be counselled on using another HIV prevention strategy during the time it takes for the method to be fully effective. Note that the procedures for stopping oral PrEP are the same whether a client is stopping oral PrEP for a specific amount of time or intends to discontinue oral PrEP use indefinitely. Ideally, clients who are discontinuing oral PrEP use indefinitely will advise their provider(s) and receive support to use other HIV prevention strategies if still needed. For these clients in particular, regular HIV testing should be encouraged.

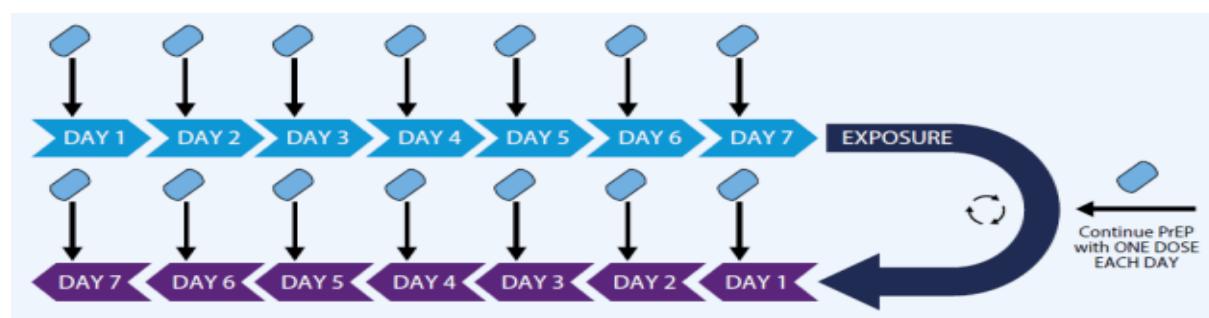


Figure 7: Starting, Using and Stopping Oral PrEP

Table 6: Starting and Stopping Oral PrEP for Different Populations

Population(s)	Often include(s)	Starting Oral PrEP	Using Oral PrEP	Stopping Oral PrEP
People assigned male at birth who are not using estradiol-based exogenous hormones and are using oral PrEP to prevent HIV acquisition during sex	Cisgender men transgender women who are not using oestradiol-based exogenous hormones nonbinary people assigned male at birth who are not using oestradiol-based exogenous hormones	Daily: Take a double dose 2 to 24 hrs before potential sexual exposure. Ideally, this loading dose should be taken closer to 24 hrs before potential exposure	Take one dose per day	Daily: After a single dose is taken daily for two days after the last potential exposure, PrEP can be stopped
People assigned female at birth who are using oral PrEP to prevent HIV acquisition during sex	Cisgender women Transgender men Nonbinary people assigned female at birth	Daily: Take a single dose daily for seven days before potential exposure	Take one dose per day	After a single dose is taken daily for 7 days after the last potential exposure, PrEP can be stopped
People assigned male at birth who are using oestradiol-based exogenous hormones who are using oral PrEP to prevent HIV acquisition during sex	Transgender women who are using oestradiol-based exogenous hormones nonbinary people assigned male at birth who are using oestradiol-based exogenous hormones			
People using oral PrEP to prevent HIV acquisition from nonsexual exposures	anyone who shares injection-related materials <sup>3</sup>	Daily: Take a single dose daily for seven days before potential exposure	Take one dose per day	After a single dose is taken daily for seven days after the last potential exposure, PrEP can be stopped

### Key Message

For consideration: WHO recommends the use of oral PrEP containing TDF. Zambia has adopted TDF/FTC and/or TDF/3TC for oral PrEP. Note that TDF monotherapy may not be suitable for all populations. Emtricitabine/Tenofovir alafenamide (FTC/TAF) is not currently recommended for PrEP by WHO; the U.S. Food and Drug Administration has approved its use as a daily regimen to reduce the likelihood of sexual acquisition of HIV, excluding individuals who may be exposed to HIV via receptive vaginal sex. The FTC/TAF has not been approved for prevention of parenteral acquisition. Consider including both TDF/FTC and TDF/3TC as approved medications for PrEP because having the option of using either set of approved drugs may be beneficial where first-line treatment for people living with HIV is transitioning to Tenofovir, Lamivudine, and Dolutegravir, potentially freeing up TDF/3TC, or if supply chain challenges affect the availability of one of the recommended drugs.

<sup>3</sup> Injection drug use is mentioned in this guidance; however, first-line prevention strategies for people who inject drugs are needle exchange and/or drug use harm reduction and treatment. Daily oral PrEP has some preventative effects for this population and should be offered as part of a larger prevention package.





### 4.3. Injectable PrEP Use: Long Acting Injectable Cabotegravir (CAB-LA)

Long-acting injectable Cabotegravir (CAB-LA) is an Integrase Strand-Transfer Inhibitor (INSTI) which reduces the ability of the HIV to replicate itself inside a healthy cell. It is the first in a pipeline of long-acting injectable PrEP products to reach markets and be introduced in Zambia. CAB-LA is an extended-release injectable suspension given to people who do not have HIV infection, at a dose of 600mg, intramuscularly into the gluteal muscle, 30 days apart for the first two injections and every 60 days thereafter for the prevention of HIV acquisition. CAB-LA should be injected only into the gluteal muscle; the pharmacokinetics and efficacy of CAB-LA when injected in other sites has not been studied. The current evidence shows it takes about one week for drug concentrations to reach levels at which CAB-LA is expected to be maximally effective after initiation injection 1, so clients should be counselled on using other HIV prevention strategies during the first week.

Multiple studies have shown that oral PrEP is highly effective when taken as prescribed. However, many people find it difficult to take an oral drug consistently. Evidence from two randomized controlled trials show CAB-LA is highly effective at preventing sexual HIV acquisition and may be offered as an additional prevention choice as part of combination prevention approaches. It has not yet been studied for HIV prevention for parenteral exposure or for those who may be exposed during vertical transmission during pregnancy, childbirth, or breastfeeding. CAB-LA may be suitable for clients seeking less frequent dosing or increased privacy around PrEP use. It is important to note that the relative reduction in HIV infections with CAB-LA compared with oral PrEP is likely due largely to differences in adherence.

After stopping CAB-LA, the drug concentrations markedly decline over time to levels that are gradually less protective against HIV acquisition. However, residual concentrations of Cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer).

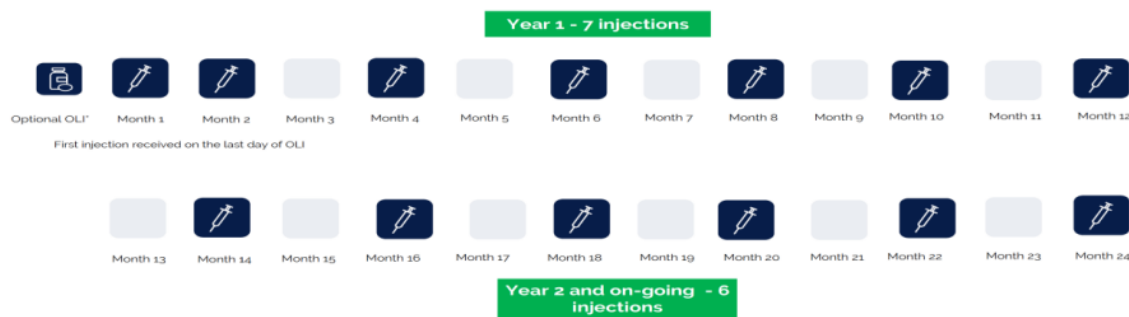


Figure 8: CAB-LA Dosing Schedule

#### 4.3.1. Formulation of CAB-LA

CAB-LA is an extended-release injectable suspension of Cabotegravir (600mg/3mL). It is designed as a dissolution-controlled depot formulation. Cabotegravir's nanoparticles enhance its dissolution and absorption and improve the syringe-ability of the formulation.



#### 4.3.2. CAB-LA Effectiveness

Like oral PrEP, CAB-LA is a highly effective HIV prevention method and reduces the risk of HIV infection by 90% or more.

If a client is using CAB-LA for HIV prevention, it is important they keep up with regular appointments for injections to make sure that there is enough Cabotegravir in their body to continue to prevent HIV infection. When a client misses a scheduled injection or discontinues CAB-LA, concentrations of the medication in the body slowly decline. During this pharmacokinetic “tail,” CAB-LA becomes gradually less protective against HIV acquisition, and sero-conversion may occur if the client continues to be exposed to HIV. For more information on the pharmacokinetic tail, refer to the Stopping CAB-LA section below.

#### 4.3.3. Considerations for Pregnant and Breastfeeding Women

Data are limited on the use of Injectable PrEP (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 Injectable PrEP (CAB-LA) may be safe during pregnancy and breastfeeding. There are no data on whether or not Cabotegravir is present in human milk, impacts human milk production, or affects breastfeeding infants among clients using Injectable PrEP (CAB-LA). While research is ongoing, pregnant and breastfeeding women may be considered for oral PrEP.

- If a client already on CAB-LA becomes pregnant, give adequate information on available evidence on the drug and pregnancy to make an informed decision to continue depending on the perceived risk at the time and careful weighing of the risks and benefits of discontinuing a highly effective prevention option during a period of increased risk of HIV acquisition
- For clients who are on CAB-LA and plan to become pregnant, they should consider switching to oral PrEP

#### 4.3.4. Potential Side Effects of CAB-LA

While CAB-LA is generally safe, side effects have been observed among people receiving it. The most common side effects include:

- Headache
- Nausea
- Diarrhoea
- Tiredness
- Injection Site Reactions (ISRs), particularly redness, pain, tenderness and swelling

Note: Clients should be counselled on the occurrence of possible side effects and informed and assured that these do not indicate a more serious underlying condition. The side effects are usually mild or moderate. The ISRs are more common than other potential side effects, becoming less frequent over time as clients get used to the injection. For information on less common side effects, review the product leaflet.



