

.....

PRE EXPOSURE PROPHYLAXIS (PrEP)

HANDBOOK

.....



JULY 2023

TABLE OF CONTENTS



Acronyms	ii
What is Pre Exposure Prophylaxis (PrEP)	1
Target Populations	1
PrEP Continuum of Care	2
Eligible Persons	3
Algorithm to Assess for PrEP Indication and Active HIV Infection (AHI) at Follow-up Visits	4
Guidelines for Clinic Visits	5
What to prescribe for PrEP	6
The management of seroconversion	6
Oral PrEP Discontinuation	7
Screening and Management of Renal Impairment on PrEP	8
Management of Hepatitis B (HBV) Infection	9
Event Driven PrEP	10
Algorithm for offering ED PrEP	11
What to prescribe for ED PrEP	12
Monitoring and Evaluation of PrEP Services	13
Additional Learning Resources	14

ACRONYMS

3TC	Lamivudine
ADR	Adverse Drug Reaction
AGYW	Adolescent girls and young women
AHI	Active HIV Infection
ART	Antiretroviral Therapy
ARV	Antiretroviral
ED	Event Driven
FTC	Emtricitabine
GBV	Gender Based Violence
HBV	Hepatitis B virus
HIV	Human Immunodeficiency Virus
HRF	High Risk Female
HRM	High Risk Male
HSTI	History of STIs
IPV	Intimate Partner Violence
M&E	Monitoring and Evaluation
MO(H)	Medical Officer (Health)
MSM	Men who have sex with men
MSP	Multiple Sex Partners
PEP	Post Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
SOP	Standard Operating Procedures
STI	Sexually Transmitted Infection
SW	Sex workers
TDF	Tenofovir
TG	Transgender women

What is Pre Exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral medication to prevent acquisition of HIV infection in appropriate persons; it should be used in combination with other HIV prevention methods.

Target Populations

- Men who have sex with men (MSM)
- Heterosexual women and men with concurrent or high number of sex partners (greater than 1 new sex partner within the last 3 months or greater than 1 sexual partner)
- Transgender women
- Women and men whose partners are known to have HIV infection
- Young women and men at substantial risk of HIV infection
- Female and male sex workers
- Individuals with recurrent STIs
- Persons with repeated use of Post Exposure Prophylaxis (PEP) (PEP use greater than twice within a 6-month period)

PrEP Continuum of Care

The PrEP continuum begins with the identification of individuals at high-risk for HIV acquisition (from the target populations) and takes them through the process of interest, screening for eligibility, PrEP initiation, adherence and retention. The continuum also makes provisions for persons who may decide to discontinue (cycle off) PrEP.

Clients should be advised that:

- ▶ It takes at least 7 days before PrEP becomes effective in both men and women.
- ▶ If they wish to discontinue PrEP, it must be continued for at least 7 days after the most recent exposure before it is stopped.
- ▶ PrEP should be taken every day at the same time.
- ▶ If a dose is missed on a given day but realized on the same day, then it should be taken when remembered.
- ▶ If a dose is missed but not remembered, there is no need to take two pills the next day. They should continue with one tablet once daily.
- ▶ Condom use is still advised, as PrEP does not protect against other STIs.

Eligible Persons

Persons who are eligible for PrEP must meet the following criteria:

