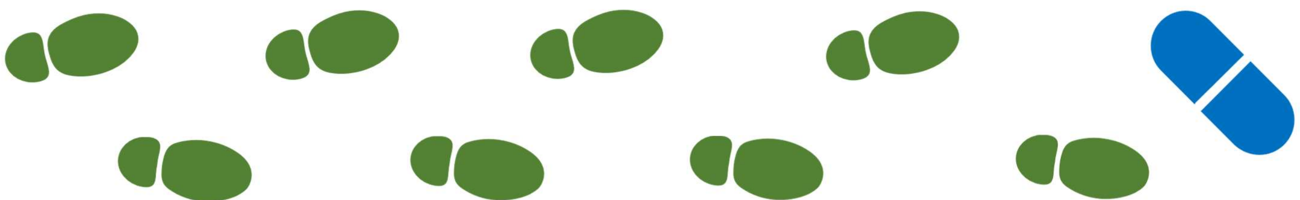
Step-by-Step with Oral PrEP

Using Oral Pre-exposure Prophylaxis for the Prevention of HIV in Liberia

August 2021

with addendum issued December 2021



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Acronyms and Abbreviations

3TC	Lamivudine
ADR	Adverse drug reaction
AHI	Acute HIV infection
AIDS	Acquired immune deficiency syndrome
AMC	Average monthly consumption
ARV	Antiretroviral
ART	Antiretroviral therapy
CrCl	Creatinine clearance
DIC	Drop-in center
ED-PrEP	Event-driven pre-exposure prophylaxis
FEFO	First expiry, first out
FSW	Female sex worker
FTC	Emtricitabine
GBV	Gender-based violence
GHSC-PSM	Global Health Supply Chain Program-Procurement and Supply Management
HIV	Human immunodeficiency virus
IBBSS	Integrated biological and behavioural surveillance survey
IEC	Information, education, and counseling
IPV	Intimate partner violence
KP	Key population
MOH	Ministry of Health
MSM	Men who have sex with men
NACP	National AIDS/STI Control Program
PEP	Post-exposure prophylaxis
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
RRHO	Resilient & Responsive Health Organizations
STI	Sexually transmitted infection
TDF	Tenofovir disoproxil fumarate
Trans	Transgender
USAID	United States Agency for International Development
WHO	World Health Organization

Acknowledgments

The *Step-by-Step with Oral PrEP* guidelines for the rollout of pre-exposure prophylaxis (PrEP) for the prevention of HIV among at-risk populations, including key populations, in Liberia was developed under the leadership of the National AIDS/STI Control Program (NACP) with support from the United States Agency for International Development (USAID) through the Meeting Targets and Maintaining Epidemic Control (EpiC) project. NACP is grateful to the oral PrEP task force for their hard work and technical input. The writing committee gratefully acknowledges the Collaboration for HIV Prevention Options to Control the Epidemic (CHOICE) consortium, a collaboration between the USAID-funded EpiC and Reaching Impact, Saturation, and Epidemic Control (RISE) projects, for making the guideline template available. Contributors include:

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National HIV Program Policy Statement

Liberia has made great progress in the HIV response, with about 19,000 people on life-saving antiretroviral therapy (ART) out of the estimated 40,000 living with the virus (Spectrum, 2020). Trends of new HIV infections have also reduced from 2,700 in 2010 to 1,900 in 2018. However, big gaps which fuel new infections and perpetuate risk still exist across a broad spectrum of the population. A 2018 Integrated Biological and Behavioural Surveillance Survey among key populations (KPs) in Liberia demonstrated that KPs are disproportionately affected by HIV and are a major driver of the HIV epidemic in our country. The IBBSS found an HIV prevalence of 37.9 percent among men who have sex with men (MSM), 27.6 percent among transgender (trans) people, 16.7 percent among female sex workers (FSWs), and 14.4 percent among people who inject drugs (PWID). Equally concerning is the high HIV prevalence among other priority populations, namely uniformed services (17.6 percent), transport workers (9.6 percent), prisoners (5.6 percent), mobile traders (3.8 percent), and miners (3 percent). In addition, national HIV program data from DHIS2 (2018–2019) showed consistently high HIV prevalence among both women (>8.5 percent) and men (~5 percent) older than 25 years. Therefore, preventing new HIV infections is a critical policy thrust of the Ministry of Health (MOH) and the National AIDS/STI Control Program (NACP).

Evidence abounds for the efficacy and effectiveness of oral PrEP for HIV prevention using the antiretrovirals (ARVs) oral tenofovir disoproxil fumarate (TDF) co-formulated with lamivudine (3TC) or emtricitabine (FTC) when taken in combination with other HIV prevention methods as appropriate for age and sex. Concerns about a potential increase in high-risk sexual behavior such as having sex without condoms, side effects of the PrEP drugs, and the development of drug resistance in cases of poor adherence have been allayed by the overriding benefits of oral PrEP at the population level. Emphasis on monitoring and regular education, including behavioral counseling and assurance of safety and efficacy, are thus important components of the PrEP program in Liberia. Other factors important in PrEP implementation include improving access, averting stigma, ensuring cost effectiveness, and providing education on oral PrEP to improve knowledge and assure people of the efficacy profiles of the ARVs used for PrEP.

This national guide was developed through extensive consultations with various stakeholders through technical working group and task force meetings. These meetings form the basis for planning, organizing, and implementing PrEP at all levels of service delivery in governmental, nongovernmental, and private health institutions in Liberia. This long and painstaking participatory methodology to adapt the oral PrEP recommendations of the World Health Organization (WHO) to the country context produced these guidelines, Step-by-Step with Oral PrEP. We hope it proves to be an effective compass for the implementation of oral PrEP in Liberia.

The program is grateful to all stakeholders who participated in the various task forces and contributed to the development of this document, including WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), UNICEF, MOH facilities, LiBNeT+, and other community-based organizations. Special thanks the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the United States Agency for International Development (USAID) for supporting FHI 360 through the Meeting Targets and Maintaining Epidemic Control (EpiC) project.

Thank you,

Dr. Julia Toomey Garbo
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Introduction to Pre-Exposure Prophylaxis

Pre-exposure prophylaxis (PrEP) is the preemptive use of antiretroviral (ARV) drugs to reduce the chances of HIV-negative individuals acquiring HIV infection, especially in people at substantial risk of acquiring HIV. This may include members of key populations (i.e., men who have sex with men [MSM], female sex workers [FSWs], transgender [trans] people, and people who inject drugs [PWID]), HIV-negative partners in serodifferent relationships, members of priority populations (e.g., uniformed services, transport workers, prisoners, mobile traders, and miners), and others who request PrEP for reasons they do not wish to disclose.

In all cases, oral PrEP should be used as part of a broader combination of HIV prevention approaches, as shown in Table 1. For instance, the first-line prevention strategies for PWID are needle exchange and/or drug use harm reduction.

Table 1. Components of combination HIV prevention

Structural	Behavioral	Biomedical
• Policies • Laws • Regulatory environment • Culture • Cash transfers	• Education • Counseling • Stigma reduction • Needle exchange and/or harm reduction • Adherence interventions	• HIV testing • Condoms • Lubricant • Prevention of mother-to-child transmission (PMTCT) • Treatment for sexually transmitted infections (STIs) • Antiretroviral therapy (ART) • Post-exposure prophylaxis (PEP) • PrEP

Effectiveness of Oral PrEP

When used as directed, oral PrEP can reduce the risk of HIV through sexual transmission among at-risk individuals by more than 90 percent, increasing even higher if combined with other HIV prevention methods as shown in Table 1.

Similar to daily oral PrEP, event-driven PrEP (ED-PrEP), also called on-demand PrEP or 2+1+1, is effective in reducing the likelihood of acquiring HIV for MSM during anal sex (see Guidance for Providers on Offering Oral PrEP). The level of prevention provided by ED-PrEP strongly correlates with level of adherence, meaning that it is important for clients to take the medication as prescribed and avoid missing any doses. While daily PrEP involves taking medication throughout an undefined period of risk—which may be indefinite—ED-PrEP involves the use of oral PrEP for a period as short as three days and is timed to correspond with anticipated sex. Further details on appropriate populations for ED-PrEP are outlined below.

Approved Drugs for Oral PrEP in Liberia

In Liberia, the current preferred regimen for daily oral PrEP is TDF/3TC. TDF/FTC can also be used for daily oral PrEP. Both drug regimens can be used for ED-PrEP.

Interactions between Oral PrEP Drugs and Other Drugs

TDF/3TC and TDF/FTC do not have any known interactions with contraceptive hormones or the gender-affirming hormones used by trans individuals.

There are no known interactions between oral PrEP medications and alcohol or recreational drugs. However, if an oral PrEP user thinks their use of alcohol or other substances is interfering with their ability to take oral PrEP regularly, the PrEP provider should discuss and support behavior change and offer additional prevention options, including condoms and lubricants.