#### 4.3.5. CAB-LA and Other Drug Interactions

The concomitant use of CAB-LA and other drugs may result in reduced drug concentration of CAB-LA. Cabotegravir is primarily metabolized by UGT1A1 with some contribution from UGT1A9. Drugs that are strong inducers of UGT1A1 or 1A9 are expected to significantly decrease Cabotegravir plasma concentrations thereby reducing its efficacy; therefore, Cabotegravir co-administration with these drugs is contraindicated. Clients using them may need to select a different PrEP method or HIV prevention strategy. Information regarding potential drug interactions with CAB-LA is provided in [Table 7](#) below:

Table 7: Drug Interactions with CAB-LA

Concomitant Drug Class: Drug Name	Effect on Concentration	Clinical Comment
Anticonvulsants: Carbamazepine, Oxcarbazepine, Phenobarbital, Phenytoin	↓Cabotegravir	Co-administration is contraindicated with Cabotegravir due to potential for significant decreases in plasma concentration of Cabotegravir
Antimycobacterials: Rifampin Rifapentine	↓Cabotegravir	
Antimycobacterial: Rifabutin	↓Cabotegravir	When Rifabutin is started before or concomitantly with the first initiation injection of Cabotegravir, the recommended dosing of Cabotegravir is one 600mg (3mL) injection, followed 2 weeks later by a second 600mg (3mL) initiation injection and monthly thereafter while on Rifabutin. When Rifabutin is started at the time of the second initiation injection or later, the recommended dosing schedule of Cabotegravir is 600mg (3mL) monthly while on Rifabutin. After stopping Rifabutin, the recommended dosing schedule of Cabotegravir is 600mg (3mL) every 2 months
Narcotic analgesic:	↔ Cabotegravir	No dose adjustment of Methadone is required
Methadone	↓Methadone	

↑= Increase ↓ = Decrease, ↔ = No change



There are no known interactions between CAB-LA and contraceptive hormones or other forms of contraception. Available evidence suggests that use of gender-affirming hormones by transgender women does not affect drug levels of Cabotegravir.<sup>4</sup>

There are also no known interactions between CAB-LA and recreational drugs or alcohol, but alcohol and drug use could affect the ability to attend necessary health appointments, potentially resulting in missed injections. If a client or potential client thinks that their use of alcohol or other substances is interfering or may interfere with effective use of CAB-LA, the provider should engage the client to understand what support or referrals might be valuable to support effective use while also discussing additional prevention options, including other PrEP methods and the use of condoms and condom-compatible lubricant.

Residual concentrations of Cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). These residual concentrations are not expected to affect the exposures of antiretroviral drugs that are initiated after discontinuation of CAB-LA.

### Box 2. Recommendations for Drug Interactions with CAB-LA

**For consideration:** Clients using Non-steroidal Anti-inflammatory Drugs for pain or anticoagulants or other antiplatelets such as high-dose Aspirin, in the past week, may have a higher likelihood of bruising or bleeding at the injection site and should be made aware and counselled on mitigation strategies, if relevant.

If a client is using CAB-LA and is diagnosed with Tuberculosis (TB), they will need to temporarily discontinue CAB-LA and receive treatment with a standard Rifampin-based regimen. In the interim, the client may use oral PrEP or other HIV prevention strategies. If the client completes TB therapy and wishes to continue with CAB-LA, they should be assessed for CAB-LA use and can restart CAB-LA with initiation injection. CAB-LA can be started two weeks after a client completes TB therapy. For information on concurrent use of CAB-LA with other PrEP products, see Switching Between PrEP Methods and Simultaneous Use section below.

Clients who receive TB preventative treatment with once-weekly Rifapentine-Isoniazid for 12 weeks (also known as 3HP) should temporarily discontinue CAB-LA for the duration of their Rifapentine use. Clients can restart CAB-LA two weeks after completing 3HP.

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<sup>4</sup> Grinsztejn B, Hanscom B, Wang Z, Donnell D, Richardson P, Sullivan P, et al. Transgender women (TGW) in HPTN 083: an evaluation of safety, efficacy, and gender affirming hormonal therapy (GAHT) interactions with long-acting cabotegravir (CAB-LA) [abstract]. 24<sup>th</sup> International AIDS Conference; 2022 Jul 29 – Aug 2; Montreal, Canada. Available from: <https://programme.aids2022.org/Abstract/Abstract/?abstractid=12707>.



#### 4.3.6. Contraindications for CAB-LA Use

CAB-LA should **not** be provided to people with:

- Unknown HIV status
- An HIV-positive test result according to the national HIV testing algorithm
- Potential exposure to HIV in the past 72 hours (these clients should be offered PEP)
- Signs of AHI (Box 1)
- Some co-administered anticonvulsants or antimycobacterials (see the CAB-LA and Other Drug Interactions section above)
- Unwillingness or inability to commit to effectively using CAB-LA
- Allergic or hypersensitivity reaction(s) with previous use of CAB or other integrase inhibitor medications
- Signs of hepatotoxicity and depressive disorders
- Viral hepatitis infection (HBV, HCV)

#### 4.3.7. Starting CAB-LA

CAB-LA can be given by providers in nationally approved health facilities. The injection requires a 23-gauge, 1.5-inch (3.8-cm) injection needle, though a client's build should be considered to select an appropriate needle length. The provider can position the client on their side, in a prone position, or in another position comfortable for the client, and should clean the injection site on the gluteal muscle on the side. It is best to inject the medication as soon as possible once the injection site has been cleaned, though the medication can remain in the syringe for up to two hours. If that time limit is exceeded, discard the medicine, syringe, and needle; do not attempt to keep the medicine fresh by refrigerating it. After the injection, the provider can use dry gauze to apply gentle pressure to the puncture site and, if needed or requested by the client, apply an adhesive bandage.

After the client receives initiation injection #1, providers should schedule the next visit for initiation injection #2, 30 days from the date of the first injection. After the first two injections, visits for follow-up injections should be scheduled every 60 days

#### Box 3. Injection Visit Scheduling

**For consideration:** The United States Food and Drug Administration Aprelude Label includes recommendations for injection visit scheduling. When scheduling administration of the first injection, providers should consider the date of the first injection as Day 0. The second injection should be scheduled 30 days, on approximately Day 30. There is a +/- 7-day window for receiving the second injection. Once injections 1 and 2 have been completed, follow-up visits should be scheduled beginning 60 days after the second injection and every 60 days after each follow-up injection. There is a +/- 7-day window for receiving follow-up injections.

60 days with continuing follow-up injections every 60 days, and continued for as long as the client wants to remain on CAB-LA and has potential exposures to HIV



### 4.3.8. Discontinuation of CAB-LA

CAB-LA may be discontinued if a client is no longer at risk and should be offered other HIV prevention strategies. The amount of Cabotegravir in the blood remains at effective levels for at least 60 days after the final injection.<sup>5</sup> The “tail period,” (see Figure 9) refers to the time period beginning 60 days after the final injection and continuing for approximately 12 months, when plasma drug concentrations are in terminal decline.

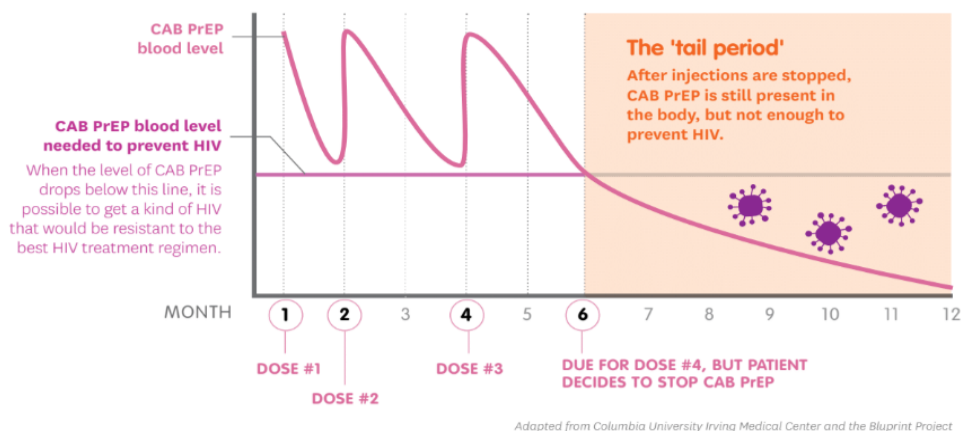


Figure 9: CAB-LA “Tail Period”

The “tail period” can last for up to 12 months, but this time frame varies for people based on gender. Data on HIV acquisition during the tail period is limited. However, it is important to note that as CAB-LA concentrations continue to decrease after a final injection, protection against HIV acquisition eventually wanes, even though non-protective concentrations may persist for some interval. It is during this period that there is a theoretical increased risk for HIV acquisition in the presence of persistent CAB-LA concentrations, which may be inadequate to suppress replication, and the risk of resistance to the drug increases. 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 healthcare 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.

### 4.3.9. Missing an Injection

Adherence to the injection schedule is important for effective use of CAB-LA. A client who misses an injection should contact their healthcare provider immediately to get advice about how to continue using CAB-LA for PrEP or to talk about switching to a different HIV prevention strategy, which may include using another PrEP method. To determine whether a client who is on CAB-LA and has missed a reinjection appointment should receive their next injection or receive PEP, consult 7040.

<sup>5</sup> Landovitz RJ, Li S, Grinsztejn B, Dawood H, Liu AY, Magnus M, et al. Safety, tolerability, and pharmacokinetics of long acting injectable cabotegravir in low-risk HIV uninfected individuals: HPTN 077, a phase 2a randomized controlled trial. PLoS Med. 2018 Nov 8;15(11):e10026900.