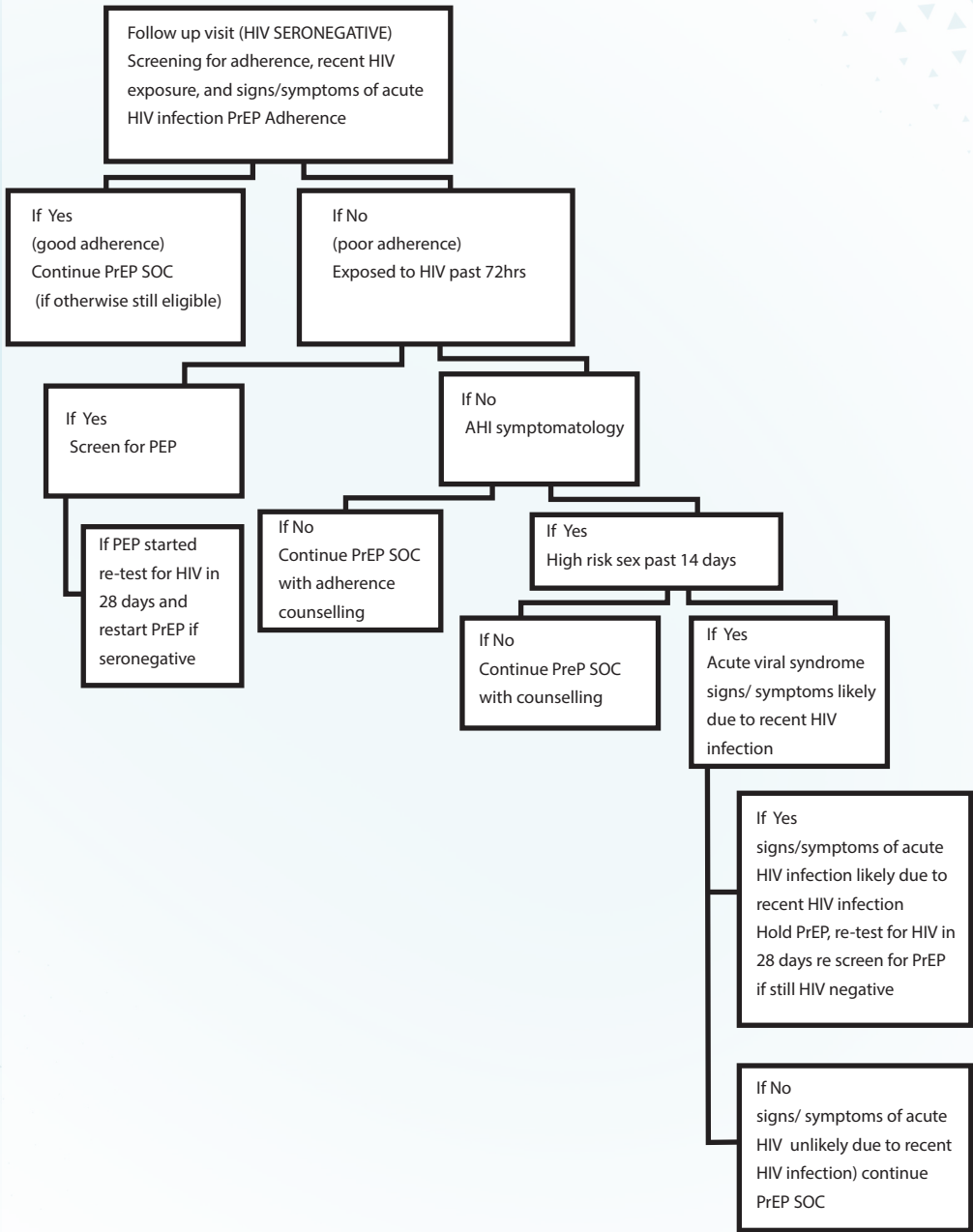
1. Be HIV negative
2. Be at substantial risk for HIV acquisition. That is, they must fall within one of the target groups previously mentioned and/or may demonstrate substantial risk for acquiring HIV
3. Clients must have a creatinine clearance of >60 ml/min*
4. Clients should not demonstrate any sign or symptom of an acute HIV infection such as:
 - Fever
 - Fatigue
 - Myalgia
 - Pharyngitis
 - Headache
 - Adenopathy
 - Rash
 - Arthralgia

Once clients are deemed eligible for PrEP, they should then be enrolled in PrEP

*Note Estimated creatinine clearance= $\text{Sex} \times ((140 - \text{Age} / (\text{Serum Creatinine})) \times (\text{weight}/72))$

*Sex is 1 for men and 0.85 for women.

Algorithm to Assess for PrEP Indication and Active HIV Infection (AHI) at Follow-up Visits



Key: AHI= acute HIV infection, PEP = post exposure prophylaxis, PrEP= pre-exposure prophylaxis, SOC= standard of care

Figure 1. Algorithm to Assess for PrEP Indication at each follow up visit.

