



**ORAL
PRE-EXPOSURE PROPHYLAXIS
(PrEP)
TRAINING FOR PROVIDERS
IN NIGERIA**

PARTICIPANT MANUAL

August 2022

**Oral Pre-Exposure Prophylaxis (PrEP) Training
for Providers in Nigeria**

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Foreword

Nigeria has made significant progress in the reduction of new HIV infections in the past decade through the scale up of HIV prevention programs. In addition, access to HIV treatment has improved the quality of life of adults and children living with HIV. Key populations at substantial risk include sex workers (SW), men who have sex with men (MSM), and people who inject drugs (PWID), as well as other priority populations such as sexually exposed adolescents and young people. This reality makes it imperative for continued efforts to expand access to effective HIV prevention interventions. It also emphasizes the need for continuing the scale-up of access to HIV treatment programs for individuals living with HIV.

HIV service providers are important gatekeepers of Pre-exposure prophylaxis (PrEP) and play a crucial role in creating HIV prevention programs that effectively reach individuals who would benefit from PrEP the most. The goal of this training manual is to equip service providers with the skills required to provide PrEP in an effective and safe manner. This training manual provides information regarding the evidence for PrEP effectiveness, procedures, monitoring and evaluation of service delivery. PrEP offers a unique opportunity to confront the HIV epidemic, prevent HIV acquisition by individuals at risk for HIV, and reach global targets. The training is intended for health care workers who are already familiar with the basics of HIV prevention care and treatment. It is anticipated that facilities will need to adapt this training to reflect specific local contexts and include evidence from new research and experience in the use of PrEP.

This training manual is therefore developed as part of government policy to guide healthcare workers in providing quality oral PrEP services.



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Acknowledgment

The Federal Ministry of Health wishes to acknowledge the contributions of everyone who participated in the development of this training manual to guide and empower healthcare workers with the requisite information on provision of quality Oral Pre-Exposure Prophylaxis (PrEP) services in Nigeria. This document will serve as an important resource material for PrEP Providers in Nigeria.

We wish to express our special appreciation to PEPFAR for providing funds through USAID to Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) under FHI360/Jhpiego to support the development of this document.

We also acknowledge the technical contributions of National Agency for the Control of AIDS (NACA), United States Agency for International Development (USAID), United States Centres for Disease Control and Prevention (CDC), US- DoD, Pharmaceutical Society of Nigeria Foundation (PSNF), Centre for Integrated Health Program (CIHP), Institute of Human Virology (IHVN), Caritas Nigeria, Heartland Alliance, APIN Public Health Initiatives, New HIV Vaccine and Microbicide Advocacy Society (NHVMAS) and Key Population Secretariat to the process of development of the training manuals.

Finally, we wish to commend the staff of the National HIV/AIDS Division for providing excellent leadership and direction for the manual development



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Acronyms

Ab/Ag	Antibody/Antigen
AHI	Acute HIV Infection
ART	Antiretroviral Therapy
ARV	Antiretroviral
CDC	Centres for Disease Control and Prevention
CHOICE	Collaboration for HIV Prevention Options to control the Epidemic
EpiC	Meeting Target and Maintaining Epidemic Control
FTC	Emtricitabine
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HIV-DR	HIV Drug Resistance
HTS	HIV Testing Services
iNSC	integrated Next Step Counselling
IPV	Intimate Partner Violence
LTFU	Lost to follow-up
MSM	Men who have Sex with Men
NSC	Next Step Counselling
PEP	Post-Exposure Prophylaxis
PMTCT	Prevention of Mother-to-Child Transmission [of HIV]
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
RCT	Randomized Controlled Trial
RISE	Reaching Impact Saturation and Epidemic Control
RNA	Ribonucleic Acid
RPR	Rapid Plasma Reagin (test for syphilis)
STI	Sexually Transmitted Infection
TasP	Treatment as Prevention
TDF	Tenofovir Disoproxil Fumarate
UNAIDS	Joint United Nations Programme on HIV/AIDS
VMMC	Voluntary Male Medical Circumcision
WHO	World Health Organization
3TC	Lamivudine

Training Overview

Training Goal

The goal of Oral Pre-Exposure Prophylaxis (PrEP) Training for Providers in Nigeria is to equip HIV service providers with the requisite knowledge and skills to deliver high-quality oral PrEP services to decrease the risk of HIV acquisition.

Competencies and Content Areas

At the end of the training, PrEP providers will be able to:

- Identify individuals eligible for PrEP.
- Assess medical eligibility for oral PrEP.
- Provide adherence education, counselling and support to oral PrEP candidates.
- Prescribe oral PrEP.
- Conduct clinical, laboratory, and risk assessments during follow-up visits.

The training content areas include:

- Oral PrEP basics
- Oral PrEP eligibility screening
- Oral PrEP initial and follow-up visits
- Monitoring and managing PrEP side effects: creatinine, seroconversion, and stigma
- Oral PrEP M&E tools
- Event-driven oral PrEP

Participant Manual

The Participant Manual is divided into 8 modules with each containing the learning objectives. The methods for delivering the contents include slide presentation, scenarios, role-plays, and small group activities.

Module 1: Oral PrEP Basics

Learning Objectives

After completing Module 1, participants will be able to:

- Define oral PrEP.
- Differentiate oral PrEP from post-exposure prophylaxis (PEP) and antiretroviral therapy (ART).
- Describe the need for oral PrEP.
- Identify people with substantial risk for HIV infection.
- Explain the relationship between oral PrEP effectiveness and adherence.
- Understand the oral PrEP regimens currently used in Nigeria in line with WHO recommendations.
- Explain the risks and benefits of oral PrEP.

Introduction to Module 1

HIV prevention needs are dynamic and change over time. Combination prevention is a mix of biomedical, behavioural, and structural interventions that decrease risk of HIV acquisition. Oral PrEP is a component of the country’s combination prevention package.