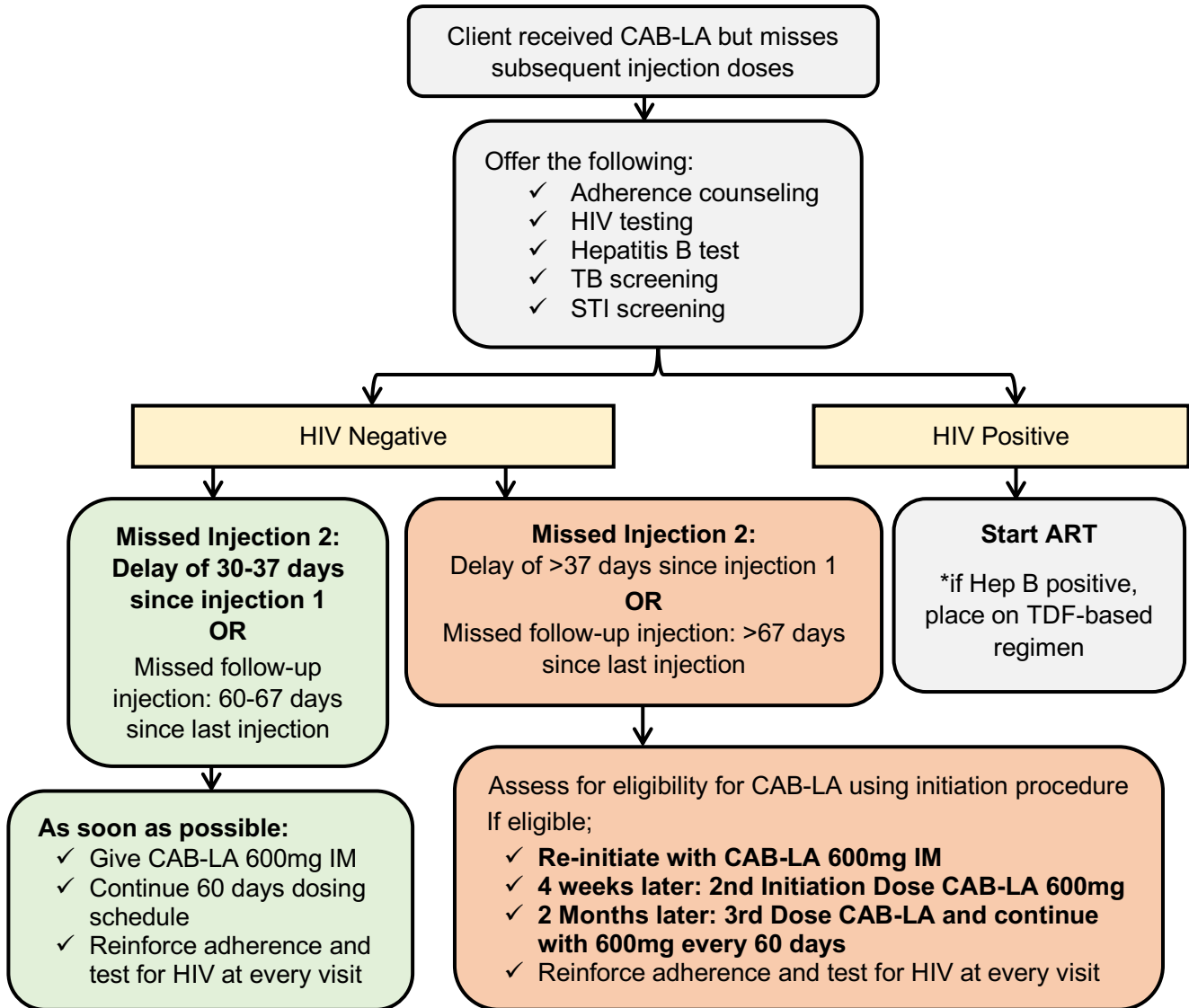


Figure 10: Algorithm for Clients who miss Scheduled CAB-LA Injection



#### Box 4. Injection Dosing Recommendations after Missed Injections

**For consideration:** At the time of writing, WHO does not have guidance on missing injections and does not make recommendations about when a client taking PrEP should be considered discontinued or what procedures are required for restarting someone on PrEP once they have discontinued. If the client does not want to continue Injectable PrEP (CAB-LA), providers should support clients by counseling them on alternative PrEP methods or another HIV prevention strategy if the client is still potentially exposed to HIV while choosing to stop CAB-LA use. The following are potential scenarios adapted from the [United States Food and Drug Administration Apretude Label](#) for those clients who miss injection visits, based on the length of time between injections:

##### Injection Dosing Recommendations after Missed Injections

Missed injection type	Time since last injection	Recommended action for provider
Initiation Injection 2	30 days since initiation injection 1	Proceed with initiation injection 2 and schedule the re-injection for 60 days later as a follow-up visit
	> 37 days since initiation injection 1	Assess the client for contraindications for CAB-LA using the initiation procedure and, if contraindications are absent, seek clinical expert opinion or call toll free 7040
Re-injection	67 days since last re-injection	Proceed with administering re-injection that day and schedule the subsequent re-injection for 60 days later as a follow-up visit
	> 67 days since last injection  *For the +/- 7-day window for receiving follow-up injections, refer to Box 3 on Injection Visit Scheduling	Assess the client for contraindications for CAB-LA using the initiation procedure and, if contraindications are absent, seek clinical expert opinion or call toll free 7040





#### 4.3.10. Restarting CAB-LA

Clients who may have stopped CAB-LA and wish to restart should be initiated on CAB-LA as per guidelines. Elicit reasons why the client had discontinued CAB-LA, and if no contraindications, readminister initiation injection 1 and schedule initiation injection 2 in 30 days. Thereafter, schedule as outlined in the Starting CAB-LA section above.

**For consideration:** For clients who have stopped CAB-LA, the clinical management of restarting them may vary based on how much time has passed since a client's last injection. Providers can refer to the injection dosing recommendations after the missed injections table outlined in the green box above.

#### 4.3.11. Switching Between PrEP Methods and Simultaneous Use

Clients may choose to switch between PrEP methods. Whatever the choice, using the chosen PrEP method in a way that is effectively prophylactic (as frequently as directed and for as long as is needed to cover periods of potential exposure) is important to optimize effectiveness of the method.

Safety and efficacy data on using more than one PrEP method at a time is limited and does not exist for some PrEP methods. Moreover, the use of multiple methods concurrently may not result in any advantage and is not likely to be well-tolerated compared to the use of each method individually.

##### **Switching from Oral PrEP to injectable**

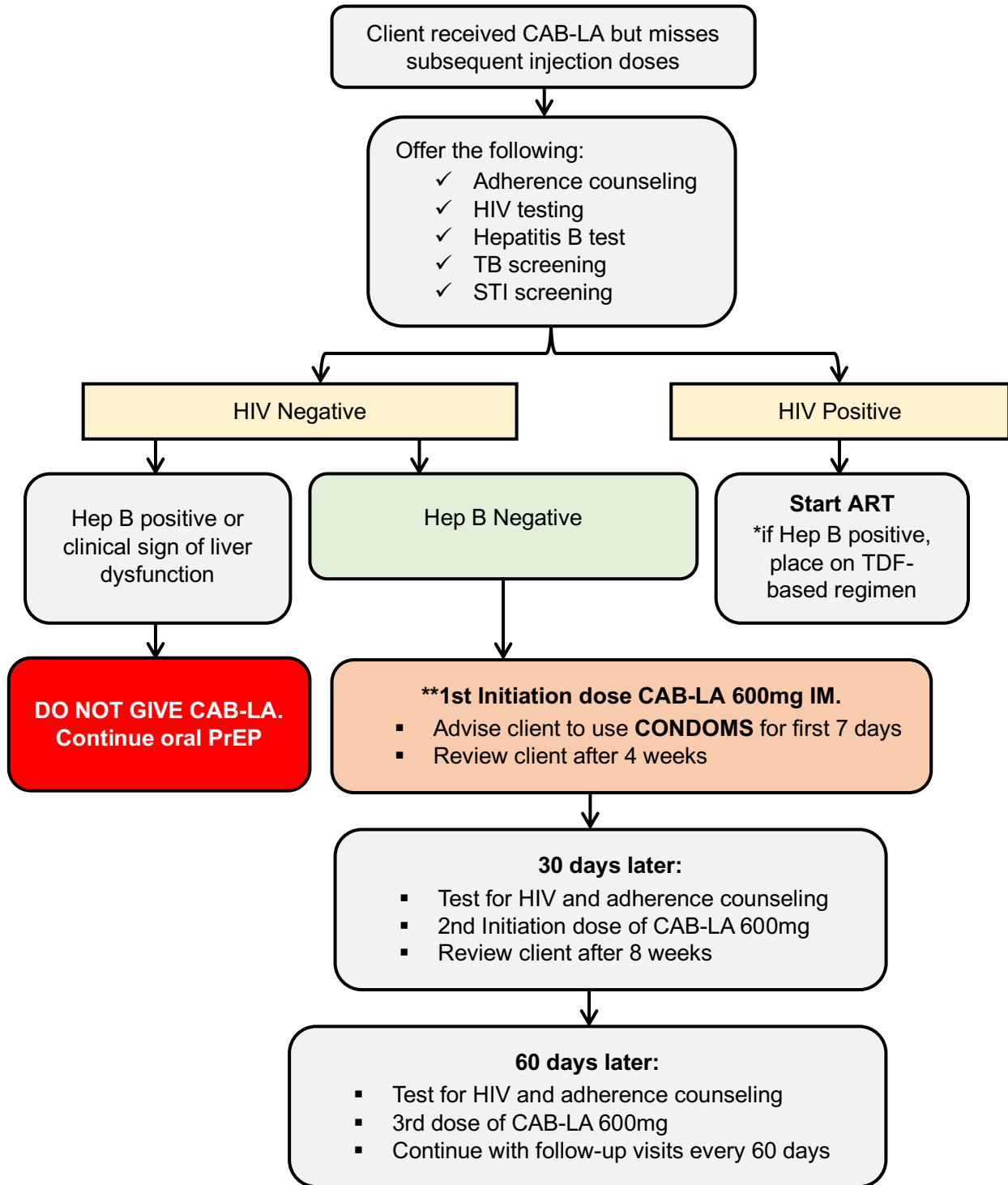
Client desiring to switch from oral PrEP to other injectable PrEP modalities should ensure the following.