Table 1: Guidelines for Clinic Visits

History	Lab Evaluation	Counseling/Education
All visits:	All visits:	All visits:
<ul style="list-style-type: none">• HIV risk Behaviors• Substance- use and alcohol use.• Symptoms or recent history of STI. Symptoms of acute HIV• Mental Health Screening• Adherence to other medications	<ul style="list-style-type: none">• HIV test• Pregnancy test (women)• Creatinine (every 3-6 months)• STI test: syphilis, gonorrhea and chlamydia (triple site testing: urine, pharynx and anal swabs if appropriate) and (in women) trichomoniasis (every 3-6 months as indicated) Hepatitis B & C serology (Ag, sAb, cAb)• Viral Load	<ul style="list-style-type: none">• Risk reduction counselling• Education about PrEP: potential benefits, risks and adverse effects• Emphasis on need for follow-up• Referral for mental/ behavioral health or substance use intervention as indicated
Follow-up visits:	Initial visit:	Follow-up visits:
<ul style="list-style-type: none">• Adherence to PrEP	<ul style="list-style-type: none">• Hepatitis B & C serology (Ag, sAb, cAb)• Viral Load	<ul style="list-style-type: none">• Reassess need for PrEP (at least yearly)

What to prescribe

The World Health Organization (WHO) recommends the use of Tenofovir/Emtricitabine one (1) tablet for 7 days after last exposure to prevent the acquisition of HIV.

The management of seroconversion

If a person using oral PrEP tests positive for HIV, oral PrEP should be stopped immediately and the person referred for prompt initiation of HIV treatment on Tenofovir/Lamivudine/Dolutegravir (TLD) and linked to a treatment site for continued follow up care.

Transition from oral PrEP to HIV treatment without gaps avoids the possibility of resurgence in viral load, immunological injury, and secondary transmissions.

Tracking seroconversion is important in informing gaps in care and in identifying needs for increased outreach to oral PrEP clients if continuation is an issue.

Oral PrEP Discontinuation

Ideally, clients should inform their service provider when they want to discontinue oral PrEP. Providers should discuss the options of when to discontinue oral PrEP with their clients.

*One pill must be continued daily for 7 days after the last potential exposure. (WHO PrEP guidelines 2022)

Oral PrEP can be stopped for the following reasons:

- Client request
- Positive HIV test (clients who seroconvert while on oral PrEP should be linked to care and initiated on ART in line with national guidelines)
- Safety concerns, such as CrCl <60mls/min (if known)
- No longer at substantial likelihood of HIV acquisition
- Persistent side effects which are not manageable
- Decision to switch to another HIV prevention strategy or method

Restarting Oral PrEP

- Some follow-up visits may be restart visits for some clients
- Clients can and should use oral PrEP when they need
- Restart visits have the same components of regular follow-up visits

Screening and Management of Renal Impairment on PrEP

Table 2. Guide for screening for renal impairment for PrEP clients.

Population	Baseline	Follow-up
Individuals 29 years and younger with no kidney-related comorbidities	Conduct once within one to three months of oral PrEP initiation.	If baseline test is normal, follow-up is optional until 30 years of age or if kidney-related comorbidities develop.
Individuals 30–49 years with no kidney-related comorbidities		<p>If conducted, and baseline test result is <90 mL/min, conduct follow-up screening every six to 12 months, if available.</p> <p>If baseline test is normal, annual screening until age 50 or kidney-related comorbidities develop.</p> <p>If baseline test result is <90 mL/min, conduct follow-up screening every six to 12 months, if available.</p>
Individuals 50 years and older -OR- Individuals of any age with kidney-related comorbidities -OR- Individuals with previous creatinine screening of <90 mL/min	Conduct once within one to three months of oral PrEP initiation.	Conduct follow-up screening every six to 12 months, if available.