Combination Prevention

Combination Prevention

Structural	Behavioural	Biomedical
<ul style="list-style-type: none"> • Policies • Laws • Regulatory environment • Culture • Cash transfers 	<ul style="list-style-type: none"> • Education • Counselling • Stigma reduction • Harm reduction • Adherence interventions 	<ul style="list-style-type: none"> • HIV testing • Condoms • Voluntary medical male circumcision • PMTCT • Treatment of STIs • Treatment as Prevention • Post-exposure prophylaxis • PrEP



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Pre-Exposure Prophylaxis

PrEP is the use of HIV prevention medications (ARVs) by people who are HIV negative to prevent the acquisition of HIV *before* exposure to the virus.

- Pre = Before
- Exposure = Activity that can lead to HIV infection
- Prophylaxis = Prevention

Global Progress on PrEP

- 2012: FDA approval in the United States
- 2015: WHO recommendation
- 2016: Southern African guidelines on oral PrEP for persons at risk, including adolescents
- 2018: Adolescents included in the oral PrEP recommendations in the United States

National Progress on Oral PrEP

- 2015–2018: Oral PrEP Demonstration Project in Anambra, Plateau, and Cross River states
- 2016: National Guidelines for HIV Prevention, Treatment, and Care included oral PrEP for serodiscordant couples and key populations
- 2017–2021: Oral PrEP included in National Strategic Framework on HIV and AIDS
- 2020: Reviewed the National Guidelines for HIV Prevention, Treatment, and Care, which included oral PrEP for exposed adolescents and young people
- 2021: Two-year implementation plan and roadmap strategy document
- 2021: Consolidated Service Delivery Guidelines on HIV and STIs for General and Key Populations in Nigeria

Oral PrEP Use in Nigeria

- A 2015–2018 demonstration project tested different models to deliver oral PrEP to serodiscordant couples in Nigeria.
- Projects include a mix of service delivery models, including one-stop-shops and facility- and community-based programming (focused on KPs).
- Some projects include oral PrEP referrals from other services (e.g., index testing, prevention of mother-to-child transmission [PMTCT], family planning).
- As of September 2020, 28,090 individuals were on PrEP in Nigeria (PEPFAR Nigeria), though there is limited data on PrEP uptake in the private sector.

Post-Exposure Prophylaxis (PEP)

- PEP is short-term antiretroviral treatment to reduce the substantial risk of HIV acquisition after potential exposure, either occupationally or non-occupationally—for example, through sexual intercourse.

Comparing Oral PrEP and PEP

Comparing Oral PrEP and PEP

Similarities	Differences
Both are used by HIV-negative persons.	Oral PrEP is started before potential exposure. PEP is taken after exposure.
Both use ARVs to prevent HIV acquisition.	Oral PrEP can be used as long as HIV exposure exists. PEP is taken for 28 days only.
Both are available from providers by prescription.	
Both are effective when taken correctly and consistently.	



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Difference Between ART and Oral PrEP

Differences Between ART and Oral PrEP

ART	Oral PrEP
Treatment for HIV requires lifelong antiretroviral therapy (ART) and consistently high adherence to have suppressed viral loads.	Oral PrEP is needed during periods of substantial exposure to HIV.
ART is taken regularly by people living with HIV to remain healthy and keep from transmitting HIV.	Oral PrEP is taken by people without HIV to avoid acquiring HIV.
	Individuals taking oral PrEP receive regular behavioural assessment. Discontinuing PrEP is appropriate when they: <ul style="list-style-type: none"> • Are no longer at substantial risk for HIV acquisition. • Decide to use other effective prevention methods.



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Why We Need Oral PrEP

Multiple demonstration projects worldwide have shown that:

- Oral PrEP is effective in reducing HIV acquisition—most effective in studies with high adherence.
- Quantifiable drug in plasma increased efficacy estimates to 74–92%.
- Oral PrEP provides an *additional* prevention intervention to be used *together* with existing interventions like condoms.
- PrEP reduces risk of acquiring HIV through sexual intercourse by about 99% when taken as prescribed.
- PrEP is safe.

Local HIV Epidemiology

- In Nigeria, there are 103,419 new infections (among ages 15–49) annually (NACA: Mode of Transmission Study, 2021).
- Most new infections in Nigeria are happening among key populations and never married females and males. These populations are an appropriate target for oral PrEP.
- Prevalence is 1.8% among women ages 15–64 and 0.8% among young women ages 15–24. (NAIIS, 2018).
- Prevalence among brothel-based female sex workers (FSWs) – 17.1%, Non-brothel-based FSW – 15%, MSM – 25%, PWID – 10.9%, Transgender people – 28.8% (NAIIS, 2018; IBBSS, 2020).

Key Population and Priority Populations

Key populations are defined groups who, due to specific high-risk behaviours, are at an increased risk of HIV infection irrespective of the epidemic type or local context. Also, there are often legal and social issues that increase their vulnerability to HIV. Key populations are important to the dynamics of HIV transmission and in the control of the epidemic.