- HIV test according to the National testing algorithm
- All clients are screened for AHI, pregnancy, HBV and other STIs
- Clients can be switched to the preferred method immediately while using barrier methods for at least 7 days to allow for protective levels to be reached

For instructions on switching between daily oral PrEP, see Oral PrEP Use above.

**For consideration:** The process for switching between PrEP methods will depend on the methods being used. When advising clients on switching between PrEP methods, providers should use their best clinical judgment, considering the time to effectiveness/waning effectiveness of each PrEP method after discontinuation, coverage of previous and future potential exposures to HIV, and client preferences.





\*If a woman is diagnosed pregnant, she cannot be transitioned to CAB-LA and should continue with oral PrEP

\*\*If a client is on 3HP, ensure they complete their course of 3HP whilst on oral PrEP. CAB-LA can be considered after completion of 3HP

Figure 11: Algorithm for Clients on oral PrEP Transitioning to CAB-LA



#### 4.3.12. Switching from Injectable PrEP (CAB-LA) to Oral PrEP

When switching from CAB-LA to oral PrEP (TDF+FTC) and if the client remains at high risk of HIV acquisition, it is recommended that the client should start taking the oral PrEP 8 weeks from the last injection. For clients who have only received the 1<sup>st</sup> injection, they should start taking oral PrEP 4 weeks after the injection.

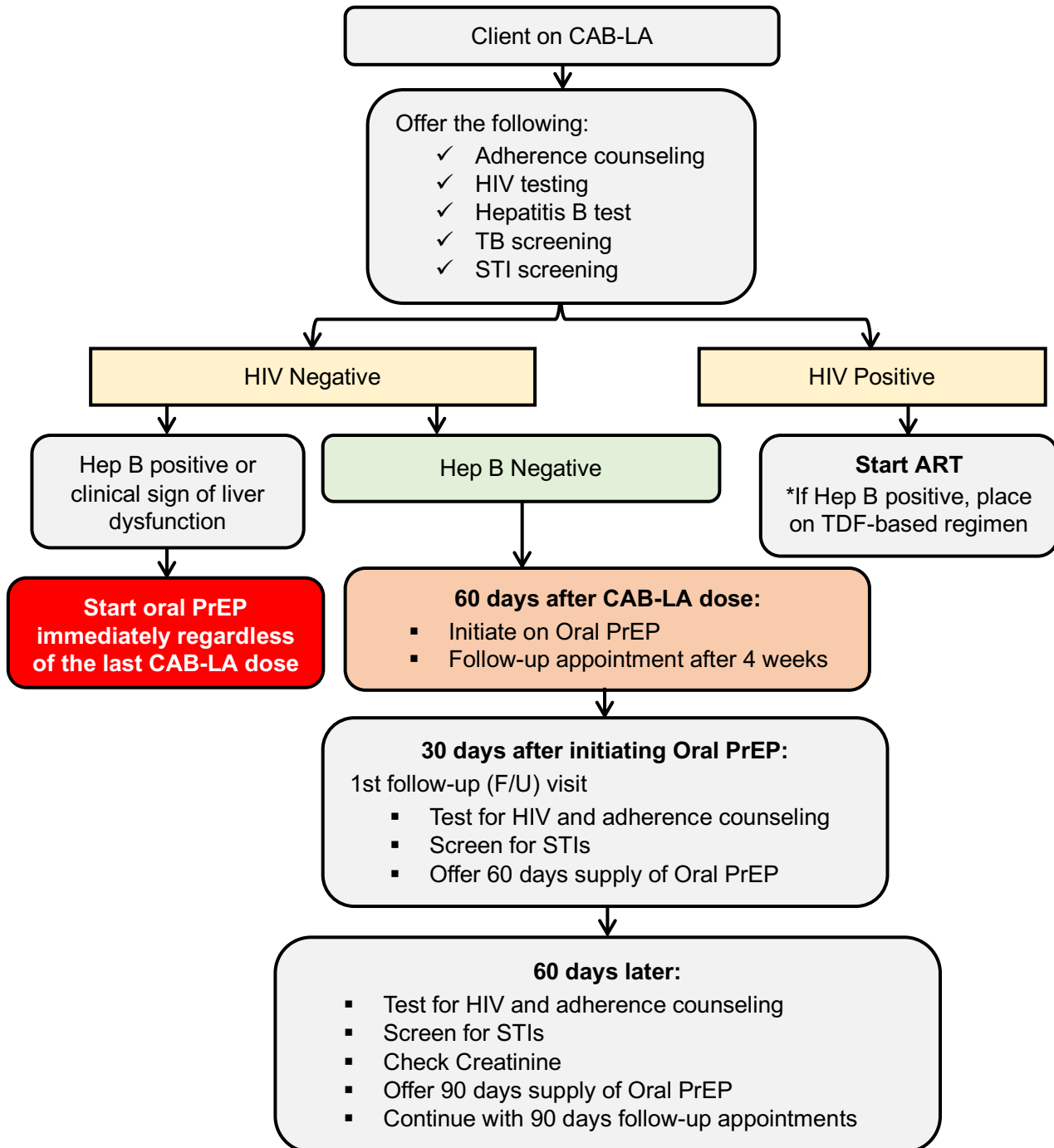


Figure 12: Algorithm for Clients on CAB-LA Transitioning to Oral PrEP

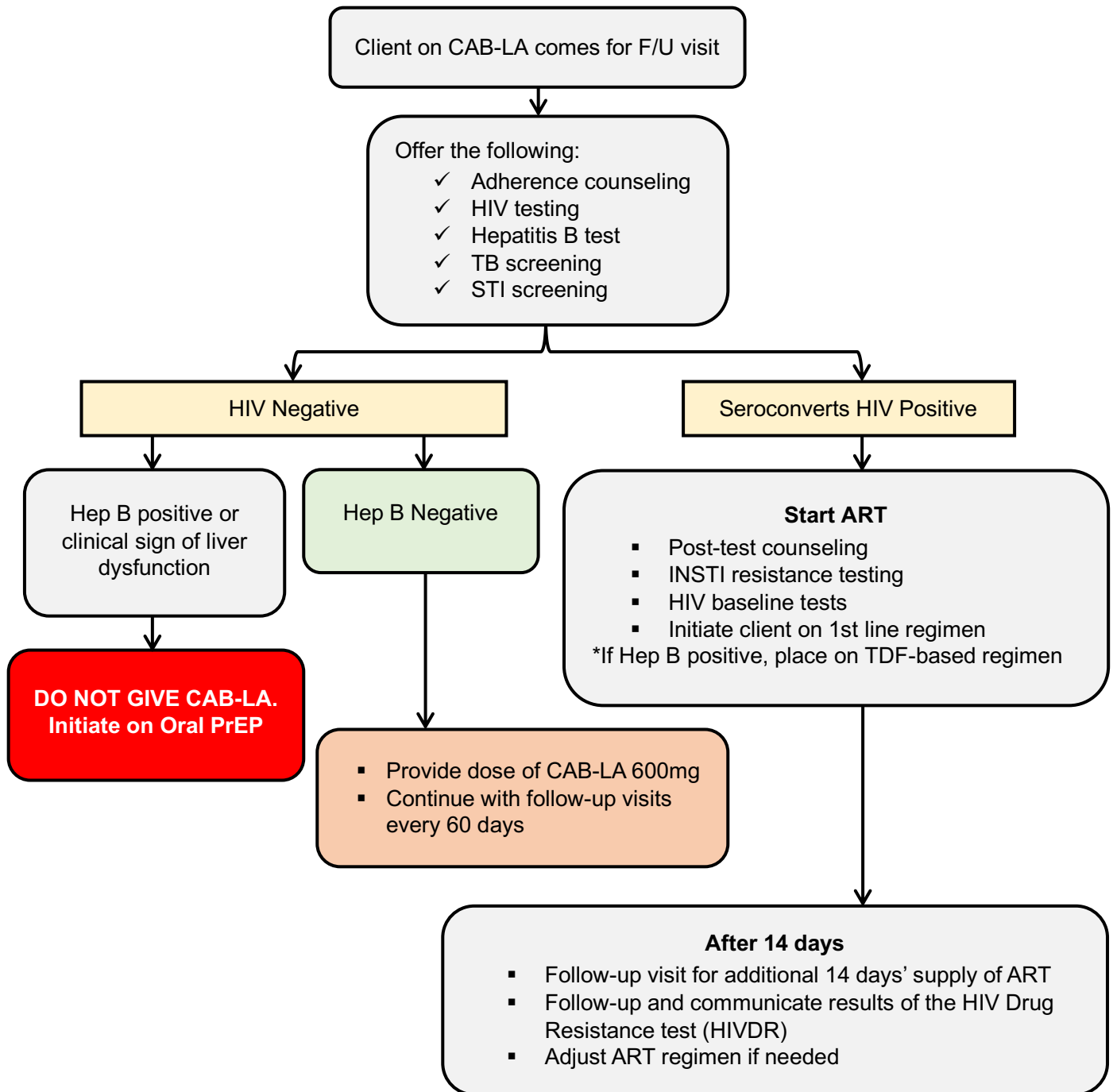


Figure 13: Algorithm for Clients who HIV-Seroconvert while on CAB-LA



### 4.3.13. Clients who Seroconvert while on CAB-LA

If a client seroconverts while on PrEP:

- Discontinue PrEP use immediately
- Confirm using national testing algorithm
- Immediately link to care and initiate on ART (per national ART guidelines)
- **Document** seroconversion and possible reason for seroconversion (non-effective use, stopped taking PrEP, or PrEP failure, i.e., breakthrough HIV while adherent to PrEP)
- Collect blood sample for INSTI resistance

**Comparing PEP and Oral PrEP:** While PEP is taken for exactly 28 days and used after (post-) exposure, PrEP can be taken for shorter or longer periods of time and is used before (pre-) exposure to prevent acquisition of HIV.