- Abnormal creatinine clearance results of <60ml/min should be followed by repeat testing on a separate day before stopping oral PrEP
- Abnormal creatinine clearance usually returns to normal levels after stopping oral PrEP
- Oral PrEP can be restarted if creatinine clearance is confirmed to be ≥ 90ml/min 1–3 months after stopping PrEP
- If creatinine clearance does not return to normal levels after stopping PrEP, other causes of renal insufficiency should be evaluated

Management of Hepatitis B (HBV) Infection

Hepatitis B vaccination is appropriate for people at substantial risk of HBV or HIV infection.

Vaccination is warranted if there is no documented history of a completed vaccine series for HBV.

PrEP can be provided whether or not HBV vaccination is available.

Tenofovir (TDF) is active against HBV infection at the same dose used for PrEP. WHO recommends TDF for treatment of HBV infection in people for whom treatment is indicated.

Not all people with chronic HBV infection have treatment indications.

Indications for treatment of HBV should be assessed according to national guidelines

If PrEP is stopped prior to three months in a patient who has HBV they can experience a HBV infection flare, thus it is recommended that a complete three months of Tenofovir (TDF) be administered as well as referral and follow up with a gastroenterologist.

Event Driven PrEP

Event-driven PrEP (ED-PrEP) is the use of a short dosing course of antiretroviral medication that is taken before and after sex to prevent the acquisition of HIV infection.

Eligibility for Event Driven (ED) PrEP

Persons eligible for ED PrEP	Persons not eligible for ED PrEP
<p>Men who have sex with men:</p> <ul style="list-style-type: none">• Who would find ED-PrEP more effective and convenient• Who have infrequent sex (for example, sex less than 2 times per week on average)• Who are able to plan for sex at least 2 hours in advance, or who can delay sex for at least 2 hours	<ul style="list-style-type: none">• Women or transgender women• Transgender men having vaginal sex• Men having vaginal or anal sex with women• People with chronic hepatitis B infection