They include:

- Sex workers
- MSM.
- Transgender people.
- People who inject drugs
- People in closed settings and correctional services

priority populations include:

- HIV-negative partners in serodiscordant relationships
- Clients of sex workers
- Exposed adolescents and youth people.
- Pregnant and Breastfeeding Mothers

Evidence That Oral PrEP Works (Group Activity)

ARVs Used in PrEP Trials

- Oral daily tablet of TDF/FTC (300mg tenofovir disoproxil fumarate/200mg emtricitabine)
- Oral daily tablet of TDF (300mg tenofovir disoproxil fumarate)
- TDF/FTC and TDF alone are both equally safe and effective for heterosexual men and women.
- TDF alone was also found to be effective among PWIDs.
 - There is limited evidence on the use of TDF alone for PrEP in MSM.
- TDF/FTC was approved for oral PrEP by the US Food and Drug Administration (FDA) in 2012.

iPrEx Study

Study Design:

- N = 2499 HIV-seronegative men (or transgender women)
- Sexual orientation: sex with men
- All received risk-reduction counselling, condoms, and STI Rx

Regimens:

- TDF/FTC (Truvada): 1 pill PO daily
- Placebo: 1 pill PO daily

Result:

- 44% reduction in incident HIV in the TDF/FTC arm

PROUD

Immediate vs. Deferred PrEP in High-Risk MSM in a 'Real World' Trial

- Randomized, open-label trial of daily oral TDF/FTC oral PrEP in MSM in 13 STI clinics in London
- Immediate (n = 267) vs. deferred for 12 months (n = 256)
- Primary endpoint: HIV infection in the first 12 months from enrolment

Results

- Incident HIV infection: 3 in immediate arm, 20 in deferred arm
- Reduction: 86% (90% CI 64–96; p=0.0001)
- Number needed to treat for 1 year to prevent 1 infection: 13 (90% CI:9–25)

ANRS IPERGAY

On-Demand Oral PrEP in High-Risk MSM

- Randomized double-blind trial
- Event-drive oral TDF/FTC (n = 199) vs. placebo (n = 201)
 - 2 tablets taken 2–24 hours before sex
 - 1 tablet taken 24 hours after sex
 - 1 tablet taken 48 hours after first event-drive dose
- Primary endpoint: HIV seroconversion

Results

- 86% reduction in risk seen in oral PrEP arm (95% CI:40–98, $p = 0.002$)
- Median of 16 pills taken per month in each arm
- Number needed to treat for 1 year to prevent 1 infection: 18

Partners PrEP Demonstration project

- Open-label multi-country study
- Integrated delivery of oral PrEP and ART in serodiscordant couples
- Oral daily TDF/FTC given as PrEP to HIV-negative partner and continued 6 months beyond Initiation of ART for partner living with HIV
- Interim analysis: 96% reduction in expected infections (*all* HIV infections)

Oral PrEP can be used as a “bridge” to fully suppressive ART in serodiscordant couples.

Key HIV PrEP Trials Using Oral Tenofovir or Tenofovir-Emtricitabine (TDF-FTC)

STUDY	STUDY POPULATION	STUDY RANDOMISATION	HIV INCIDENCE IMPACT
iPrEx (Brazil, Ecuador, South Africa, Thailand, US)	2499 MSM and TG women	Daily oral TDF-FTC or placebo	TDF-FTC: 44% ↓
Partners PrEP Study (Kenya, Uganda)	4147 heterosexual HIV-discordant couples	Daily oral TDF, TDF-FTC, or placebo	TDF: 67% ↓ TDF-FTC: 75% ↓
TDF2 Study (Botswana)	1219 heterosexual men and women	Daily oral TDF-FTC or placebo	TDF-FTC: 63% ↓
FEM-PrEP (Kenya, South Africa, Tanzania)	2120 women	Daily oral TDF-FTC or placebo	TDF-FTC: no protection
VOICE (South Africa, Uganda, Zimbabwe)	5029 women	Randomized to daily oral TDF, TDF-FTC, oral placebo, TDF vaginal gel, or gel placebo	TDF: no protection TDF-FTC: no protection TDF gel: no protection
Bangkok TDF Study (Thailand)	2143 PWID	Randomized to daily oral TDF or placebo	TDF:49% ↓
IPERGAY (France, Quebec)	400 MSM	Randomized to “on-demand” oral TDF-FTC or placebo	TDF-FTC: 86% ↓
PROUD (United Kingdom)	545 MSM and TG women	Randomized to daily oral TDF-FTC immediately or delayed	Immediate TDF-FTC: 86% ↓

Sources: **iPrEx:** Grant RM, et al. *N Engl J Med.* 2010;363:2587–99. **Partners PrEP:** Baeten JM, et al. *N Engl J Med.* 2021;367:399–410. **FEM-PrEP:** Van Damme L, et al. *N Engl J Med.* 2021;357:411–22. **Bangkok TDF Study:** Choopanya K, et al. *Lancet.* 2013;381:2083–90.

Global Expansion of Oral PrEP

- By late 2018, an estimated 380,000 individuals had been prescribed oral PrEP across nearly 70 countries.¹
- Over 20% of WHO member states had adopted guidelines for oral PrEP or were poised to do so.²
- National guidelines in low- and middle-income countries as well as high-income countries.
- Regional guidelines from:
 - European AIDS Clinical Society
 - Southern African HIV Clinicians Society
 - Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine.

¹ Fitch Let al. Tracking global oral PrEP provision: the who, what, and where of oral PrEP. Paper presented at HIV Research for Prevention Conference (HIV R4P 2018); 23 October 2018; Madrid. Abstract OA04.01

² Hodges-Mameltzis A, et al. Going global: the adoption of the World Health Organization's enabling recommendation on oral pre-exposure prophylaxis for HIV. Sex Health. 2018;15(6):489-500.

Defining Adherence

Adherence to drugs means that an individual is taking prescribed medications *correctly* and *consistently*. It involves taking the correct drug in the correct dose:

- With consistent frequency (the same number of times per day)
- At a consistent time of day

Adherence with follow-up means that clients attend *all* scheduled clinical visits and observe all required protocols, including:

- Clinic and lab assessments
- Prescription refills

Importance of Adherence

Adherence to ART is necessary for:

- Achieving sustained suppression
- Delaying the onset of drug resistance
- Enhancing immune recovery
- Improving the overall health and quality of life of an individual

Poor or non-adherence to ART results in suboptimal viral suppression, which may lead to the emergence of drug resistance and loss of future treatment options.