Table 8: Comparing PEP to PrEP

	Use	Dosage (adults and adolescents ≥ 30kg)	Duration
<b>PEP</b>	To prevent acquisition of HIV within 72 hours after potential exposure	Three-drug regimen preferred: <b>Tenofovir 300mg (TDF) + Lamivudine 300mg (3TC) + Dolutegravir 50mg (DTG)</b>  If DTG is not available or contraindicated, refer to Integrated HIV Management Guidelines	Take daily for 28 days following potential exposure
<b>Oral PrEP</b>	To prevent acquisition of HIV before exposure to the virus and is for daily use	Fixed-dose combination recommended: <b>TDF 300mg + 3TC 300mg</b>	For daily use: Take one pill daily starting at least 7 days prior to period of potential exposure and continue for at least 7 days after last potential exposure.



#### 4.4. 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 (NNRTI), 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 *1) are unable to use other PrEP options or 2) do not want to use other PrEP options or 3) when other PrEP options are not available or 4) in addition to other prevention methods*. **Therefore, the use of the Dapivirine Vaginal Ring (DVR) must be under the guidance of healthcare experts and must not be the first choice or option unless under the criteria set above.** 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.

##### 4.4.1. Potential Side Effects of the PrEP Ring

Possible side effects of the ring are typically mild and include:

- Urinary tract infections (UTIs)
- Vaginal discharge
- Vulvar itching
- Pelvic and lower abdominal pain

These side effects usually occur during the first month of use and resolve without the need to remove the ring. Clients using the ring should be counseled on possible side effects and advised to contact their health care provider if they experience any urinary or reproductive tract changes, because these could be a sign of an STI or UTI needing treatment.

##### 4.4.2. PrEP Ring and other Drug Interactions

There are currently no data on concurrent use of vaginally administered antimicrobial products for vulvovaginal infections and the PrEP ring; therefore, concomitant use is not recommended.

Evaluations of co-administered use of Miconazole and the ring have not been fully resolved, and clients should be advised to use additional preventative measure for HIV when co-treated with vaginal Miconazole.



Co-administration of Clotrimazole as a water-based vaginal cream with the ring was well-tolerated; however, given methodological issues that limit the reliability of the pharmacokinetic results of both clotrimazole and Dapivirine, concurrent use should be undertaken with caution.

Because there are no data on concomitant use of the ring and Metronidazole or Clindamycin, and no current data on concomitant use of the ring and other vaginal rings (contraceptive rings or diaphragms), concurrent use is not recommended.

There are no known interactions between Dapivirine and contraceptive hormones, hormones used for gender-affirming hormone therapy, alcohol, or recreational drugs. However, if a client or potential client thinks their use of alcohol or other substances is interfering or may interfere with effective use of the ring, the provider should engage the client to understand what support or referrals might be valuable to support effective use while also discussing additional prevention options, including other PrEP methods and the use of condoms and condom-compatible lubricant.

#### 4.4.3. Contraindications for PrEP Ring Use

The ring should not be provided to people with:

- An HIV-positive test result according to the national HIV testing algorithm
- Potential exposure to HIV in the past 72 hours (these clients should be offered PEP)
- Signs of AHI (Box 1) *AND potential exposure within the past 14 days*
- Unwillingness or inability to commit to effectively using the ring and attending scheduled follow-up visits
- Allergy or hypersensitivity to active substance or other substances listed in the product information sheet

#### 4.4.4. PrEP Ring Insertion and Removal

##### Inserting the PrEP Ring

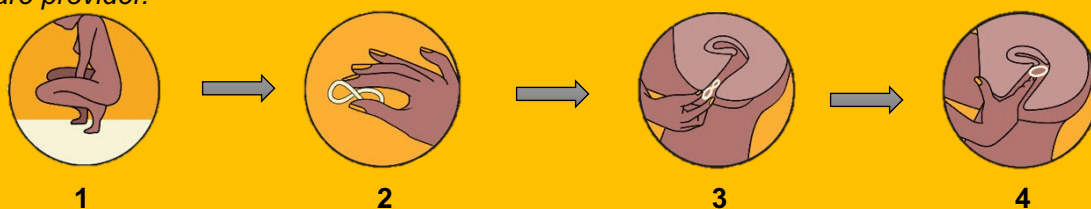
Clients should be given initial information, demonstration and support on ring insertion and removal, and once confident, clients can continue to use the ring on their own. Some clients are comfortable using the ring on their own with minimal support from their first use. However, for clients who prefer 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 are listed in Box 5.



## Box 5: 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.*



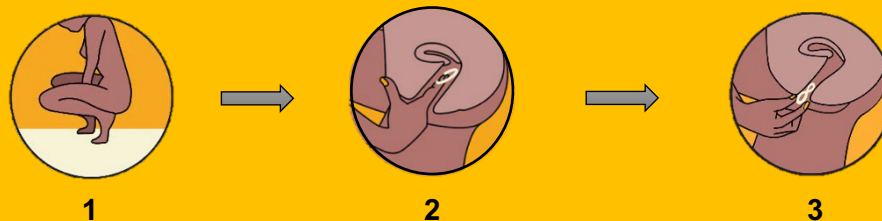
## Removing the PrEP Ring

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 in Box 6.

## Box 6: 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.*





#### 4.4.5. Switching from the PrEP Ring to other PrEP Options

Table 9: Switching Between PrEP Options

PrEP ring to Oral PrEP	PrEP ring to CAB-LA
<ul style="list-style-type: none"> <li>• After removal of the ring, the client should take oral PrEP for at least 7 days before a potential exposure</li> <li>• If the client is to have sex before taking oral PrEP for at least 7 days, they should:               <ul style="list-style-type: none"> <li>○ Use a condom for at least 7 days after removal of the ring, * or</li> <li>○ Take oral PrEP for at least 7 days before removal of the ring</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• 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</li> <li>• If the client is to have sex within 7 days of removing the ring and receiving a CAB-LA injection, they should:               <ul style="list-style-type: none"> <li>○ Use a condom for at least 7 days after removal of the ring, *or</li> <li>○ Get a CAB-LA injection 7 days</li> <li>○ before removal of the ring</li> </ul> </li> </ul>
<p>* 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.</p>	



## Chapter 5: Differentiated PrEP Service Delivery

Service delivery options may also influence client PrEP choices. Through Differentiated Service Delivery (DSD) models, PrEP services should be tailored to respond to specific challenges or barriers faced by clients and aim to offer high quality care, client satisfaction and improved health outcomes. The DSD models seek to adapt timing, location, nature, and content of services to reduce burden and maximise effectiveness, while improving the efficiencies of the health system. By providing differentiated care, the health system can reallocate resources to those most in need. This differentiated PrEP delivery supports comprehensive, person-centred services, adapting them to the needs and preferences of the people who could benefit from PrEP, and supports uptake, continuation and effective use. To ensure increased PrEP coverage, service provision should be de-medicalised.

A standardized framework for differentiated PrEP service delivery encompasses four key elements: service location (where), service provider (who), service frequency (when), and service package (what). These elements can vary depending on the stage of PrEP treatment (initiation, continuation, or re-initiation) and the specific PrEP products being used. The following models will be employed for PrEP Differentiated Service Delivery (DSD). See [Table 10](#) below.



Table 10: WHO Framework for Differentiated PrEP Service Delivery<sup>6</sup>

Building block	PrEP initiation, initial follow-up (0-3 months) and re-initiation			PrEP Continuation (3+ months)	
	Initiation	Initial follow-up (0–3 months) if required	Re-initiation after discontinuation	PrEP refill	Follow-up
<b>Where?</b> Service location (e.g., primary healthcare facility, community setting, virtual setting)	Locations for PrEP assessment and initiation	Locations for initial follow-up	Locations for PrEP re-initiation	Locations where PrEP refills can be collected	Locations where follow-up services will be provided
<b>Who?</b> Service provider (e.g., physician, nurse, pharmacist, peer)	Service provider(s) authorized to assess for and initiate PrEP	Service providers who can carry out initial follow-up visit(s)	Service provider(s) authorized to re-initiate PrEP	Service provider(s) who can dispense PrEP refills	Service provider(s) who conduct follow-up
<b>When?</b> Service frequency (e.g., monthly, every 3 months)	Timing of PrEP assessment and initiation	Timing of initial follow-up	Timing of PrEP re-initiation	Frequency of PrEP refill visits (length of supply)	Frequency of follow-up services
<b>What?</b> Service package (including HIV testing, clinical monitoring, PrEP prescription and dispensing, and comprehensive services)	Service package for PrEP assessment and initiation	Service package at initial follow-up	Service package for PrEP re-initiation	Service package with PrEP refill	Service package with follow-up

<sup>6</sup> Adapted from the International AIDS Society Framework for Differentiated Service Delivery (61)



**WHERE:** Facilities offering PrEP should meet a minimum required level of service delivery. Although PrEP constitutes antiretroviral medication, PrEP care and treatment can be given in non-ART sites including community and mobile models of service deliveries. PrEP service delivery should include both facility and community models of service.

Many providers now have experience providing oral PrEP outside of clinic settings. Oral PrEP can be accessed through a range of services, including:

- Services for HTS, ART, VMMC, STIs, YFS and sexual and reproductive health
- Antenatal and postnatal care (MNCH) and primary health care
- Community and mobile service delivery models including community posts/safe spaces

Injectable PrEP should be integrated in existing services that reach populations at risk. Facilities must offer relevant services including HIV and STI testing, ART, MNCH, VMMC, OPD and family planning, and must have access to laboratory services and have follow-up capabilities. Delivery of CAB-LA should be flexible and differentiated with services available in health facilities and the community in areas that do not instil discrimination against clients.

WHO: The human resources required for PrEP services must undergo PrEP training and satisfy requirements of PrEP service delivery. These may include nurses and midwives, clinical officers, medical licentiates, medical officers, and specialists. Others may include pharmacists, pharmacy support staff, counselors and community-based volunteers. Task sharing among a range of health care providers continues to play an increasingly prominent role in the delivery of PrEP.