Services for Oral PrEP Service Delivery

The National AIDS/STI Control Program (NACP) recommends that the following services form part of oral PrEP service delivery:

- HIV testing and counseling
- Creatinine clearance screening and monitoring (urinalysis for proteinuria may be used to assess kidney function if/when serum creatinine testing is unavailable or not feasible)
- Screening for hepatitis B (all populations) and C (MSM, prisoners, and PWID only)
- Comprehensive HIV prevention, including risk-reduction counseling and condom/lubricant distribution
- Assessment of need for contraceptives and/or pregnancy testing
- STI screening, diagnosis, and treatment
- Screening for noncommunicable diseases, such as diabetes mellitus and hypertension
- Referral for gender-based violence (GBV) and intimate partner violence (IPV) services
- Referral for substance use and mental health concerns identified during counseling and screening
- Adherence assessment and counseling, including help identifying possible barriers to appropriate adherence
- Counseling for all PrEP clients on the possibility of side effects, what these side effects may be, and what to do if side effects occur

Full offer of these services is not required for oral PrEP initiation. See Tables 2–5 for the required components of oral PrEP service delivery.

Guidance for Providers on Offering Oral PrEP

Oral PrEP providers should be aware of the following facts about oral PrEP for HIV prevention:

- Oral PrEP should be used during periods of substantial risk of HIV acquisition.
- It can be stopped at any time during periods of low or no risk or at the client's request. Oral PrEP does require dosing after the last potential exposure to be maximally effective. Therefore, it is important that providers share information with clients about effective timing for stopping oral PrEP.
- Oral PrEP must be taken daily unless the client is using ED-PrEP, which is more appropriate for some clients (primarily MSM, as described in Box 1).

Regimen for All Clients except MSM

Oral PrEP must be taken daily and should be used for at least seven consecutive days before it is considered effective. It must be continued for 28 days after the last potential exposure.

Regimens for MSM

Oral PrEP may be offered to MSM as a daily regimen or an event-driven regimen (ED-PrEP). MSM should be provided the opportunity to decide which regimen works best for them. ED-PrEP should not be the only option for MSM.

ED-PrEP may be appropriate for MSM who find the dosing schedule more effective and convenient, have infrequent sex (for example, less than two times per week, on average), and are able to plan for sex at least two hours in advance or can delay sex for at least two hours after taking the loading dose of two pills. However, ED-PrEP is only recommended for the prevention of HIV acquisition during anal sex. MSM with other potential exposures to HIV should consider daily oral PrEP or use other prevention methods for other types of exposures.

Box 1. Appropriate populations for ED-PrEP

ED-PrEP is recommended for the prevention of HIV acquisition during anal sex between people assigned male at birth in the absence of gender-affirming hormones. In most instances, this will be sex between cisgender men who have sex with cisgender men.

ED-PrEP may be appropriate for other populations who are insertive partners during vaginal or anal sex or for receptive partners during anal sex. However, very little is known about the dosing preferences or pharmacokinetics of oral PrEP drugs for these populations or the impact gender-affirming hormones may have on drug effectiveness.

ED-PrEP is not recommended for the prevention of HIV acquisition for receptive partners during vaginal sex.

Daily PrEP regimen for MSM

To prevent HIV acquisition during sex with other men: Start daily oral PrEP with a loading dose of two pills at PrEP initiation and delay sex for at least two hours, at which time drug levels will be sufficient to provide protection. Continue taking one pill of PrEP at the same time daily. To discontinue, these MSM should continue one pill of PrEP daily until two days after the last potential exposure.

To prevent HIV acquisition during other exposures: Oral PrEP must be taken daily and should be used for at least seven consecutive days before it is considered effective. It must be continued for 28 days after the last potential exposure.

ED-PrEP regimen for MSM

Start ED-PrEP with a loading dose of two pills taken two to 24 hours before having sex to ensure that drug levels are maximally effective. Continue taking one pill daily at the same time as the loading dose until two days after the last potential exposure. Figures 1–3 provide examples of ED-PrEP

dosing that correspond to different exposure scenarios. This process should be repeated for each period of potential exposure to HIV.

Figure 1. Example of ED-PrEP dosing schedule for sex one time or in one day

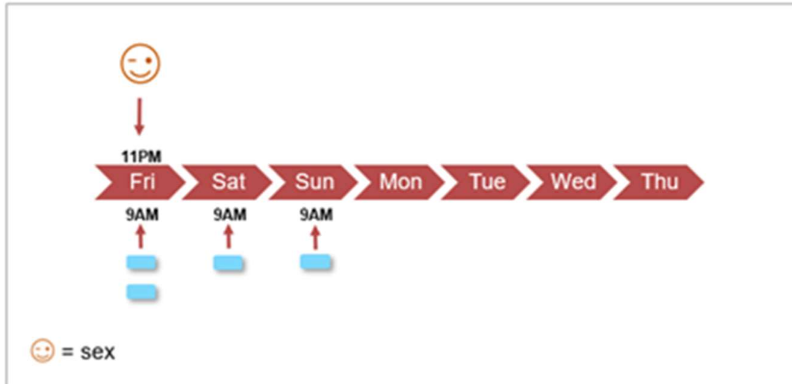


Figure 2. Example ED-PREP dosing schedule for sex on multiple consecutive days

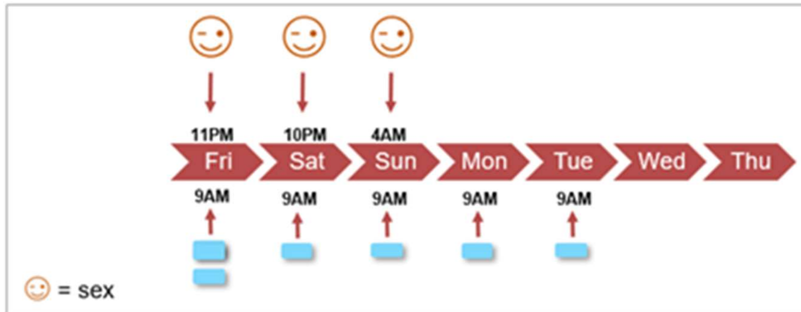
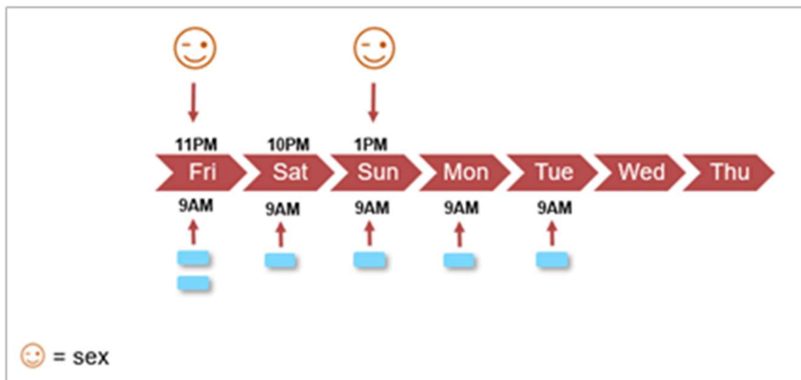


Figure 3. Example ED-PrEP dosing schedule for sex on multiple nonconsecutive days