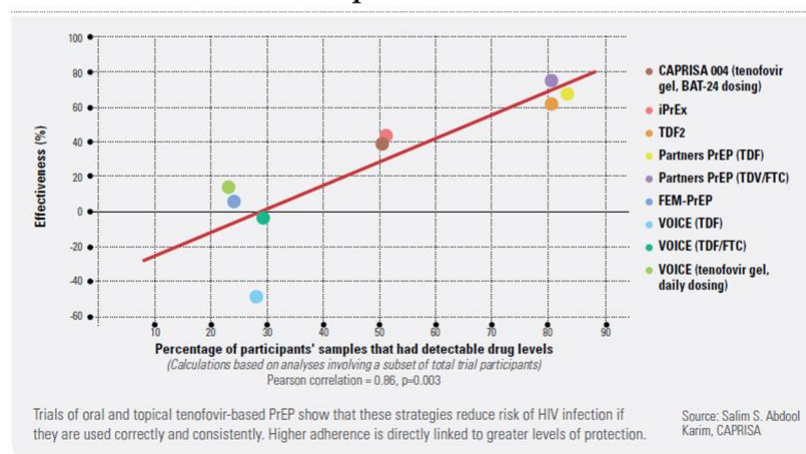
Adherence and Oral PrEP Efficacy

When taken as prescribed, oral PrEP works!

- Like ART, oral PrEP must be taken correctly and consistently.
- The highest oral PrEP effectiveness was reported in trials where there was an adherence of greater than 70% (risk ratio = 0.30, 95% confidence interval: 0.21–0.45, $P < 0.001$ compared with placebo). (Fonner et al., 2016)
- The higher percentage of participant samples with detectable oral PrEP drug level, the greater the efficacy.

Evidence for Effectiveness with Adherence

**Effectiveness and Adherence
in Trials of Oral and Topical Tenofovir-Based Prevention**



ARVS Recommended For Oral PrEP

ARVs Recommended for Oral PrEP

- In line with WHO guidelines, the following regimens should be considered for oral PrEP:

1. Combined tablet of emtricitabine (FTC) 200 mg/tenofovir disoproxil fumarate (TDF) 300 mg PO daily

2. Combined tablet of lamivudine (3TC) 300 mg/TDF 300 mg PO daily.

3. Single-agent TDF 300 mg PO daily.
(Note the limited evidence on the use of TDF alone for PrEP for MSM.)

- The National Guidelines for HIV Prevention, Treatment and Care (2020) recommends TDF/FTC or TDF/3TC as the preferred drug regimen for daily oral PrEP. The alternate regimen for daily oral PrEP is a daily dose of TDF.

- TDF/FTC or TDF/3TC can be used for event-driven oral PrEP (ED-PrEP)



WHO. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. Recommendation for a Public Health Approach, 2nd edition. Geneva: World Health Organization; 2016. License: CC BY-NC-SA 3.0 IGO.

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Oral PrEP Side Effects

Evidence from iPrEx open-label extension (OLE) study and randomised controlled trial (RCTs) shows that participant experienced side effects, which included:

- Gastrointestinal (GI) side effects (nausea, flatulence, diarrhoea, abdominal pain, and vomiting), headaches, and skin problems or itching)
- Creatinine elevation: typically reversible
- Loss of bone mineral density; recovers after stopping PrEP.

The side effects were mild and usually did not persist beyond the first month.

- A “start-up” syndrome was reported that resolved within one month. (iPrEx OLE study)
- The reported start-up syndrome is transient but can influence adherence. Therefore, adherence counselling should focus on the transient nature of the start-up syndrome.

Risk Behaviours, HIV Drug Resistance, And Sexually Transmitted Infections

Will oral PrEP encourage people to use condoms less often or to have more sexual partners (i.e., ‘risk compensation’)?

- There was *no* evidence of this in clinical trials, where participants received regular counselling, screening, and access to condoms and lubricants.
- Evidence from real-world PrEP implementation shows declines in self-reported condom use and increases in diagnoses of sexually transmitted infections (STIs) (though increased testing may also play a role in this) among some oral PrEP users.

Combination prevention should include quality counselling and access to condoms and lubricants.

Will PrEP lead to more HIV drug resistance?

- HIV drug resistance (HIVDR) in oral PrEP users was rare in clinical trials.
- HIVDR occurred mostly in cases where the person had undiagnosed HIV infection when starting oral PrEP.
- HIVDR will not occur when adherence to PrEP is high and HIV seroconversion does not occur.
- There can be a risk of HIVDR if adherence is suboptimal and HIV infection occurs while the individual is on oral PrEP.
- Optimal oral PrEP adherence is crucial.
- Health providers must support and monitor adherence and teach oral PrEP users to recognize signs and symptoms of acute HIV infection (AHI).

Does PrEP protect against other STIs?

- PrEP does *not* prevent syphilis, gonorrhoea, chlamydia, or human papilloma virus (HPV).
- Only condoms prevent other STIs and pregnancy.
- Oral PrEP prevents HIV.
- Oral PrEP should be provided within the minimum package of prevention services, contraceptives.

Oral PrEP Minimum Package of Services

- HIV testing and counselling, including index testing, self-testing, and couple testing.
- Urinalysis should be offered as baseline screening when eGFR (estimated glomerular filtration rate) results are delayed or when eGFR is not available in the health care facility.
- eGFR and monitoring of kidney function
- Hepatitis screening
- Comprehensive HIV prevention, including risk-reduction counselling and condom/lubricant distribution
- Assessment of need for contraceptives and/or pregnancy testing
- STI screening, diagnosis, and treatment
- Screening for noncommunicable diseases (NCDs), such as diabetes mellitus and hypertension
- Referral for services for gender-based violence, legal aid, or mental health issues identified during counselling
- Adherence assessment and counselling, help identify possible barriers to good adherence

Can PrEP be used with other medications and substances?