Differentiated PrEP service delivery is an approach that prioritizes the needs of individuals and communities at high risk of acquiring HIV while minimizing the strain on the healthcare system. By simplifying and adapting PrEP services, this client-centered approach aims to enhance accessibility and acceptability, as well as support PrEP uptake, persistence, and effective utilization.

### 5.1. Multi-Month Dispensation for PrEP

The Multi Month Dispensation (MMD) model is designed for established PrEP users who have been on oral PrEP for more than three months and can commit to regular follow-ups. During a three-month visit, users receive a three-month supply of oral PrEP medication. Screening for acute HIV infection, STI HIV testing, and adherence assessments are conducted at each visit. The MMD model offers convenience, improved adherence, and reduced healthcare burden. It can be applied to all PrEP options and enhances the delivery and effectiveness of PrEP service.

### 5.2. Community PrEP Delivery Points

Community PrEP delivery points are static locations in the community with the necessary infrastructure and testing capacity to offer PrEP services. They are connected to health facilities for oversight, commodity and data management. These delivery points ensure convenient access to PrEP, provide comprehensive services and facilitate the monitoring of PrEP users. They play a crucial role in expanding PrEP access, reducing HIV transmission, and improving health outcomes. This model is applicable for oral, injectable and other PrEP options.



### 5.3. Mobile Community PrEP Delivery

Mobile Community PrEP delivery model is an innovative approach that brings PrEP services close to individuals using mobile clinics or vehicles. The goal is to overcome barriers and increase access to PrEP for populations facing challenges in conventional healthcare settings. Mobile teams travel to different locations, such as markets and community centers, where they set up temporary clinics equipped with necessary medical supplies. These clinics offer HIV testing, PrEP dispensation, counseling support, education, and monitoring. Trained healthcare professionals address the specific needs of the community being served. The aim is to reach individuals at higher risk of HIV infection who may have limited access to healthcare due to factors like transportation, stigma, or lack of awareness.

### 5.4. PrEP Home/Community Delivery

PrEP Home/Community Delivery: refers to a healthcare strategy that aims to provide Pre-Exposure Prophylaxis (PrEP) medication directly to individuals in their homes or community settings. PrEP Home/Community Delivery takes a different approach by offering convenience and accessibility to individuals who may face barriers in accessing healthcare facilities.

- a. **Peer-Led Model:** In this model, trained community health workers deliver PrEP medication to individuals' homes or community-based locations. This can involve scheduled visits where the CHW brings the medication, provides education on proper usage, discusses potential side effects, and conducts necessary HIV tests and distributes other prevention commodities
- b. **Healthcare Worker Led:** in this model a trained healthcare worker PrEP provider delivers PrEP medication to individuals' homes or community-based location. comprehensive support services such as injection, adherence counseling, sexual health education, specimen collection, HIV testing, screening for acute HIV infection and regular follow-ups to monitor the individual's progress and address any concerns
- c. This model is particularly beneficial for people with mobility issues, transportation challenges, privacy concerns, or those residing in remote areas where access to healthcare services may be limited. By bringing PrEP directly to individuals' homes or community settings, this model targets to increase PrEP uptake, improve persistence, and enhance overall HIV prevention efforts

### 5.5. PrEP Pharmacy Delivery Model

A PrEP pharmacy delivery model refers to a system where pharmacies provide PrEP medications and related prevention services directly to individuals who require them for HIV prevention. The pharmacy in the community is linked to the public health facility for consultation, commodity support. The health facility will supply pre-packed PrEP drugs with details of the PrEP user to the pharmacy monthly. Prior to each dispensation, the pharmacy will screen for acute HIV infection and conduct the HIV test as per the national algorithm. This model is for oral PrEP.



## Chapter 6: Clinical Monitoring of a Client on PrEP

Clinical monitoring includes history and examination, as well as evaluation of adherence, side effects and relevant drug toxicities. This section addresses the clinical monitoring considerations that a healthcare worker should focus on as they provide either oral or long-acting injectable PrEP.

Table 11: PrEP Initial Check List

PrEP Initial Check List	
1	Assess HIV Status using Blood Rapid test
2	Assess substantial Risk of HIV acquisition
3	Provide PrEP information
4	Screen for Renal impairment
5	Screen for liver impairment and hepatitis B
6	Screen for signs of Acute HIV infection
7	Screen for pregnancy and other hormonal use
8	Screen for STI
9	Screen for IPV
10	Other oral and injectable PrEP considerations (TB Patients, clients on anti-convulsant, etc.)

Table 12: PrEP Follow-up Visit Check List

PrEP follow up Visit Check-List		1 month	Injectables (every 8 weeks after FU visit 1)	Oral PrEP (every 3 months after FU visit 1)
1	Assess HIV Status using Blood Rapid test	x	x	x
	Assess HIV Status using HIVST			x
2	Assess substantial Risk of HIV acquisition/Provide risk reduction counseling	x	x	x
3	Provide PrEP information	x	x	x
4	Screen for clinical signs of Renal impairment	x	x	x
5	Screen for Clinical signs of liver impairment and hepatitis	x	x	x
6	Screen for signs of Acute HIV infection	x	x	x
7	Screen for Pregnancy and other hormonal use	x	x	x
8	STI screening	x	x	x
9	Screen for IPV	x	x	x
10	Other oral and injectable PrEP considerations (TB Patients, clients on anticonvulsant drugs, etc.)	x	x	x



## Chapter 7: Laboratory Monitoring

This section addresses the laboratory monitoring considerations that a healthcare worker should focus on as they provide either oral or long-acting injectable PrEP

Table 13: Laboratory Monitoring of a Client on PrEP

Laboratory monitoring of a client on PrEP		Initiation	1 month	Injectables (every 60 days after FU visit 1)	Oral PrEP (every 90 days from FU visit 1)	At 12 Months
1	Assess HIV Status using Blood Rapid test	x	x	x	x	x
	Assess HIV Status using HIVST (optional)				x	
2	kidney function test using CrCl or urinalysis for oral PrEP (ref to clinical guidance)	x				x
3	Liver Function Test (ALT) for injectables	x				x
4	Hepatitis B (injectables)	x	x			x

### 7.1. Monitoring Toxicity and other Adverse Outcomes

Monitoring adverse outcomes such as seroconversions, drug-related toxicities, and HIV drug resistance in cases of PrEP failure is important for PrEP programmes to ensure the safety of their clients. Monitoring adverse events in most settings should also cover people who test HIV-positive after receiving PrEP, non-HIV seroconversion clinical events such as renal issues, and enhanced monitoring of pregnancy and birth outcomes among women who take PrEP during pregnancy. (See Chapter 7 for additional information.)

## Chapter 8: Monitoring, Evaluation and Learning (MEL)

To ensure that Zambia healthcare system is implementing high fidelity data-driven PEP and PrEP programs and service delivery, efforts will be made to put in place processes and systems to routinely track, collect, aggregate, and analyse data that are useful to monitor, evaluate and learn from the following aspects of the program namely: demand creation and service delivery, drug resistance monitoring and surveillance, pharmacovigilance monitoring and adverse events surveillance reporting including routine and active toxicity monitoring in addition to pregnancy and birth defects surveillance, as well as healthcare commodities logistics monitoring, data reporting and data use for program improvement, decision making and policy formulation.

Tracking and reporting on the incidents and magnitudes of occurrence of adverse outcomes amongst PEP and PrEP adopters and users in cases such as: HIV seroconversions, drug-related toxicities and HIV drug resistance in cases of PEP and PrEP failure are important for HIV program managers, decision and policy makers to have hard evidence to continue to ensure and assure the safety of clients or learn about the tipping points to make policy change. In most settings, monitoring adverse events in PrEP and PEP program would often cover both clients who test HIV-positive after receiving PEP or PrEP (i.e., HIV Seroconversion) as well as non-HIV seroconversion clinical events such as renal issues, and enhanced monitoring of pregnancy and birth outcomes among women who take PrEP during pregnancy as described in the preceding chapters of this guidelines i.e., under the laboratory and clinical monitoring for PEP and PrEP clients in Zambia.

This chapter i.e., the MER component shall therefore focus on outlining and describing the procedures, tools, data elements and indicators that will be tracked and reported to the sites, sub-national and national levels as required for monitoring, evaluation and learning (MEL) for PEP and PrEP programming. This will be in consistency with the 2022 National PrEP program M&E implementation plan.

### 8.1. Demand Creation and Service Delivery

The recently launched National PrEP program M&E implementation plan is a compendium that describes in detail the nature of the data management system and core and non-core data elements and indicators that all PrEP implementers in Zambia are encouraged to collect and report on for the purpose of harmonized reporting into the National HMIS and feeding into all local and international reporting obligations such as GAM, WHO Global PEP and PrEP reports. In summary, the implementation plan recommends that PrEP and PEP program data should be collected using the client-level as against an aggregated data management system and this should be in such a manner that allow for the understanding of the HIV PrEP Service Cascades whereby, data users are able to understand the areas with potential gaps in the cascades from the point of demand creation for the service to the point of exit from the program including the reason for exit. [Figure 14](#) below project the core indicators and their levels on the HIV PrEP cascade.