Identifying Clients Indicated for Oral PrEP

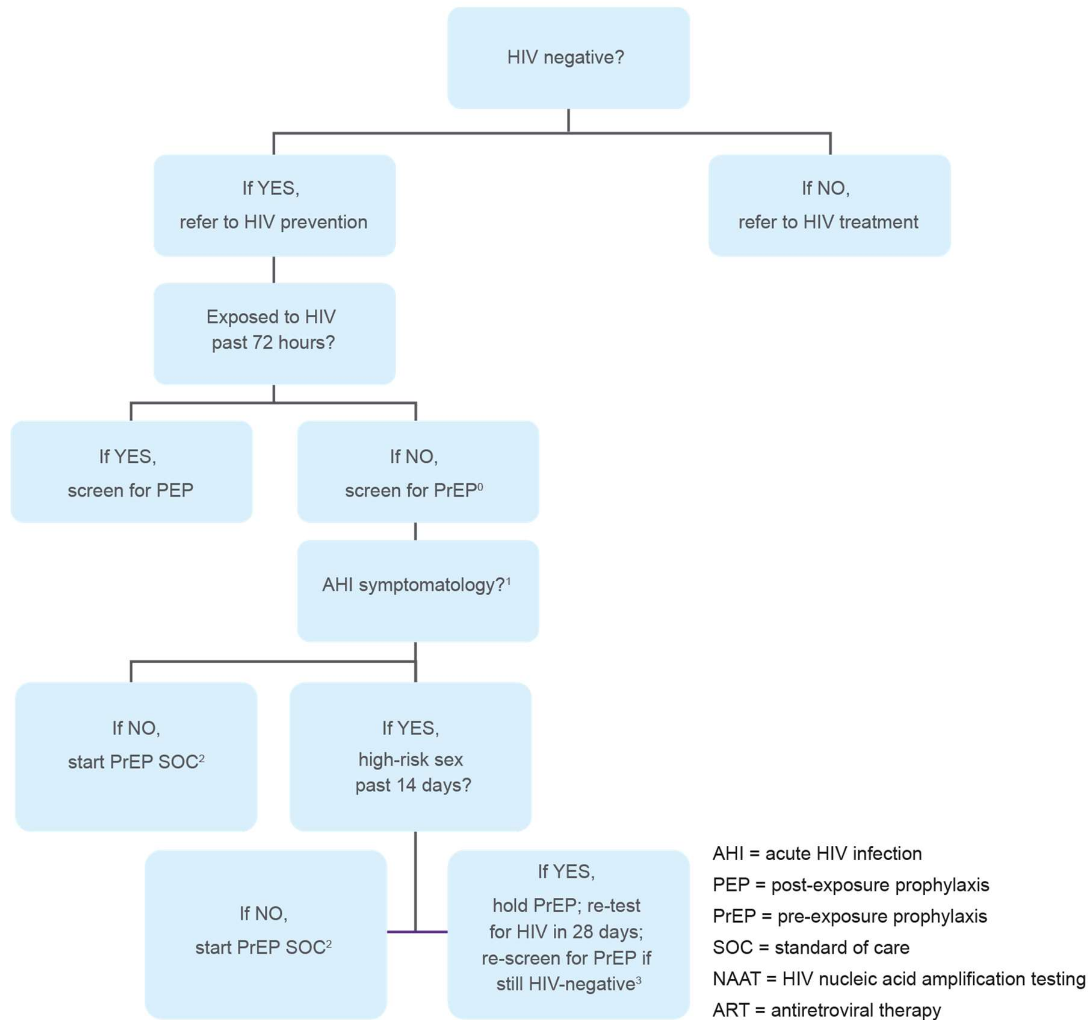
Indications for Oral PrEP

Oral PrEP is for HIV-negative individuals who are at substantial risk of acquiring HIV. Figure 4 illustrates the process through which clients may be identified as potential candidates for PrEP initiation after HIV testing and before further screening is conducted. Box 2 provides screening questions which may be used to inform this process and assist in identifying clients who are at substantial risk of acquiring HIV. However, any client who asks for oral PrEP should be assessed for

medical eligibility regardless of the results of the risk assessment. **Requesting oral PrEP has been shown to be an indicator of substantial risk.**

In addition, individuals must have no other contraindications for oral PrEP (see section "Contraindications for Oral PrEP" below) after careful evaluation.

Figure 4. Algorithm to assess for Acute HIV Infection (AHI) PEP indication and oral PrEP potential



[0] An answer of "No" to the question "Exposed to HIV past 72 hours?" means no known past exposure to HIV at all or known HIV exposure that was 73+ hours ago.

[1] Signs/symptoms mimicking acute HIV infection (sore throat, fever, sweats, swollen glands, mouth ulcers, headache, rash, muscle aches) are commonly due to illnesses other than HIV; providers need to use discretion in determining whether the symptomatology is consistent with HIV or whether an alternative cause may explain them.

[2] PrEP standard of care: clinical eligibility screening and risk assessment per WHO/national guidelines, e.g., creatinine clearance, medical history, hepatitis screening

[3] If HIV nucleic acid amplification testing (NAAT) is available, PrEP may be started earlier than 28 days if the client is NAAT negative; the clinician may consider fully suppressive ART in the 28-day interim if the client must wait 28 days to re-test for HIV.

Algorithm developed by Jhpiego in collaboration with Jared Baeten (University of Washington) and Rachel Baggaley (WHO)

Note: If the client is determined to be at risk for HIV and AHI is ruled out, clinical eligibility for oral PrEP should be assessed.

Box 2. Risk assessment screening questions to identify clients at substantial risk

HIV Risk Assessment for oral PrEP and PEP screening			
What was your sex at birth?	Male	Female	Other
What is your current gender?	Male	Female	Other
What is your current age?	______________years		
In the past six months:			
With how many people did you have vaginal or anal sex?	0 1 2* 3+* men 0 1 2* 3+* women		
Did you use a condom every time you had sex?	Yes	No*	Don't know*
Did you have a sexually transmitted infection?	Yes*	No	Don't know
Do you have a sexual partner who has HIV?	Yes	No	Don't know*
If "Yes," has he or she been on antiretroviral therapy for six or more months?	Yes	No*	Don't know*
If "Yes," has the therapy suppressed viral load?	Yes	No*	Don't know*
In the past three days:			
Have you had sex without a condom with someone with HIV who is not on treatment?	Yes**	No	Don't know**
Have you had a "cold" or "flu" such as sore throat, fevers, sweats, swollen glands, mouth ulcers, headache, or rash?	Yes***	No	Don't know
*Consider offering PrEP; **consider offering PEP; ***consider further assessment for AHI			

All clients testing HIV negative per the national testing algorithm and who are at substantial risk should be counseled on oral PrEP and assessed for clinical eligibility. The first steps in determining whether someone is clinically eligible to take oral PrEP are to ascertain whether there has been HIV exposure in the past 72 hours and to rule out AHI (see algorithm in Figure 4).

Contraindications for Oral PrEP

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

- HIV-positive test result using the national HIV testing algorithm
- Known exposure to HIV in the past 72 hours (offer PEP)
- Symptoms of AHI (Box 3) *AND potential exposure or risk within the past 14 days*. (Defer oral PrEP and consider PEP counseling for clients with a history of unprotected sex in the past three days, even in the absence of symptoms of AHI.)
- Inability to commit to adhere to oral PrEP and to attend scheduled oral PrEP clinical visits
- Drug allergy to any component of the drugs being used for oral PrEP
- Creatinine clearance less than 60 mL/min, if known
- Concurrent nephrotoxic medication
- Chronic hepatitis B infection (ED-PrEP only)

Box 3. Symptoms of acute HIV infection (AHI)

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

Oral PrEP Initiation Visit and Readiness Assessment

For most clients, oral PrEP can be initiated the same day they are screened. However, in some scenarios (see Table 2), it is recommended that oral PrEP initiation be deferred.

Additional components of oral PrEP initiation visits for clients beginning ED-PrEP are outlined in Table 3. Once the required components have been completed, Box 4 can be used to confirm client readiness and PrEP can be initiated.

Table 2. Required and recommended components to initiate clients on oral PrEP

Required Components for Oral PrEP Initiation	Description

HIV testing
 	
(per national HIV testing guidelines)
	• Same-day HIV testing is recommended.
	  - If the client is HIV positive, do not initiate oral PrEP and immediately initiate the person on/refer for ART.
	  - If the test result is inconclusive, defer oral PrEP initiation and follow the national algorithm until a definitive HIV test result is obtained for all clients not pregnant or breastfeeding. Provide risk reduction counseling.
	• For pregnant or breastfeeding women with inconclusive HIV test results, refer to PMTCT guidelines, which advise starting these clients on ART until the results are received. If the results come back HIV positive, continue the client on ART. If the results are negative, switch the client from ART to oral PrEP if still interested. Provide risk reduction counseling.

Assessment to identify clients exposed to HIV in past 72 hours	If a client reports an exposure to HIV in the past 72 hours, screen for possible eligibility for PEP instead of oral PrEP. • TDF+3TC+DTG for 28 days is the recommended three-drug PEP regimen in Liberia. • Educate clients on the difference between PEP, PrEP, and ART and offer risk reduction counseling. • After 28 days on PEP, a client may be transitioned to oral PrEP without delay if still HIV negative and at risk of acquiring HIV.
Assessment to identify clients at risk of AHI	If a client presents with signs and symptoms of HIV infection and possible exposure to HIV in the previous 14 days: • Defer oral PrEP. Provide risk reduction counseling as well as STI screening, diagnosis, and management. • Repeat HIV testing after four weeks. • If the client is negative, initiate oral PrEP.
Counseling	• Assess whether the client is at substantial risk of HIV. • Discuss prevention needs and provide condoms and lubricants. • Discuss interest in and willingness to take oral PrEP. • Select daily oral PrEP or ED-PrEP (MSM only). • Develop a plan for effective oral PrEP use. • Assess client’s experience of GBV, including IPV. Provide appropriate GBV and IPV response, including first-line support and referral where necessary, and support clients to identify ways to effectively use and continue oral PrEP. *(Clients experiencing GBV, including IPV, should not be prohibited from receiving oral PrEP if they can effectively use it.)* • Assess substance use and mental health issues.