- There is no known evidence that using other medications or substances affects the safety or effectiveness of oral PrEP.
- However, alcohol and other substances could make you forget to take oral PrEP.

- An oral PrEP user who thinks their alcohol or drug use might affect their ability to use oral PrEP effectively should talk with their health care provider to develop an individualized plan.
- Clients with history of substance abuse should be referred for appropriate support services.

Module 1 Key Points

- Oral PrEP can be used by people who are HIV-negative to *reduce* the risk of HIV acquisition.
- Daily oral PrEP or event-driven Oral PrEP with TDF-containing regimens is the current national recommendation.
- Oral PrEP should be taken with consistent and correct condom use in *addition* to other prevention intervention.
- Oral PrEP is *effective* if taken correctly and consistently.
- Oral PrEP can be used by anyone who is at substantial risk of acquiring HIV.
- Oral PrEP is *safe* and has minimal side effects.

Module 2: Oral PrEP Screening and Eligibility

Learning Objectives

After completing Module 2, participants will be able to:

- Know the policy recommendations regarding oral PrEP
- List the various entry points for Oral PrEP
- Know the criteria for oral PrEP Use the Oral PrEP Eligibility Form to screen clients for substantial risk of HIV acquisition.
- List the contraindications for oral PrEP.
- Explain how to exclude acute HIV infection (AHI).

Policy Recommendations on Oral PrEP Use

The **World Health Organization** Recommends that Oral PrEP containing TDF should be offered as an additional prevention choice for people with substantial likelihood of HIV acquisition as part of combination HIV prevention approaches.

Also, The **National Guidelines on HIV Prevention, Treatment and Care (2020)** states that daily oral PrEP is effective in reducing the risk of acquiring HIV infection using TDF-based ARV drug combinations. The level of protection does not differ by age, sex, or mode of acquiring HIV (rectal, penile, or vaginal exposure).

(The trainer will provide the national algorithm.)

Entry Points for Oral PrEP

1. Out-patient clinic or facility

- HIV testing services (index testing, recency testing)
- STI services
- Sexual and gender-based violence services
- Harm reduction and drug treatment services
- Antenatal services
- Sexual and reproductive health services
- Adolescent and youth friendly clinic (Operation Triple Zero)

2. In-patient

- Referred from emergency room or hospital staff

3. Community-based and outreach HIV testing—clients tested for HIV in community and outreach settings such as:

- One-stop shops
- Drop-in centres
- Adolescent and youth friendly centres
- Community pharmacies

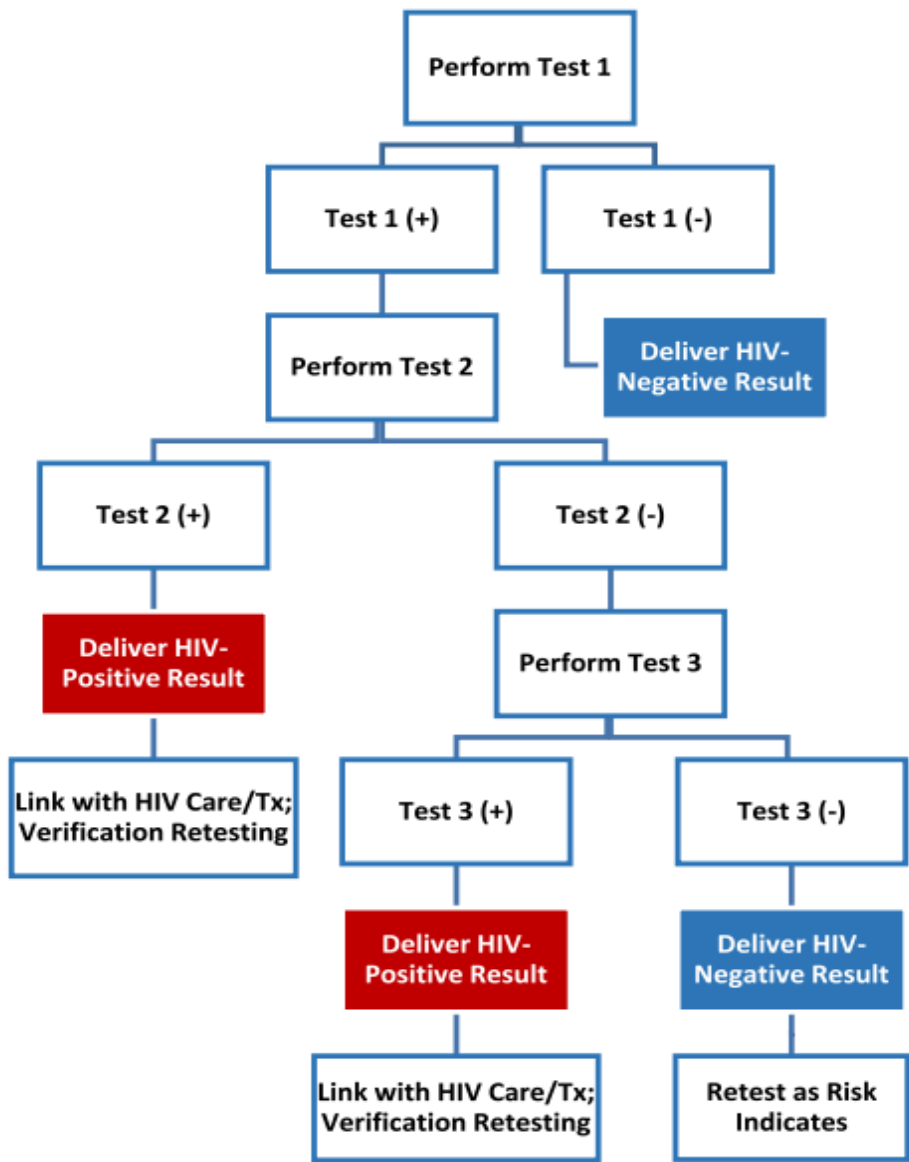
- HIV self-testing (followed by a confirmatory test at a health facility).
 - Outreaches
 - Peer support group
4. **PMTCT**—HIV-negative partners of HIV-positive pregnant women should be offered oral PrEP.
 5. **PEP**—Clients on repetitive PEP services should be offered oral PrEP.