Algorithm for offering ED PrEP

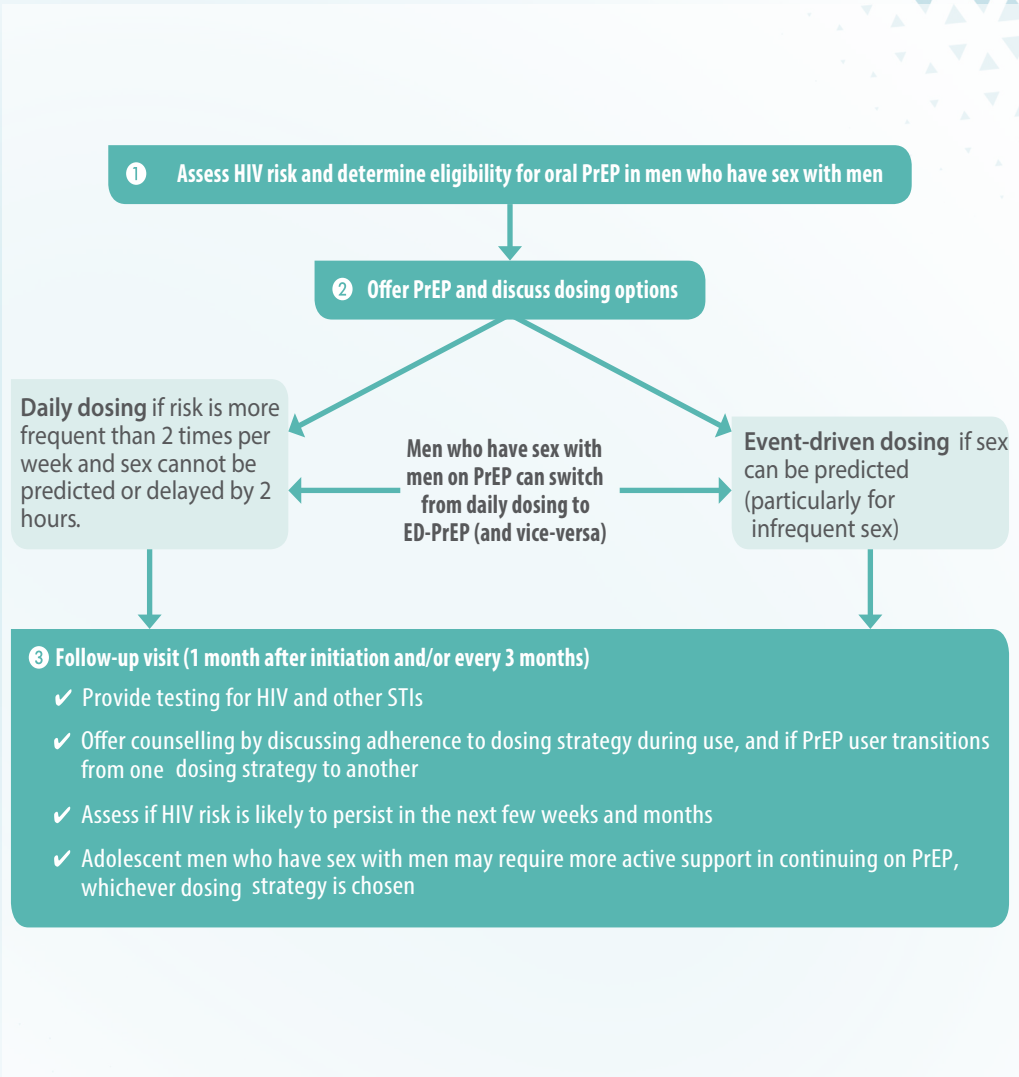


Figure 3. Algorithm for assessment of clients for ED PrEP

What to prescribe for ED PrEP

Two pills of Tenofovir/Emtricitabine (TDF/FTC) taken between a time period of 2 and 24 hours in advance of having sex, a third pill 24 hours after the first two pills, and a fourth pill 48 hours after the first two pills.