Required Components for Oral PrEP Initiation	Description
	• Assess fertility intentions and offer contraception or safer conception counseling. Discuss oral PrEP safety during pregnancy and while breastfeeding if the client wishes to conceive or is currently breastfeeding (or intends to breastfeed). • Discuss potential side effects with clients and how to manage them. **Note to providers**: See Tables 6 and 7 for counseling and education messages specific to oral PrEP.
Assessment of oral PrEP contraindications	• Assess for contraindications of oral PrEP. If there are none, provide oral PrEP for one month (consider multimonth dispensing on a case-by-case basis).
Serum creatinine testing (requirement varies by population and based on availability)	Individuals younger than 30 years with no kidney-related comorbidities: • Optional Individuals 30 years of age and older or individuals younger than 30 years with kidney-related comorbidities: • If available, conduct once within one to three months after oral PrEP initiation The serum creatinine should be used to estimate creatinine clearance using the following Cockcroft-Gault formula: **Est. Creatinine Clearance** = [[140 - age(yr)]*weight(kg)]/[72*serum Cr(umol/L)] (multiply by 0.85 for women) **NACP notice:** Please download the free mobile app HIV Oral PrEP by WHO and Jhpiego from the Google Play and iOS app stores. It has a very convenient creatinine clearance (CrCl) calculator that reports results in either mg/dL or umol/L. If creatinine clearance is <60 mL/min, see section "Management of Clients in Specific Situations: Management of Creatinine Elevation" below.

Recommended Components for Oral PrEP Initiation	Description
Hepatitis B surface antigen (HBsAg) testing	• Clients can begin daily oral PrEP while waiting for results. • Clients cannot begin ED-PrEP while waiting for results, as these results are required before initiation (see Table 3). • HBsAg negative: Offer hepatitis B vaccination (as per national hepatitis guidelines, if available). • HBsAg positive - Daily oral PrEP is not contraindicated in clients with hepatitis B infection; if the HBsAg result is positive, the client can initiate daily oral PrEP. - Additional assessment can be considered for people with hepatitis B infection who are considering oral PrEP. - Clients with hepatitis B infection who are not interested in oral PrEP or who want to stop oral PrEP should be referred to relevant management/treatment services.
Hepatitis C antibody testing *(for MSM, prisoners, and PWID)*	• Clients can begin oral PrEP while waiting for results. • If positive, consider referral for assessment and treatment for hepatitis C.
Syndromic screening for STIs	• If syndromic, manage STIs as per STI standard treatment guidelines.
Pregnancy testing	• Determine last normal menstrual period; do pregnancy test if indicated and requested by the client. **(Remember, neither pregnancy nor breastfeeding are contraindications to daily oral PrEP use.)**
Mental health status assessment	• Screen for mental health concerns including depression and alcohol/other substance abuse, which might increase risk or affect adherence to oral PrEP. • Link to follow-up mental health care. **(Clients with mental health concerns should not be prohibited from receiving oral PrEP if they can effectively use it.)**

Table 3. Additional required components to initiate clients on ED-PrEP

Additional Required Components for ED-PrEP	Description
Education and counseling	Deliver key education and counseling messages related to ED-PrEP initiation and effective use (see Table 7).
Hepatitis B surface antigen (HBsAg) testing	Conduct screening for hepatitis B. If the client has chronic hepatitis B, the client cannot use ED-PrEP. The client may be a candidate for daily oral PrEP (if otherwise clinically eligible).

Box 4. Readiness assessment recommended by NACP to conduct prior to oral PrEP initiation

Oral PrEP Readiness Assessment		
1. HIV test is nonreactive on oral PrEP initiation day	[__] True	[__] False
2. Client is at substantial risk for HIV infection (or client has requested to use oral PrEP as an HIV prevention method)	[__] True	[__] False
3. Client was not exposed to HIV in the prior 72 hours	[__] True	[__] False
4. Client is not suspected to have AHI	[__] True	[__] False
5. Client is willing/able to come to follow-up appointments	[__] True	[__] False
6. Client has no contraindications to oral PrEP medicines (i.e., TDF, 3TC, FTC)	[__] True	[__] False
If "True" is marked for all six questions, initiate oral PrEP.		

Oral PrEP Client Follow-Up

Once clients have started oral PrEP, they should be encouraged to have a one-month follow-up visit to address the following:

- Assess and confirm HIV-negative test status
- Assess for early side effects (although unlikely)
- Discuss any difficulties with medication adherence (see Figure 5) and any other client concerns

After the one-month follow-up visit, clients should have follow-up visits every three months. The suggested follow-up schedule of every three months applies to all clients taking oral PrEP, including MSM on ED-PrEP, since HIV testing needs to be completed during these quarterly visits even if additional PrEP is not dispensed.

Table 4 outlines the components for each of the follow-up visits. These visits are the minimum number of visits an oral PrEP client will require. However, visits can be more frequent (and refills shorter) if oral PrEP is integrated with another service (e.g., antenatal care or family planning); therefore, visits should be aligned as much as possible. Additional components of follow-up visits required for ED-PrEP users only are outlined in Table 5.

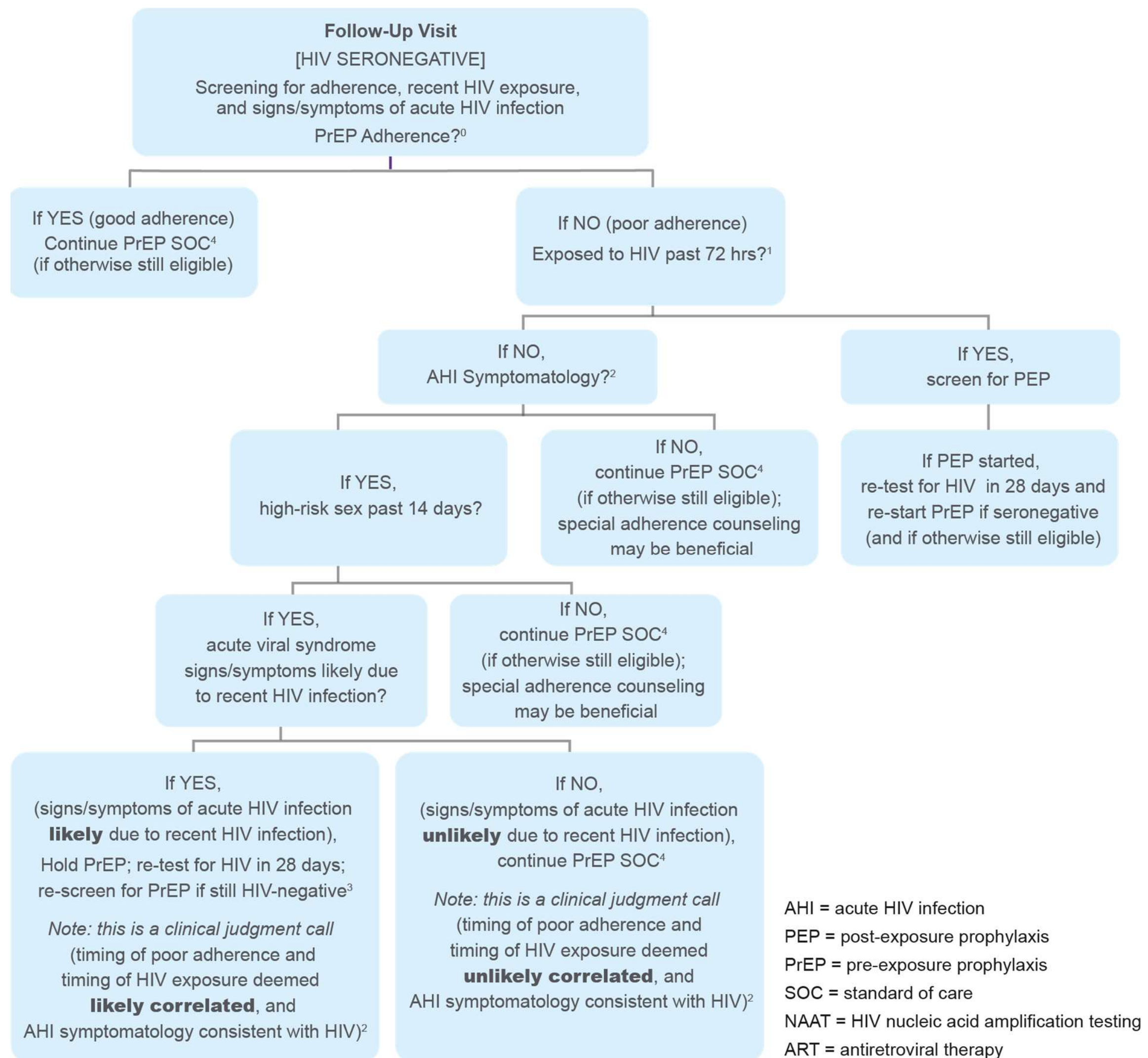
Table 4. Components of oral PrEP follow-up visits

Visit	Component
Every visit (one month after initiation and quarterly thereafter)	• Provide HIV testing and counseling. • Review oral PrEP adherence, recent HIV exposure and symptoms of AHI using Figure 5 as a guide. • Review oral PrEP adherence and provide risk reduction counseling. • Assess for adverse drug reactions (ADRs) (and manage as needed). • Provide counseling on STI prevention and recognition of STI symptoms, issues related to mental health, GBV/IPV, and substance use. • Provide refills, including multimonth dispensing. • Remind oral PrEP users of the dosage of oral PrEP required to achieve ARV levels adequate for effectiveness. Until these adequate ARV levels are achieved as outlined below, safer-sex practices should be encouraged (including abstinence and condoms/lubricant). - *For everyone other than men whose only exposure to HIV is through sex with men:* One pill must be taken daily for seven consecutive days prior to exposure to have maximum efficacy, followed by one pill taken daily at approximately the same time. To discontinue oral PrEP safely, one pill must be continued daily for 28 days after the last potential HIV exposure. - *For men whose only exposure to HIV is through sex with other men:* For those taking a daily regimen: Two pills must be taken at least two hours before sex to have maximum efficacy. Thereafter, one pill must be taken daily at approximately the same time. To discontinue oral PrEP safely, one pill must be taken daily until two days after last potential exposure.
Within one to three months after oral PrEP initiation	*For individuals 30 years of age and older or those younger than 30 years with kidney-related comorbidities*: If creatinine clearance screening is available, conduct at some point during this time.
Semiannually or annually	*For individuals of any age with a history of kidney-related comorbidities, individuals 50 years of age or older, or individuals with a previous creatinine clearance result of <90 mL/min*: If creatinine clearance screening is available, conduct after the baseline screening and every six to 12 months thereafter.