Criteria for Oral PrEP initiation

1. HIV sero-negative:
2. No suspicion of AHI
3. Substantial risk of HIV acquisition
4. Urinalysis to rule out proteinuria
5. Willingness to use oral PrEP as prescribed

HIV testing must be done using national guideline and algorithms

National HIV Testing Algorithm



Key:

Test 1: Screening

Test 2: Confirmatory

Test 3: Tie Breaker

Contraindications For Oral PrEP

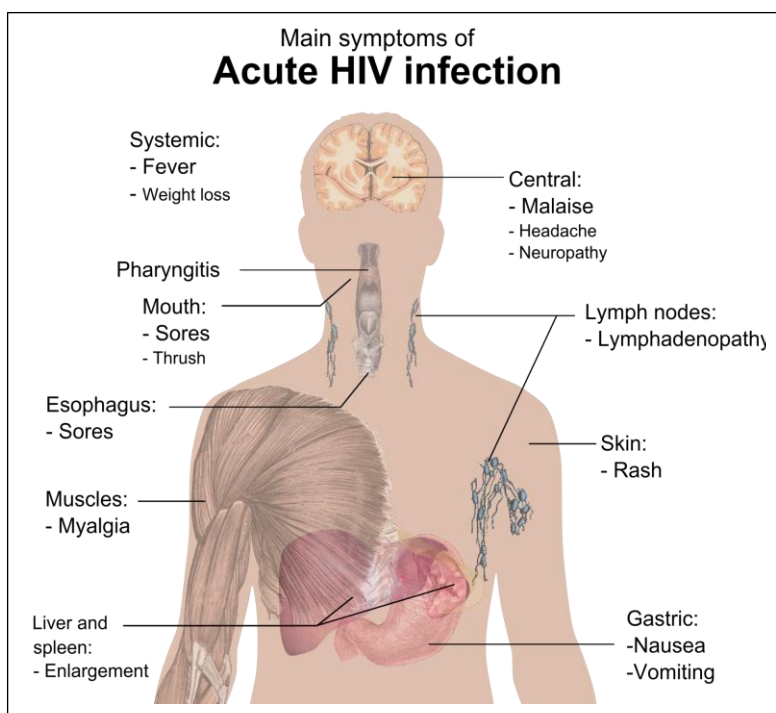
PrEP should NOT be provided to people with:

- HIV positive test on the day of PrEP initiation using
- the Nigeria national HIV testing algorithm
- Known exposure to HIV in the past 72 hours (requires PEP)
- Signs of Acute HIV Infection (AHI) (Box 7.1)
- (Defer PrEP and consider PEP counselling for
- clients with a history of high-risk unprotected sex in
- the past three days, even in the absence of symptoms
- of AHI).
- A client unable to commit to PrEP adherence, and to
- attend scheduled PrEP visits
- Drug allergy to TDF or FTC
- eGFR < 60 ml/min
- Concurrent nephrotoxic medication

Acute HIV Infection (AHI)

AHI is the early phase of HIV disease characterized by an initial burst of viremia. AHI develops within 2 to 4 weeks after someone is infected with HIV. Approximately 40–90% of clients with AHI will experience ‘flu-like’ symptoms. These symptoms are not specific to HIV but occur in many other viral infections. Clients with AHI can be asymptomatic.

Note: Oral PrEP should not be started if AHI is suspected.



Other Symptoms of Acute HIV Infection

- Fatigue
- Anorexia
- Mucocutaneous ulceration
- Headache
- Aseptic meningitis
- Radiculitis, myelitis

Diagnosis of Acute HIV Infection

During AHI, antibodies might be absent or be below the level of detection. Serological testing using rapid tests might be negative. This can be diagnosed using ‘direct’ viral tests such as HIV RNA or HIV antigen testing. In the absence of HIV RNA and antigen testing, defer oral PrEP for 4 weeks if the client has symptoms of AHI* and has been exposed to HIV 2 weeks prior to the test.

These symptoms are not specific to HIV; they occur in many other viral infections. Remember, many clients with AHI are asymptomatic.

Repeat the HIV serological test after 4 weeks to reassess HIV status.

Screening For Substantial Risk of HIV Acquisition

screening and eligibility form should be used to identify clients at substantial risk of HIV acquisition. Service providers can initiate clients on oral PrEP based on outcome from risk assessment or clients’ request after screening.

Based on history in the past 6 months: If the client is sexually active in a high HIV prevalence population (either in the general population or a key population or adolescent group) and reports any one of the following:

- Unprotected vaginal or anal intercourse with more than one partner
- Has sex partner (s) with substantial risk for HIV acquisition
- History of an STI (based on lab test, syndromic STI treatment, or self-report)
- The client reports a history of sharing of injection material and/or equipment with another person
- The client reports having a sexual partner who is HIV positive and has not been on effective HIV treatment.
- History of recurrent use of PEP

Note: *Providers should assess if client had an exposure to HIV within 72 hours.*

- *If a client reports an exposure to HIV within 72 hours, client should be screened for possible eligibility for PEP instead of oral PrEP and provided PEP or linked to PEP services. After 28 days of PEP, client may be directly transitioned from PEP to oral PrEP without a gap if the client is still HIV-negative and has ongoing exposure to HIV.*
- *A client who presents more than 72 hours after exposure should be screened for HIV. If negative, the individual should be retested after 3 months.*

Screening for Substantial Risk of HIV Acquisition

- Frame screening questions in terms of people’s behaviour rather than their sexual identity.
- In your screening questions, refer to a defined time period (e.g., 6 months).
- As an oral PrEP provider, remember to be sensitive, inclusive, nonjudgmental, and supportive.
- Be careful not to develop a screening process that might discourage oral PrEP use.