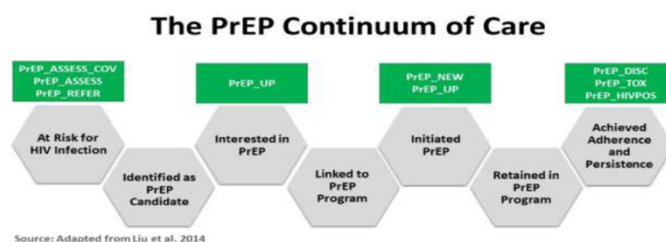


Figure 14: PrEP Continuum of Care and Core Indicators for National Level Reporting

## 8.2. Drug Resistance Monitoring and Surveillance

Data collected and obtained from the HIV Drug Resistance Monitoring (DRM) among PrEP users who have seroconverted, and understanding ways to reduce the risk of resistance, will help to ensure the long-term effectiveness of both PrEP and antiretroviral treatment options. Also important for resistance risk reduction is for PrEP users to adhere to PrEP medication and the HIV testing schedule, as per WHO and country guidelines. Drug Resistance testing is where the laboratories perform a resistance test using an approved genotyping assay that is validated for sequencing the HIV-1 reverse transcriptase and/or integrase gene, per laboratory standard operating procedures. PrEP clients who seroconvert will have 2 blood samples collected for drug resistance and baseline viral load. All information received by the testing laboratories will be recorded on both SmartCare and DISA system for computations. [Table 14](#) below outlines the standard procedures for identifying and reporting on PrEP drug resistance monitoring in Zambia.

Table 14: Standard Operating Procedure for Monitoring Drug Resistance in PrEP Clients who Seroconvert

Key Steps	Procedure(s)
Identify PrEP clients that seroconvert	<ol style="list-style-type: none"> <li>All PrEP Clients on a follow-up ARV refill visit must be tested for HIV before refill</li> <li>Site performs HIV test on all the client</li> <li>Site to determine the HIV test result for each client</li> </ol> <p>If result is HIV Negative and client willing to continue PrEP, he/she be refilled with ARV as appropriate (Oral or Injectables)</p> <p>If result is HIV Positive, client needs to be schedule for HIV DRM testing immediately</p>
Seroconverted PrEP client submit for DRM testing same-day	<ol style="list-style-type: none"> <li>Site collect blood sample from the HIV positive PrEP client for drug resistance testing on the same day the client gets a positive HIV test result using the modified National HIV Drug Resistance Form (NHIVDRF)</li> <li>Lab performs or send the sample for the drug resistance testing DR testing result is documented on the DISA and then sent to the site clinician and documented on SmartCare.</li> </ol>
Interpretation and use of the DRM testing results	<ol style="list-style-type: none"> <li>DRM testing results are interpreted by the clinician and discussed with the client on the next appointment visit</li> <li>Based on the DRM testing result, clinician will take the next clinical step as indicated in the consolidated national ARV guidelines</li> </ol>



### 8.3. Compilation and Use of DRM Testing Results/Data:

Each PrEP client who seroconverts will be tested for HIV drug resistance once at the time of identifying the seroconversion. The numerator (number of HIV seroconverts exhibiting HIV DR) and denominators (number of HIV seroconverts tested for HIV DR) would be summed over time (i.e., quarterly, or annual) to assess HIV DR rates. This can be further disaggregated by the type of PrEP (i.e., Oral or Injectables) being used by the HIV seroconvert. When combined with analyses of other programmatic factors that influences PrEP adherence and retention so that programs can better understand factors associated with resistance. Therefore, PrEP drug resistance monitoring may collect additional data on:

1. **Past PrEP or PEP use** - To monitor future risk for resistance related to previous PrEP use and for those that transition from PEP to PrEP, antiretroviral treatment registers or electronic medical records could record whether a client failing first line treatment was a PrEP and or PEP user in the past
2. **Communication of results to clients** - As part of high quality of care, programs should set a target for and measure how quickly test results are communicated back to clients
3. **PrEP stockout** - Stockouts of PrEP drugs always have a negative impact on client adherence, which may increase the risk of drug resistance. Programs should measure the total number of days per month any facility experiences a PrEP drug stockout
4. **HIV test stockout** (HIVST, Determine) - Stockouts of HIV tests are also important to measure due to the risk of drug resistance when PrEP is initiated or continued with a client who is already HIV infected. As with PrEP drug stock outs, the number of days a facility is without HIV tests should be measured
5. **Reasons for discontinuing PrEP**-Documenting reasons for discontinuing PrEP in HIV prevention programming is crucial for evaluating program effectiveness, improving service delivery, tailoring interventions, enhancing client care and retention, and contributing to research and policy development in the field of HIV prevention

All laboratory specimens and Laboratory data collection forms will be identified by coded number only to maintain participant confidentiality. Drug resistance analysis will be disaggregated by PrEP regimen (e.g., Oral and Injectable). In rare situations, a sample may be collected after ART initiation. In those cases, ART initiation dates and regimen will be collected, and results may be analysed separately. The proportion of clients with drug resistance who have detectable levels of the PrEP drug prescribed (TDF/TAF + XTC and/or CAB) will be estimated. Assessment of the presence of PrEP drugs associated with a different rate of resistance and analysed by the PrEP method.

It is important to consider the potential for HIV drug resistance in cases where there has been incomplete uptake of post-exposure prophylaxis (PEP), as well as in individuals who have repeatedly used PEP and are now transitioning to pre-exposure prophylaxis (PrEP) due to the recurrent use of PEP. Therefore, for the collection and use of HIV DRM testing data, we shall measure and report as HIVDRM testing cascade with each data element disaggregated by age-category, sex, Previous PEP use, and type of PrEP drug. The main data elements are:



1. # of HIV Seroconvert PrEP/PEP Users
2. # of HIV Seroconvert PrEP/PEP Users whose samples were drawn and submitted for HIV DRM testing
3. # of HIV Seroconvert PrEP/PEP Users whose sample sent with HIV DRM testing results
4. # of HIV Seroconvert PrEP/PEP Users with HIV DRM testing results resistant
5. % of HIV Seroconvert PrEP/PEP Users with HIV DRM testing results resistant

#### 8.4. Pharmacovigilance Monitoring and Adverse Events Reporting

The MoH has established a strong and robust HIV case-based surveillance system for Zambia. This system allows for documentation and tracking of clinical records of any individual (HIV positives on ART and HIV negatives on PrEP/PEP) in a way that allows for the addition of care and treatment events and outcomes over time covering the entire HIV prevention, care and treatment cascade.

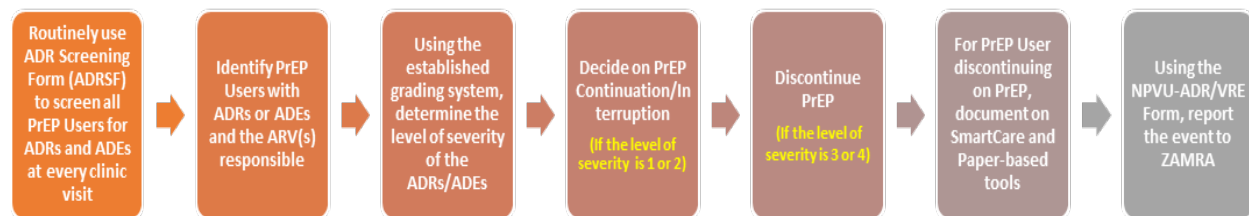


Figure 15: Standard Process flow for Implementing Pharmacovigilance Monitoring and Reporting at Site Level

Oral PrEP, CAB-LA and all emerging PrEP products used in Zambia will be monitored for safety including reporting on incidence of any adverse drug reactions (ADRs) and adverse drug events (ADEs) by using the Adverse Drug Reaction Screening Form (ADRSF) at every visit as needed for reporting issues of concern. The ADR Screening Form will use a scoring or grading method to make the screening more objective. Each client screened will be observed and scored by both a clinician and pharmacist. A 4-grade system – 1,2,3, and 4 will be adopted as follows:

1. **Grade 1 (Mild):** Transient or mild discomfort, no limitation of activity, no medical intervention/therapy required
2. **Grade 2 (Moderate):** Mild to moderate limitation in activity, some assistance may be needed, no or minimal medical intervention/therapy required
3. **Grade 3 (Severe):** Marked limitation in activity, some assistance usually required, medical intervention/therapy required, hospitalization possible
4. **Grade 4 (Life-threatening):** Extreme limitation in activity, significant assistance required, significant medical intervention/therapy required, hospitalization and hospice care

As an outcome of the PV screening process, each site is to determine if the PrEP user needs to discontinue on PrEP based on the levels of severity of the ADRs/ADEs identified. If the grade level is either 3 or 4, it is recommended that the PrEP user be discontinued on PrEP and that information is updated on the SmartCare and paper-based records including the reason(s) for Stopping PrEP. In addition to screening for ADRs and ADEs amongst PrEP users, each site needs to document cases of ADRs and ADEs and report same to ZAMRA by completing NPVU Adverse Drug or Vaccine Reaction/Event Form (NPVU-ADR/VREF - Appendix 2 of NPVU guidelines) in

line with the Guidelines for detecting and reporting adverse drug or vaccine reaction and event in Zambia (2006).

Measurements and use of data from pharmacovigilance (PV) process with each data elements disaggregated by age-category, sex, and type of PrEP drug:

1. # of PrEP/PEP Users reporting ADRs/ADEs
2. # of PrEP/PEP Users screened with ADRs/ADEs
3. # of PrEP/PEP Users with ADRs/ADEs with level of severity Grade 3 and 4 discontinued on PrEP use
4. % of PrEP/PEP Users with ADRs/ADEs with level of severity Grade 3 and 4 discontinued on PrEP use (PrEP/PEP\_TOX)

### 8.5. Routine Toxicity Monitoring

Many people experience minor symptoms within 2–4 weeks of starting PEP and or PrEP. These often disappear with time and usually can be managed by counseling prior to and during the early stages of starting PrEP or PEP. Monitoring these mild adverse events is useful for patient monitoring at a site level, but likely will not need to be reported to the sub-national or national level. Serious toxicity associated with PrEP is expected to be low. However, experience with large-scale PrEP programmes and longer exposure has been limited. Therefore, as PrEP programmes scale up, it is important to integrate PrEP monitoring with existing routine HIV patient monitoring systems which should capture serious ARV associated toxicities as part of the national health M&E system. With this approach, only ADRs and ADEs that continue beyond the 4 weeks threshold and with level of severity in the grade 3 or 4 will be recommended for discontinuation on PrEP. Routine monitoring tools such as PrEP registers should be used for reporting PrEP-related toxicities.