Table 5. Additional components of oral PrEP follow-up visits for clients using ED-PrEP

Additional Required Steps for ED-PrEP Clients	Description
Education and counseling	See Table 7 for key education and counseling messages related to ED-PrEP follow-up.
Hepatitis B surface antigen (HBsAg)	Conduct screening for hepatitis B. If client has chronic hepatitis B, ED-PrEP cannot be used. The client may be a candidate for daily oral PrEP (if otherwise clinically eligible).

Figure 5. Algorithm to assess for AHI and PEP indication at oral PrEP follow-up visits



[0] If adherence was so poor as to constitute PrEP discontinuation, consider the client as restarting oral PrEP (see guidance on Restarting Oral PrEP below)

[1] An answer of "No" to question "Exposed to HIV past 72 hours?" means no known past exposure to HIV at all or known HIV exposure was 73+ hours ago.

[2] Signs/symptoms mimicking acute HIV infection (sore throat, fever, sweats, swollen glands, mouth ulcers, headache, rash, muscle aches) are commonly due to illnesses other than HIV; providers need to use discretion in determining whether the symptomatology is consistent with HIV, or whether an alternative cause may explain them.

[3] If NAAT is available, PrEP may be started earlier than 28 days if the client is NAAT negative; the clinician may consider fully suppressive ART in the 28-day interim if the client must wait 28 days to re-test for HIV.

[4] PrEP standard of care: clinical eligibility screening and risk assessment per WHO/national guidelines, e.g., creatinine clearance, medical history, hepatitis screening

Algorithm developed by Jhpiego in collaboration with Jared Baeten (University of Washington) and Rachel Baggaley (WHO)

Discontinuing and Restarting Oral PrEP

Discontinuation of Oral PrEP

Ideally, clients should inform their service provider if they want to discontinue oral PrEP. The duration of oral PrEP use may vary by client. Individuals are likely to start and stop oral PrEP depending on assessment of their individual risk at different periods in their lives, including changes in sexual relationship status, behaviors, and ability to adhere to an oral PrEP maintenance program.

For everyone other than men whose only exposure to HIV is through sex with men:

- One pill must be continued daily for 28 days after the last potential HIV exposure.

For men whose only exposure to HIV is through sex with other men taking a daily regimen:

- One pill must be taken daily until two days after the last potential HIV exposure.

Box 5. Key points on discontinuation of oral PrEP recommended by NACP

Health care workers should discuss with their clients when to discontinue oral PrEP. Oral PrEP may be stopped for the following reasons:

- Client request
- Positive HIV test (clients who seroconvert while on oral PrEP should be immediately linked to care and initiated on ART in line with national guidelines)
- Safety concerns, such as persistent creatinine clearance <60mL/min
- No longer at substantial risk
- Decision to switch from oral PrEP to different HIV prevention method(s)
- Persistent side effects

In addition, be sure to:

- Explore risks and alternative prevention/risk reduction strategies.
- Advise the client that a negative HIV test is required to re-start oral PrEP.
- Remind the client of the oral PrEP schedule required after the last potential exposure (at least two days for men whose only potential exposure to HIV is through sex with other men and at least 28 days for other clients).
- Encourage ongoing links to appropriate HIV prevention and contraceptive services, as well as the use of other HIV prevention strategies, as needed.
- Refer to the national guidance on hepatitis B infection, as appropriate.

Restarting Oral PrEP

Individuals restarting oral PrEP will need to be retested for HIV to confirm their HIV-negative serostatus. They must also have no contraindications for oral PrEP before restarting (see section "Contraindications for Oral PrEP").

Management of Clients in Specific Situations

This section outlines management of clients in specific situations outside of regular client follow-up.

Management of Creatinine Elevation

Very few clients experience creatinine elevation, and approximately 80 percent of creatinine elevations are self-limiting (and can be addressed without stopping oral PrEP). Creatinine elevations may be caused by:

- False-positive test result
- Dehydration
- Exercise
- Diet (always rule out and manage other causes of elevated creatinine)
- Some disease conditions that could cause creatinine elevation include:
  - Diabetes mellitus
  - Hypertension
  - Liver failure
  - Hepatitis C virus

Serum creatinine is not a good marker of kidney function. Calculate creatinine clearance as per the Cockcroft-Gault formula (or by using the calculator in the mobile app **HIV Oral PrEP by WHO and Jhpiego**).

Est. Creatinine Clearance =

[[140 - age(yr)]*weight(kg)]/[72*serum Cr(umol/L)]

(multiply by 0.85 for women)

Most people can remain on oral PrEP and have the creatinine clearance repeated on a different day from a different blood sample. If the second sample result is still <60 mL/min, discontinue oral PrEP and re-test later if the person wants to try again.

Box 6. Notes on creatinine clearance from NACP

If the calculated creatinine clearance is <60 mL/min after second sample result:

- Stop oral PrEP and refer to NACP.
- Creatinine clearance usually returns to normal levels after stopping oral PrEP.
- Oral PrEP can be restarted if creatinine clearance is confirmed to be ≥60 mL/min one to three months after stopping PrEP.

Management of HIV Seroconversion

- If a client seroconverts after starting oral PrEP (even if the client has stopped taking oral PrEP or is not taking oral PrEP consistently):
  - Confirm reactive rapid test results according to the national testing algorithm.
  - Immediately link to care and initiate on ART (as per national ART guidelines).
  - Document seroconversion and possible reason for seroconversion (nonadherence, stopped taking oral PrEP, oral PrEP failure [i.e., breakthrough infection while adherent to oral PrEP]).

Management of Side Effects and Adverse Drug Reactions (ADRs)

- Minor side effects are relatively common, but they are mild and self-limiting and often do not require discontinuation of oral PrEP. These side effects include:
  - Nausea and/or vomiting
  - Diarrhea and/or flatulence
  - Dizziness
  - Headache
  - Weight loss
- Side effects should be managed symptomatically, and counseling should be provided.
- Major toxicities (including renal toxicity and metabolic complications) associated with TDF and FTC are rare in oral PrEP exposure to date. Consult NACP if these occur.
- Any side effects should be recorded in client records and ADR forms regardless of severity.
- Complete the national ADR form and report as per standard operating procedures.
- If oral PrEP will be discontinued, record the outcome in the oral PrEP register.

Education and Counseling for Oral PrEP Clients

Education and counseling for clients considering oral PrEP, or clients already on oral PrEP, are important to ensure effective use of the drug.

Oral PrEP counseling should be based on the following principles:

- Client-driven, based on client needs, resources, and preferences
- Based on a foundation of respect and include an open and honest relationship between provider and client
- Recognition that behavior change is not easy and human beings are not perfect
- Validation and normalization of client concerns, seeking to affirm and encourage client efforts, and not prescriptive or judgmental
- Identification of small wins and achievable next steps in reducing risk and/or making pill-taking easier
- Inclusion of contingency planning when common barriers encountered

Special populations such as key populations and adolescent girls and young women will need additional tailored counseling.

Risk Reduction Counseling for Potential Oral PrEP Clients

Risk reduction counseling is a behavioral intervention that attempts to decrease an individual's chances of acquiring HIV and other STIs. It includes counseling about prevention of HIV and other STIs, prevention of unintended pregnancy, GBV/IPV prevention and mitigation, and other sexual and reproductive health issues. It should be provided at all follow-up visits for oral PrEP users.

The main objective of risk reduction counseling is for clients to assess individual risk, acknowledge self-risk, and set realistic goals for behavior change that could reduce their risk of acquiring HIV and other STIs, as well as prevent unintended pregnancies. This counseling, which is most effective when nonjudgmental and user-centered, can be provided by any trained health care provider and should:

- Explore the context of the client's specific sexual practices and psychosocial status and help the client recognize any of their behaviors that are associated with higher risks for HIV

infection or unintended pregnancy. Health care providers should also be aware that clients might not always perceive their own risk or may be in denial about it.