Screening Questions

Consider oral PrEP if a client from a high-prevalence setting or population answers ‘yes’ to any of the following questions.

Over the past 6 months:

- Have you had anal or vaginal sex with more than one partner without a condom?
- Do any of your partners have potential exposure to HIV?
- Have you been diagnosed with or had symptoms of any STIs?
- Have you used PEP?
- Have you injected drugs or hormones using shared injection material or equipment?
- Have you had sex with person when did not know their HIV status?

Have you...

- Received money, housing, food, or gifts in exchange for sex?
- Been forced to have sex against your will?
- Been physically assaulted by anyone, including a sex partner?
- Used recreational or psychoactive drugs?
- Been required to leave your home? (Internal displacement, banditry, ethnic/religious clashes, etc.)
- Moved to a new place?
- Lost your job?

Oral PrEP for Serodiscordant Couples

- Oral PrEP can be used to prevent HIV acquisition in serodiscordant relationships if the partner living with HIV has been on ART for less than 6 months.
- Oral PrEP use by the HIV-negative partner can be continued until the partner living with HIV has a suppressed viral load.
- Oral PrEP should be considered if:
 - The HIV-negative partner is not sure of their partner’s adherence to treatment or has other sexual partners besides the partner on treatment.
 - The HIV-negative partner is aware of gaps in their partner’s treatment adherence.
 - The couple is not communicating openly about treatment adherence and viral load test results.
 -

Questions to Help Identify Serodiscordant Couples for Oral PrEP

- Is your partner taking ART for HIV?
- Has your partner been on sustained ART for more than 6 months?
- Do you regularly discuss your partner's adherence to HIV treatment (i.e., at least monthly)?
- Do you know your partner's last viral load? What was the result? And when was the testing done?
- Do you wish to have a child with your partner?
- Are you and your partner consistently using condoms?

Renal Screening

- Urinalysis is used as a screening test to exclude proteinuria.
- Creatinine clearance is highly recommended for facilities that have the capacity and potential to run the test.
- TDF can be associated with a small decrease in estimated creatinine clearance (eGFR) early during PrEP use. Usually this does not progress.
- PrEP is not indicated if eGFR* is < 60ml/min.

*eGFR = estimated glomerular filtration rate using Cockcroft-Gault equation:
 Estimated CrCl = [140-age (years)] x weight (kg) x f
 where f=1.23 for men and 1.04 for women / [72 x serum creatinine (µmol/L)]

Oral PrEP Use in Pregnancy

- The National Guidelines for HIV Prevention, Treatment and Care (2020) recommend oral PrEP in pregnant and breastfeeding women who are at substantial risk of HIV acquisition.
- WHO guidelines state that there is no safety-related rationale for disallowing or discontinuing oral PrEP use during pregnancy and breastfeeding.

Oral PrEP is safe and does not prevent pregnancy.

Oral PrEP and Hormonal Contraceptives

- Oral PrEP does not affect the efficacy of hormonal contraceptives.
- Taking oral PrEP and hormonal contraceptives together does not make either less effective.

Willingness To Use Oral PrEP as Prescribed

- Education and counselling are provided to support clients to make an informed choice about oral PrEP use.
- Clients must not be coerced into using oral PrEP.

- Research indicates that adherence is higher among people who are aware that they are at substantial risk of HIV infection and are motivated to take oral PrEP.

Clinical Scenarios

Clinical Scenario 1

Ricky, a 22-year-old transgender man, presents at the clinic because he is interested in starting oral PrEP. He reports using condoms sometimes during sex with his male partner who is living with HIV. His partner has been on ART for 4 years. His partner's most recent viral load from 'a few months ago' was reported as 1200 copies/mL. Their last unprotected intercourse was four weeks ago. Ricky is in good health and takes no medications. His rapid HIV test today is negative.

Is Ricky a candidate for oral PrEP?

- Why or why not?
- Do you need more information?

Clinical Scenario 2

Tracy, an 18-year-old female sex worker, comes to the clinic because she feels sick and thinks she might have HIV. She reluctantly explains that during the past year, she has been having sex for money or gifts to support her 2 children. Some of her partners have used condoms and others have not. She does not know whether her partners have HIV. Tracy reports that she has been feeling run-down and sick for the past few weeks. Her HIV test today is negative.

- Is Tracy a candidate for oral PrEP?
- Why or why not?
- Do you need more information?

Clinical Scenario 3

Hauwa, a 30-year-old wife and mother presents at the clinic because she has heard that she can get drugs that will prevent her from getting HIV. She suspects that her husband has been injecting drugs because he has needle marks on his arms. She reports that her husband has not been tested. Hauwa's HIV test result today is negative.

- Is Hauwa a candidate for oral PrEP?
- Why or why not?
- Do you need more information?

Module 2 Key Points

- Providers should inform and counsel potential oral PrEP users and conduct an individualized behavioral assessment.
- Criteria for oral PrEP use:
 - HIV negative.
 - No suspicion of AHI
 - At substantial risk of HIV acquisition
 - Urinalysis to rule out proteinuria

- Willingness to use PrEP as prescribed.
- Oral PrEP screening questions should be framed in terms of a person's behaviour.
- Side effects in clinical trials were rare and when they occurred, mild

Module 3: Oral PrEP Initial and Follow-Up Visits

Learning Objectives

After completing Module 3, participants should be able to:

- Understand Oral PrEP initial and follow-up visits
- Describe the content of counselling for oral PrEP initial and follow-up visits.
- Follow the Integrated Next Step Counselling (iNSC) process to counsel clients on sexual health and oral PrEP adherence.
- List possible challenges encountered in providing oral PrEP services and how to manage them.
- Know the appropriate guidelines in providing oral PrEP services.