### 8.6. Active Toxicity Monitoring

Active toxicity surveillance through a variety of approaches is recommended to complement routine toxicity monitoring. For active reporting, serious adverse drug reactions are defined as those that lead to the interruption or discontinuation of oral or injectable PrEP such as impaired kidney function, toxicity and other serious side-effects. Programs providing PrEP should follow the standard process flow of implementing Pharmacovigilance (see [Figure 16](#) above) for discontinuation and interruption of PrEP in order to monitor both the number of discontinuations and the reasons for it.

At the site level, any toxicity-associated event should be followed up with standardized clinical management protocols, and data should be reported to ZAMRA using the NPVU Adverse Drug or Vaccine Reaction/Event Form. The analysis of overall rates of drug-associated toxicities should be analysed at the national level, as the frequencies are likely to be too small to have significance at the individual site level. Ultimately, data on drug-related toxicity should be harmonized and pooled from several sites in order to produce evidence at a larger scale to inform policy decisions and direction.



### 8.6.1. Pregnancy and Birth and Defects Surveillance

The monitoring of HIV status and pregnancy outcomes is a critically important aspect of safety monitoring, both for women who become pregnant while on PrEP or who initiate PrEP while pregnant or breastfeeding and for their infants. Pregnancies exposed to PrEP in any trimester (first, second or third) should be followed. The first trimester is critical to organ development, and additional drug safety data would provide confidence about the level of risk, if any. Adverse maternal and birth outcomes among pregnancies exposed to PrEP should be collected through active toxicity monitoring (See section 7.3.2 above), birth defect surveillance and pregnancy registries extended to include 18-month-old infants and mother–infant pairs during breastfeeding.

### 8.7. Healthcare Commodities Logistics Monitoring

Achieving effective and seamless healthcare service delivery relies heavily on a secure healthcare commodities supply chain. Proper Procurements and Supply Chain Management Systems (PSCMS) must align with PrEP and PEP service modalities. Routine data collection including LMIS data is vital, ensuring constant restocking of HIV testing kits, STI screening tools, and necessary ARVs in oral and injectable forms at both community and facility-based sites.

For oral and injectable PrEP, this guideline therefore recommends that at each site level, data on monthly PrEP commodities consumption patterns need to be collected and used in forecasting the needs for the new months and quarters. For example, it's important to know the following:

Data Element	Data Source
# of new PrEP Users (PrEP_NEW)	PrEP register
# of PrEP Users restarting PrEP	
# of PrEP Users continuing on PrEP by type (Oral and Injectables) (PrEP_CT)	
# of PrEP Users discontinuing on PrEP by type (Oral and Injectables)	
# of PrEP Users switching from Oral to Injectables	
# of PrEP Users switching from Injectable to Oral	
# of PEP users	PEP register
# of PEP users switching to PrEP by Type (Oral and Injectables)	
Volume of PrEP dispensed by type of PrEP (Oral and Injectables)	Primary source Pharmacovigilance records Secondary sources PrEP/PEP registers
Volume of PrEP commodity on the stock balance by type of PrEP (Oral and Injectables)	
Volume of PEP dispensed	



This guideline recommends the roll-out and use of healthcare commodity report and requisition (RR) Form for PrEP in all sites. Therefore, for each site to accurately compute their monthly need, they need to utilize the data elements highlighted above in arriving at the consumption need factoring, utilization, wastages, and stock adjustments. For example, every client being initiated on CAB-LA injectables, at least 6 vials of the LA-injectable should be reserved to complete the course of 1 year prophylaxis at the minimum. This then follows that the Supply Chain Management System (SCMS) to be put in place at the site level should be such that it takes cognizance of the deductible system for calculating the balance of stocks.

## 8.8. Data Reporting and Use

This section outlines methods for documenting and monitoring PrEP service delivery across different levels. Tools facilitate data aggregation, ensuring timely interventions and safe PrEP usage. Records should encompass regular counseling on adherence, HIV risk, contraception, and sexual health, guaranteeing effective and secure PrEP usage.

Gender-responsive M&E will be adopted to measure and evaluate gender-related changes over time, showing how far and in what ways the gender equity objectives are being achieved. The following disaggregation will be considered in collecting and analyzing PrEP data at all levels:

1. **Sex disaggregation** pertain to only women or only men, or subgroups among them
2. **Age-category disaggregation** - measure differences in relation to a particular age-bands (e.g., 16-19yrs, 20-24 yrs, etc)
3. **Disaggregation by population subtypes** - measuring the difference in PrEP uptake and use by general, priority and key population sub-types (e.g., sero-discordance couples, Pregnant and Breastfeeding Women, AGYW, ABYM and so on)

The Zambia National PrEP M&E implementation guide (2022) is a repository of a detailed list of PrEP indicators and standard data collection and reporting tools for PrEP service delivery programs in Zambia. These tools include the PrEP register, the initiation form, the follow-up form, SmartCare and so on (see annexes in the Zambia National PrEP M&E implementation guide (2022)). These are used to track individuals along the PrEP cascade to optimise PrEP service delivery. Therefore, all PrEP and PEP program managers should reference the national PrEP M&E guidelines (2022)



## 8.9. Data Use

Enhancing PrEP data quality and availability is crucial for program effectiveness. Utilising this data at all levels is vital for targeted interventions and understanding PrEP cascade gaps. Regular monitoring and evaluations, including qualitative methods, help measure program impact and identify barriers. A structured data analysis plan ensures effective use of this information in decision-making and policy planning.

Policymakers, program implementers, and clinicians will utilise routinely collected data to:

1. improve service delivery by identifying underserved populations
2. detect side effects promptly
3. estimate the cost
4. forecast the demand for PrEP and PEP to prevent stock out
5. ensure adequate financing
6. understand how PrEP can avert new HIV infections

The National PrEP Task Force shall continue to provide oversight of the PEP and PrEP M&E system. The MoH and NAC, along with the PrEP Task Force, will coordinate an annual report of PrEP provision across all PrEP service providers, to be coordinated in October of each year (in line with the end of the PEPFAR fiscal year).



## Annex 1: Managing PrEP Side Effects for Pregnant and Breastfeeding Clients

PrEP use is generally well-tolerated outside of and during pregnancy and the postnatal periods. However, some side effects are possible. The table below highlights side effects that may be related to PrEP use.

### Side Effects

Sign or symptom	Possible expected finding in pregnancy	Possible expected finding in postnatal period	Expected with some (not all) FP methods	May be related to PrEP	May be related to another condition such as:
Back pain	X	X			Back injury
Constipation	X				Iron pills
Nausea or vomiting	X		X	X	Foodborne illness
Diarrhoea				X	Foodborne illness
Mild abdominal pain or cramping	X (especially round ligament pain or heartburn)	X (uterine involution or post-cesarean pain)	X	X	Preterm contractions, foodborne illness
Vaginal discharge	X	X (if consistent with normal lochia)	X		Vaginitis or sexually transmitted infection
Frequent urination	X				Urinary tract infection
Dizziness	X		X	X	Anaemia, dehydration
Headache	X		X	X	Pre-eclampsia (serious complication of blood pressure)
Fatigue	X	X	X	X	Anaemia or depression, other possibilities
Sleep issues	X	X		X	Anxiety or depression
Abnormal kidney function tests (e.g., serum creatinine)				X	Pre-eclampsia

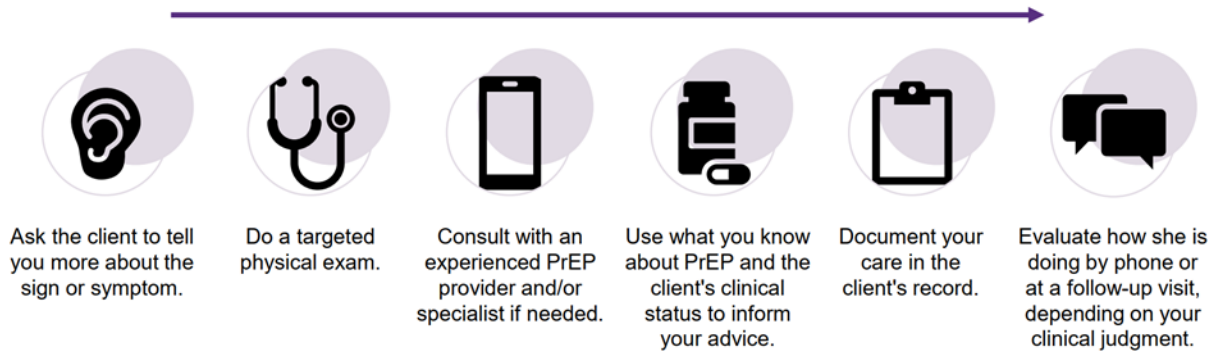




## Deciding Whether to Pause or Stop PrEP Use for PBFW

Before deciding to pause or stop PrEP use, it is important to consider whether or not there is

### Evaluating Potential Side Effects of PrEP



reasonable suspicion that a complaint was caused by PrEP use.

Clinicians can consider the following guiding questions

- What is the sign or symptoms noted by the client?
- Did the problem begin soon after the start of PrEP use?
- What is the sign or symptom noted by the client?
- If the client has already stopped PrEP use, has there been any improvement after stopping?
- Did the issue come back if the client stopped and restarted PrEP?
- Is the problem something that has been seen before in other people using PrEP?
- Is it plausible (does it make sense) that PrEP could have caused the problem?
- Is there any other explanation?



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<https://www.prepwatch.org/resources/guidance-standard-operating-procedures-for-addressing-partner-relationships-and-gender-based-violence-in-pre-exposure-prophylaxis-prep-services/>
- MOSAIC PrEP M&E indicator proposal. available on  
<https://www.prepwatch.org/resources/proposed-new-national-level-indicators-for-me-for-all-forms-of-prep/>
- RISE- Providing PrEP to Pregnant and Breastfeeding women- Training course