- If the client discloses that they have experienced or are at risk of GBV, including IPV, provide first-line support and make referrals as appropriate. Discuss how violence and fear of violence affects their risk and prevention behaviors and discuss ways to stay safe and protect themselves in the context of their relationship(s).
- Identify the sexual health protection needs of the potential oral PrEP user and reflect on his or her main concerns.
- Strategize with the client about how they can manage these concerns or needs.
- Agree on which strategies the client is willing to explore and provide guidance on how to implement them.

Messaging for Oral PrEP Clients

Additional counseling and education messages specific to oral PrEP are provided in Table 6. These messages should be conveyed to all oral PrEP clients (including ED-PrEP clients).

Table 6. Counseling and education messages for all oral PrEP clients (including ED-PrEP clients)

Topic	Key Messages
What is oral PrEP?	Oral PrEP is one of several HIV preventions options and, where possible, should be used in combination with condoms and other prevention methods. Oral PrEP does not protect against other STIs or prevent unintended pregnancy.
Oral PrEP works if taken as prescribed.	For oral PrEP to be effective, you must take oral PrEP as prescribed, which for most people is every day throughout their time at risk.
Oral PrEP is not for life.	You should take oral PrEP for as long as you feel you are at risk of HIV infection. Some people only need to take oral PrEP during certain times in their lives, while others have an ongoing need.
Starting and stopping oral PrEP	**Regimen for All Clients except MSM** Oral PrEP must be taken daily and should be used for at least seven consecutive days before it is considered effective. It must be continued for 28 days after the last potential exposure. **Regimens for MSM** *Daily PrEP regimen for MSM* To prevent HIV acquisition during sex with other men: Start daily oral PrEP with a loading dose of two pills at PrEP initiation and delay sex for at least two hours, at which time drug levels will be sufficient to provide protection. Continue taking one pill of PrEP at the same time daily. To discontinue, these MSM should continue one pill of PrEP daily until two days after the last potential exposure. To prevent HIV acquisition during other exposures: Oral PrEP must be taken daily and should be used for at least seven consecutive days before it is considered effective. It must be continued for 28 days after the last potential exposure.

Topic	Key Messages
	ED-PrEP regimen for MSM Start ED-PrEP with a loading dose of two pills taken 2–24 hours before having sex to ensure that drug levels are maximally effective. Continue taking one pill daily at the same time as the loading dose until two days after the last potential exposure. Figures 1–3 provide examples of ED-PrEP dosing that correspond to different exposure scenarios. This process should be repeated for each period of potential exposure to HIV.
Ways to support adherence	**Daily oral PrEP** can be taken any time of the day, with or without food. If you forget a dose of daily oral PrEP, take it as soon as you remember. Some people find it easy to remember to take their oral PrEP when they integrate it into a daily routine and take it the same time each day. For example, you could take oral PrEP when you brush your teeth (either in the morning or evening), or when watching a favorite TV show or listening to a favorite radio program. It is helpful to pair taking oral PrEP with a routine that makes you feel good. *(Providers should explore and emphasize adherence and pill-taking reminders specific to each individual.)* **ED-PrEP** clients may want to integrate a daily reminder into their schedules when they can consider whether they may have sex and take the loading dose or take follow-up doses as needed.
Oral PrEP and alcohol or other recreational drugs	Taking oral PrEP while you are using alcohol or other recreational drugs will not hurt you. However, alcohol or other recreational drugs may cause you to forget to take your oral PrEP, so be sure to take it in advance of any substance use.
Oral PrEP, pregnancy, and breastfeeding	Oral PrEP does not prevent pregnancy. Be sure to use a modern method of contraception to avoid an unintended pregnancy. Taking oral PrEP while you are pregnant or breastfeeding will not hurt you or your baby. Since HIV can be transmitted during pregnancy and breastfeeding, taking oral PrEP during this time prevents both you and your baby from acquiring HIV. You can use oral PrEP throughout pregnancy and breastfeeding. (**Note to providers:** Assess needs and offer family planning, as appropriate.) (**Note to providers:** Offer oral PrEP to pregnant or breastfeeding women at high risk of HIV as a priority after all the risks and benefits have been explained to the client.)
Oral PrEP and other medications	Oral PrEP is safe and effective. It can be taken with hormonal contraceptives, gender-affirming hormones, or non-prescription drugs.
No STI protection other than HIV	Oral PrEP does not prevent any other STIs. To prevent other STIs, use a condom correctly whenever you have sex.

Topic	Key Messages
Side effects	More than 90 percent of people will not experience any side effects. Those who do will experience only mild side effects, including: • Gastrointestinal symptoms (diarrhea and nausea, decreased appetite, abdominal cramping, and flatulence) • Dizziness • Headaches Most of those side effects disappear within one month. However, your health care provider can help you manage them.
Other ways to lower risk of HIV	To lower your risk of HIV: • Adopt safer sexual practices, including consistent condom and lubricant use. • Engage in nonpenetrative sex, including mutual masturbation. • Receive screening, diagnosis, and treatment for other STIs. • Ensure an HIV-positive partner in a serodifferent couple has been on effective ART for at least six months, has an undetectable viral load, and remains adherent to ART. • Receive voluntary medical male circumcision. • Reduce your number of sexual partners. • Access drug harm reduction and treatment services.
Switching between HIV prevention options	It is okay to start oral PrEP and decide later that you want to use another option to prevent HIV infection, like condoms. Many people switch between methods as their needs change. I am here to help you to make the best decision for you.
Importance of follow-up visits	It is important that you attend follow-up visits for the following reasons: • To verify your HIV status and, if positive, be referred for ART • To reduce your likelihood of drug resistance if you have acquired HIV • To get support on adherence, managing side effects, and address any other concerns you may have
Selection of daily oral PrEP or ED-PrEP (MSM only)	Your choice between taking daily PrEP or ED-PrEP depends upon the frequency and predictability with which you have sex, as well as your preferences. ED-PrEP may be more appropriate if you find it more effective and convenient, have infrequent sex (for example, less than two times per week on average), and are able to plan for sex at least two hours in advance or delay sex for at least two hours. You may wish to transition between daily and ED-PrEP use according to your circumstances. **Note to providers:** PrEP providers and MSM clients should determine together whether daily PrEP or ED-PrEP may be most appropriate by discussing the frequency and predictability of sex and asking about dosing preferences. Steps for ED-PrEP initiation are the same as those for all oral PrEP clients (Table 2), with a few additional components as outlined in Table 3. **Note to providers:** See Table 7 for messaging about switching between daily PrEP and ED-PrEP.

Additional Messaging for ED-PrEP Clients

Counseling about adherence for those on ED-PrEP may require additional time, given that habitual daily use is not the goal and effective use requires coordination of timing with sex. For some clients seemingly suited to the ED-PrEP dosing schedule, daily dosing may be more appropriate for reasons of personal preference, including those related to anticipated ease of adherence. Adolescent MSM also may prefer or be better suited to daily PrEP rather than ED-PrEP, even if they report infrequent and predictable sex. Table 7 outlines key counseling and education messages specific to ED-PrEP, which should be covered in addition to the messages in Table 6 for all PrEP users.

Table 7. Additional education and counseling messages for ED-PrEP clients

Topic	Key Messages
Potential HIV exposures, frequency of sex, and planning for sex	What are your possible exposures to HIV? **Note to providers**: Remember, ED-PrEP is only for MSM, though ED-PrEP should not be the ONLY option available for MSM How often do you have sex with other men? If you have sex more often than two days a week, daily oral PrEP may be better for you. Would you be able to plan for sex at least two hours in advance or delay sex for at least two hours? What could make this planning difficult?
Advantages and disadvantages to using ED-PrEP	ED-PrEP has these potential advantages: • It may require you to take fewer pills. • It may be more convenient if you have potential exposures which are typically planned or irregular. • It may make it easier for you to keep using PrEP. ED-PrEP also has these potential disadvantages: • You will need to plan before sex. • You must remember to take all doses in the correct way. • MSM who start ED-PrEP may be more likely than MSM using daily oral PrEP to develop resistance if you start taking it during acute HIV infection. • There is no evidence that ED-PrEP prevents HIV infection during any other types of potential exposures.
Effective use	**Note to providers:** • Walk through basic regimen with client (2+1+1) • Provide client with information, education, and counseling (IEC) materials showing some different scenarios for ED-PrEP use **Messaging for clients:** • It is very important for you to take follow-up doses at the same time of day you took the loading dose. • For ED-PrEP to be effective, take PrEP according to the dosing schedule prescribed.