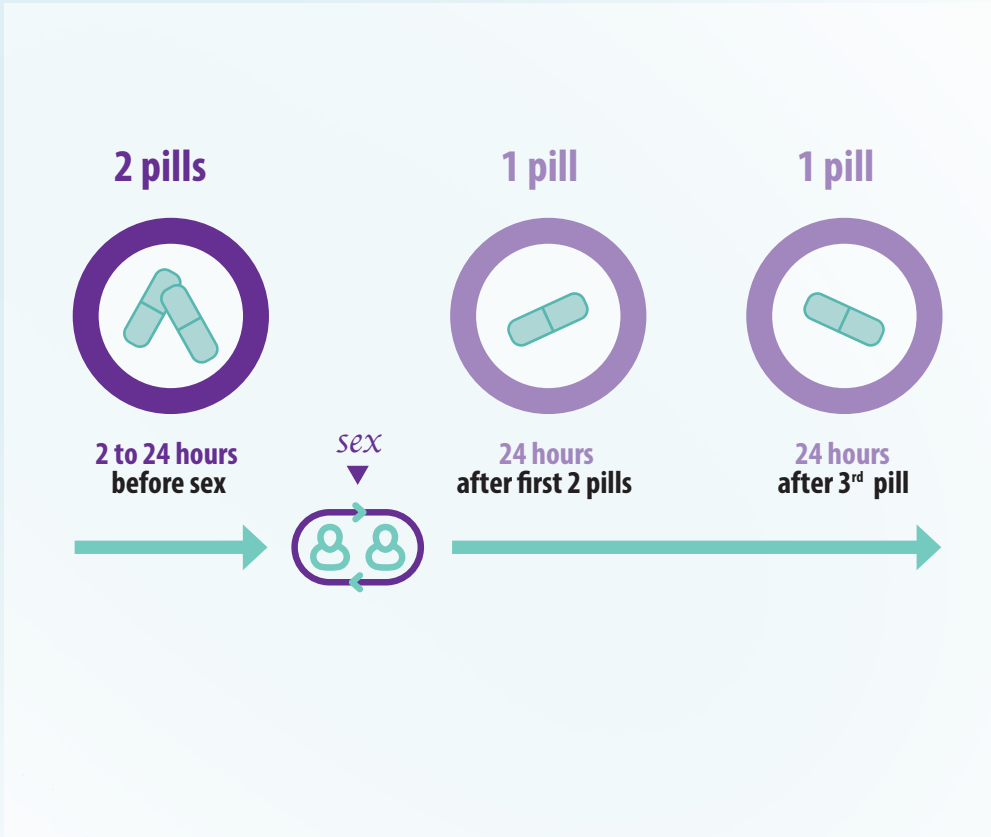


Figure 4. Dosing guide for clients on ED PrEP

Monitoring and Evaluation of PrEP Services

Data Flow

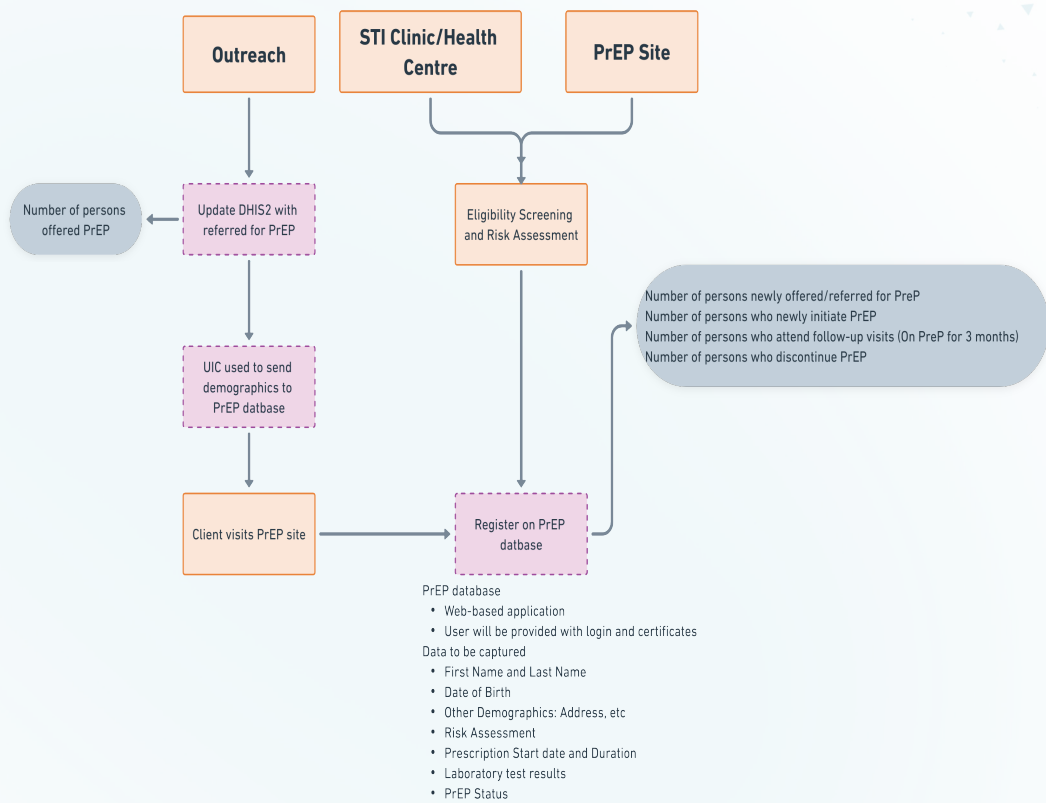


Figure 5. Monitoring and Evaluation of PrEP services

Additional Learning Resources

The Oral PrEP eLearning course created through a collaboration between WHO and Jhpiego is a self-paced, free eLearning course available at hivoralprep.org.

The training prepares clinicians to provide both daily oral PrEP and ED-PrEP.

**World Health Organization**

**jhpiego**
Jharkhand Health Promoting University Affiliate

**ORAL PrEP**

HOME

OUR COURSES

MOBILE APP

WHO TOOL

RESOURCES

CONTACT

Oral PrEP eLearning Resource Package:

A Collaboration Between WHO and Jhpiego



The Oral PrEP eLearning Resource Package (eLRP) introduces health care providers to Oral Pre-Exposure Prophylaxis (PrEP) for HIV infection. The eLRP includes eLearning courses for clinicians with an accompanying Oral PrEP Implementation Tool App.



MINISTRY OF
**HEALTH &
WELLNESS**



PRE EXPOSURE PROPHYLAXIS (PrEP) HANDBOOK

JULY 2023