Topic	Key Messages
Starting and stopping oral PrEP	• You must first take two pills 2–24 hours before having sex to get the maximum efficacy. This is the "loading dose." • One pill should then be taken daily at the same time as the loading dose until two days after the last potential exposure. • This process should be repeated for each period of potential exposure to HIV. **Note to providers:** When counseling clients on starting and stopping ED-PrEP, clients may benefit from job aids with visual representations of how doses should be taken over time in different scenarios.
Delayed loading dose	Take the loading dose and try to delay sex until two hours after the loading dose. However, if you do NOT take the loading dose at least two hours before sex: • If you are unable to delay sex, you should use a condom and lubricant. • Have other types of sex which come with nearly no likelihood of HIV acquisition (oral sex, mutual masturbation, etc.). • If you did not use a condom, you may be a candidate for a 28-day course of PEP (per the national guidelines).
Missed ED-PrEP dose(s)	If you miss an ED-PrEP dose(s), you may be a candidate for a 28-day course of PEP per the national guidelines. **Note to providers:** Because the timing and type of the sexual event will vary for each client in relation to the timing of the missed dose(s), such cases will require individual adjudication and a best clinical judgment.
Switching between ED-PrEP and daily PrEP	**Note to providers:** Since the frequency and predictability of sex may vary over time, the best PrEP dosing option for a client may change repeatedly. **Messaging for clients:** *To transition from ED-PrEP to daily oral PrEP*: You should continue taking PrEP every day after your last exposure. You should continue this daily dosing until sex becomes less frequent or more predictable again, or for as long as you prefer the daily dosing option. *To transition from daily oral PrEP to ED-PrEP*: You should stop daily dosing two days after the last potential exposure and then start following the ED-PrEP regimen until sex becomes more frequent or less predictable.

Figure 6. Example of transitioning from ED-PrEP to daily PrEP

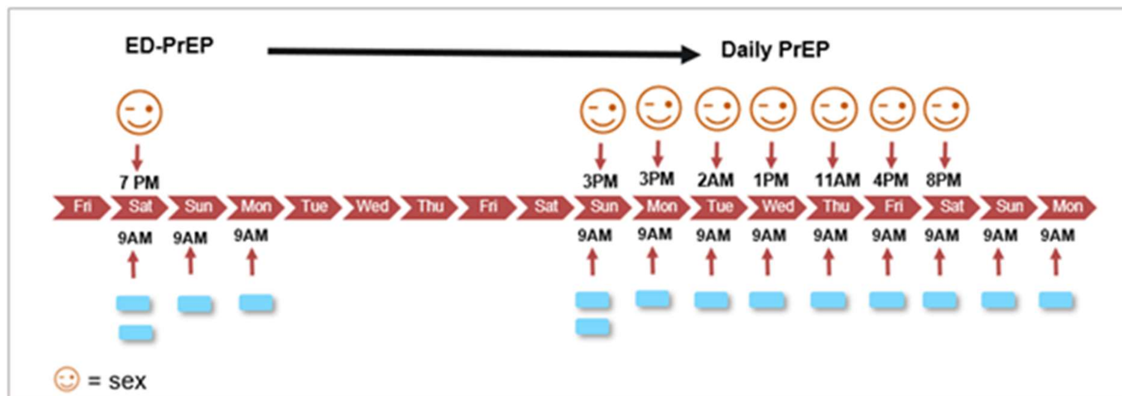
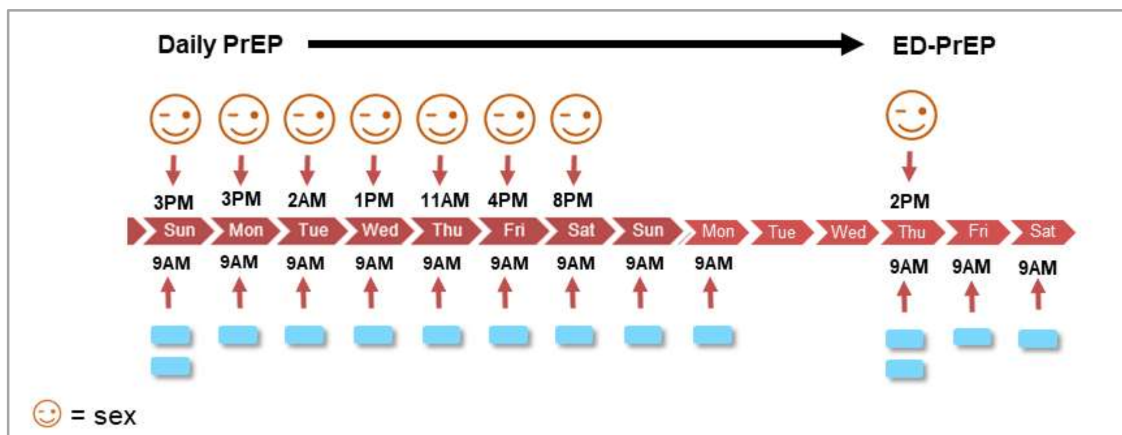


Figure 7. Example of transitioning from daily PrEP to ED-PrEP



Demand Creation, Location, and Delivery of Oral PrEP

Oral PrEP implementation can be integrated in any setting that meets the conditions for initial evaluation and initiation and has an appropriately trained cadre(s) of workers who have been approved to perform medical assessments and provide prescriptions for ARVs as oral PrEP according to national guidelines. Potential PrEP users may be found in the facility and within the community.

Health facilities

Common service delivery points where potential PrEP users may be found include:

- STI clinic: Many people accessing health services for STIs may not identify as a member of a high-risk population. Careful use of the PrEP eligibility screening form will help define the indication.
- Outpatient department (through active referrals from the outpatient clinic)
  - For HIV testing (the most common)
  - Testing for STIs
- Antenatal and family planning clinic
  - To identify women in serodifferent relationships
- HIV-negative pregnant and breastfeeding women in settings with high HIV prevalence
- Sexual and gender-based violence services

- Harm reduction and other drug treatment services
- PEP services (clients completing PEP services may be referred for PrEP)

Community

In Liberia, common locations that could enhance access to potential PrEP users include:

- Key population civil society organizations
- Hot spots
    - MSM and FSW hot spots should be targeted with appropriate messaging
- Drop-in centers (DICs)
    - Safe space for key population community activities with peer navigators and educators
- Community-based and outreach HIV testing
    - Clients tested may be referred for or started on oral PrEP through accredited services
- Accredited community pharmacies
    - Liberia is supporting ARV dispensing for ART clients and HIV self-testing in prequalified community pharmacies for eligible people living with HIV)

Delivery Locations

PrEP may be accessed in various places that are user-friendly and where other people with high risk of acquiring HIV commonly access health services. In Liberia, the following places are approved to provide PrEP services:

- STI clinics
- Outpatient departments
- Antenatal and family planning clinics
- ART clinics
- DICs
- Drug treatment centers
- Accredited community organizations and outreach services
- Accredited community pharmacies
- Accredited virtual space
- Primary care services

Who Should Prescribe PrEP

The following categories of individuals are recommended to be trained to provide PrEP services:

- Clinicians (e.g., doctors, physician assistants)
- Nursing cadres
- Pharmacy cadres (e.g., pharmacists, dispensing assistants)
- Counselors
- Case managers
- Peer educators
- Outreach workers

Pharmacovigilance

Pharmacovigilance refers to the activities set up for the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

- ADRs can be detected by either a drug user, guardian, or health care practitioner.
- Serious ADRs should be reported as soon as possible to the NACP and the Liberia Medicine and Herb Products Regulatory Authority
- ADRs are considered serious if they result in any of the following: death, life-threatening, disability, hospitalization, congenital anomaly, require intervention to prevent impairment/damage, and any other important medical event. Serious ADRs (e.g., death) must be reported within 24 hours.

How to Fill Out the ADR Reporting Form

All sections of the form must be filled in with adequate details. The following basic information is required:

- Identifiable source of information or reporter
- Identifiable patient
- Name(s) of the suspected product(s)
- Description of the suspected reaction

Supply Chain

PrEP commodity procurement and distribution is covered under the national HIV program supply chain management, as described in the 2020 National Integrated Guidelines for Prevention, Care and Treatment of HIV and AIDS in Liberia HIV (Chapter 21, p. 91).

The PrEP dispensing officer for every location shall be responsible for determining commodity order or re-ordering of quantities based on consumption patterns and available stocks and submitting the orders to the logistics management information system for review by the NACP and Central Medical Store.

Preparing the Stock Report

The PrEP dispensing officer uses the following information to complete logistics reports:

- Consumption data from PrEP dispensing register
- Stock-on-hand data from stock card or physical count report
- Losses and adjustments data from the stock card

PrEP logistics report should be completed at the end of every month for timely requisition and resupply of PrEP drugs:

- Confirm each commodity is sorted by the expiry date
- Ensure all stocks are available to be counted, including those in bulk at the clinic store and at HIV testing rooms, etc.
- Do a physical count of available stocks to determine the stock on hand

Receiving ARVs and Medical Supplies at Facility Store

- PrEP ARV supplies should be received by the facility stores according to the recommended practices of the Ministry of Health.
- The person receiving the commodities at the facility should inspect the entire consignment based on facility regulations.
- Physically count all re-packed/loose units. Originally sealed boxes do not need to be opened for counting of units.
- Check expiry date for all ARV packs.
- Write the physical count for each item into the respective box on the delivery document. Write zero for any items not received—do not leave any check box empty.
- Sign, date, and stamp the delivery note to confirm receipt of the items as indicated.
- The person who signs the delivery note is accountable for all items for which they have signed. The PrEP dispensing officer will be held responsible for any discrepancies noted later.

Moving ARVs and Medical Supplies to Storage

- Immediately move the ARVs received into a secure storage area at the facility (clean, dry, cool, and off the floor).
- Enter quantity and date of receipts on stock cards without delay.
- Arrange items by expiry date to make it easy to follow the "first expiry, first out" (FEFO) principle.

Issuing ARVs and Medical Supplies to Clinic or Pharmacy

- Fill requisition and issue vouchers for all commodities requested from the clinic.
- ALWAYS follow the FEFO principle.
- Update stock card immediately when moving items out of the pharmacy/clinic.

Requesting Adjustment and Stock Redistribution

Good planning and coordination will prevent PrEP ARV expiry and stock-outs. However, in the unlikely event of a risk of PrEP ARV stock expiry or stock-out, PrEP focal persons should establish contacts with the regional health directorate immediately and contact a neighboring facility for stock redistribution. Before establishing the contact, prepare the following information:

- Number of packs/bottles of PrEP ARVs required
- Expiry date for each ARV drug
- Number of PrEP users on the regimen at your facility and approximate average monthly consumption (AMC)

Monitoring and Evaluation

NACP relies heavily on accurate and timely data for program evaluation, strategic planning, and research. Cleaned data will be collated and shared with donors and stakeholders for complimentary activities in the national response. PrEP data analysis and reporting will be done from client PrEP dispensing cards and facility registers at the approved PrEP facilities and community locations.

- Reporting is done monthly for PrEP, even though daily and weekly summaries are advisable to track missed appointments and losses to follow-up.
- All PrEP reports are to form part of the integrated HMIS reporting form to the NACP.
- Reports from facilities are to be completed within five working days after the end of the reporting period.
- PrEP monitoring and evaluation will be part of the comprehensive PrEP training schedule.

Commonly Used Tools for PrEP Monitoring and Evaluation

- PrEP screening for substantial risk and medical eligibility
- PrEP facility register
- PrEP follow-up register (PrEP client card)
- PrEP monthly summary form
- Seroconverter tracker
- PrEP quarterly cohort report

Addendum Issued December 2021

National AIDS/STI Control Program
Ministry of Health
JFK Memorial Hospital Compound, Sinkor, Monrovia

Subject: Guideline Addendum on Oral PrEP
Date: 1st December 2021

Introduction

This guideline addendum serves as an update to previous national guidance on oral PrEP in Liberia published in August 2021. The content below about who can use event-driven PrEP (ED-PrEP), contraindications for ED-PrEP, and starting and stopping oral PrEP overrides previous requirements and recommendations.

ED-PrEP

ED-PrEP can be used to prevent HIV acquisition during sex by all people assigned male at birth (AMAB) who are not using exogenous hormones. Chronic hepatitis B infection is not a contraindication for ED-PrEP, therefore testing for hepatitis B before initiating ED-PrEP is not required.

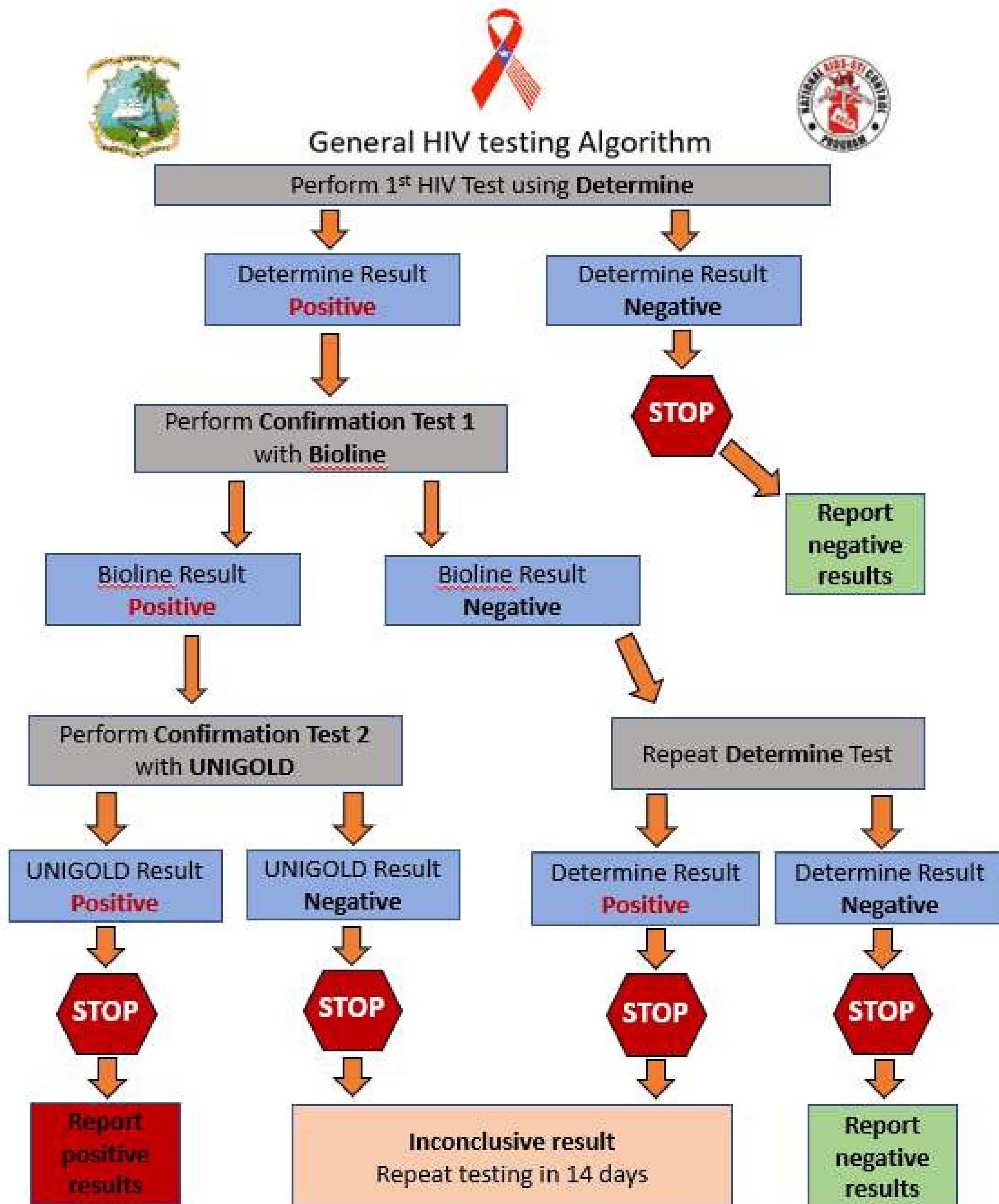
Starting and Stopping Oral PrEP

Regimen for all clients using oral PrEP to prevent HIV acquisition from non-sexual exposures, all clients assigned female at birth (AFAB) and for clients AMAB who are using exogenous hormones:
Oral PrEP must be taken daily and should be used for at least seven consecutive days before it is considered effective. It must be continued for 7 days after the last potential exposure.

Daily PrEP regimen for clients AMAB using oral PrEP to prevent HIV acquisition from sexual exposures and who are not using exogenous hormones:
Start daily oral PrEP with a loading dose of two pills at PrEP initiation and delay sex for at least two hours, at which time drug levels will be sufficient to prevent HIV acquisition from sexual exposures. Continue taking one pill of PrEP at the same time daily. To discontinue, continue one pill of PrEP daily until two days after the last potential sexual exposure.

ED-PrEP regimen for clients AMAB using oral PrEP to prevent HIV acquisition from sexual exposures and who are not using exogenous hormones:
Start ED-PrEP with a loading dose of two pills taken two to 24 hours before having sex to ensure drug levels are maximally effective. Continue taking one pill daily at the same time as the loading dose until two days after the last potential sexual exposure. This process should be repeated for each period of potential exposure to HIV.

Appendix A: Liberia HIV Testing Algorithms



Pregnant woman HIV testing Algorithm

Perform 1st HIV Test using **HIV/Syphilis Dual Rapid Test**

- Dual Syphilis Result **Positive** → STOP → **Treat for syphilis with 2.4 IU of benzathine penicillin IM** if not allergic
- Dual HIV Result **Positive** → Perform **Confirmation Test 1** with **Determine**
  - Determine Result **Positive** → Perform **Confirmation Test 2** with **UNIGOLD**
    - UNIGOLD Result **Positive** → STOP → **Report positive results**
    - UNIGOLD Result **Negative** → STOP → **Inconclusive result** Repeat testing in 14 days
  - Determine Result **Negative** → Repeat **HIV/Syphilis Dual**
    - Dual HIV Result **Positive** → STOP → **Inconclusive result** Repeat testing in 14 days
    - Dual HIV Result **Negative** → STOP → **Report negative results**
- Dual Syphilis & HIV Results **Negative** → STOP → **Report negative results**