Oral PrEP Initial Visit

This is the first visit by a potential PrEP user to a PrEP service provider for information and possible initiation of PrEP services. It involves investigations and interventions undertaken at first PrEP visit.

Minimum Package and Reasons for Services Provided During Oral Prep Initial Visit

Service	Reasons for service
HIV testing and counselling, including index testing, self-testing, and couple testing	Assessment of HIV infection status
<ul style="list-style-type: none"> • Urinalysis should be offered as baseline screening when eGFR (estimated glomerular filtration rate) results are delayed or when eGFR is not available in the health care facility. • eGFR and monitoring of kidney function 	To rule out renal impairment
Hepatitis screening	<ul style="list-style-type: none"> • To be aware of the risk of exacerbation of hepatitis B which can occur when PrEP is discontinued (due to TDF Toxicity).

	To assess for diabetes mellitus and hypertension, etc
Pregnancy testing	<ul style="list-style-type: none"> To guide ANC, contraceptive and safer conception counselling, and to assess risk of MTCT. <p>*Pregnancy is not a contraindication for oral PrEP</p>
Counselling	<ul style="list-style-type: none"> Assess substantial risk of HIV, To discuss need, and provide condom and lubricants To discuss desire for PrEP and willingness to take PrEP To develop plan for effective PrEP use, sexual and reproductive health To assess Intimate Partner Violence (IPV) and GBV, substance use and mental health for possible referral To assess fertility intentions and offer contraception or safer conception counselling. To help identify possible barriers to adherence and agree on possible solutions
STI screening (syndromic or aetiologic)	To diagnose and treat STIs
	To assess need for contraceptives

	<p>To assess substantial risk for HIV acquisition</p> <p>To provide information and HIV prevention options</p> <p>Discuss risk-reduction,</p> <p>Provide condoms and lubricants</p> <p>To discuss desire for oral PrEP and willingness to take oral PrEP</p>
PrEP Initiation and Adherence Counselling	To reduce the risk of HIV acquisition
	To ensure correct and consistent oral PrEP use

Oral PrEP Initial Visit Counselling

This is a process whereby the provider interacts and counsels a prospective client to enable the person make an informed decision. Oral PrEP counselling helps clients identify factors that either facilitate access to oral PrEP or act as barriers. It helps clients to identify factors that influence their behaviours positively.

During initial visit counseling, the counselor should:

- Increase awareness of oral PrEP as a choice.
- Explain how oral PrEP works.
- Cover sexual health and oral PrEP as part of combination HIV prevention, including how to reduce exposure to HIV.
- Help clients decide whether oral PrEP is right for them.
- Counsel on the importance of adherence and follow-up visits.
 - Explain the symptoms of AHI.
 - Discuss and reinforce common adherence strategies
 - Describe common oral PrEP side effects and management.
 - Assess for substantial risk of HIV acquisition using risk stratification tools.
 - Assess for gender-based violence, including intimate partner violence, and provide first-line support and referrals where needed.
 - Assess for need of mental health or legal-aid referrals.
 - No prevention method, including oral PrEP, is 100% effective except abstinence.

Provide oral PrEP efficacy messages to include;

- Oral PrEP is safe and works when taken as prescribed.
- Oral PrEP reaches maximum effectiveness after 7 daily doses for receptive anal sex and 21 daily doses for vaginal sex and for people who inject drugs. Oral PrEP does not prevent other STIs or unwanted pregnancies.

Features of Oral PrEP Counselling

- It is context specific.
- Valuing each client’s context, situation, and decisions
- It is client centred.
- Attentive to unmet needs that may challenge oral PrEP use or adherence
- It is focused on problem solving, with an emphasis on the client’s choice.

Client-Centred Counselling

- The term ‘client centred’ refers to seeing clients as the experts on their own lives. Client-centred counselling emphasizes respecting an individual’s experiences and choices.
- This approach can increase a client’s motivation to use oral PrEP correctly and consistently, because it addresses clients’ perceptions about the consequences of non-adherence vs. adherence.

Key Approach - For Effective Oral PrEP Counselling

Integrated Next Step Counselling (iNSC)

The iPrEx OLE (initiation PrEP Open Label Extension) study used iNSC to counsel individuals on SRH promotion more generally, with specific emphasis on oral PrEP adherence. The model is client centred and focused on problem solving. This counselling is a discussion about an individual’s activities to protect their sexual health. The iNSC is used to deliver negative HIV test results and serves both as post-test HIV counselling and as counselling on the decision to use and continue oral PrEP. The iNSC steps are as contained in the table below.

iNSC Step	Critical Components	Example Prompts
<p>Introduce the counselling session.</p>	<p>Explain what you are talking about and why. Get permission to proceed.</p>	<p><i>I would like to take a few minutes to check in with you about your goals and how to meet them. Is that okay?</i></p>

<p>Review the client’s experiences.</p>	<p>Ask about what the client already knows about oral PrEP and how they learned it.</p>	<p><i>Thank you. Can you tell me a little about what you have heard about oral PrEP and about your experiences with oral PrEP?</i></p>
<p>Explore the context of client-specific facilitators and barriers.</p>	<p>Use open-ended questions to explore factors or situations that help make pill taking a little easier; and those that make it harder or a little more difficult.</p>	<p><i>What seems to make oral PrEP easy to take or harder to take?</i></p>
<p>Tailor the discussion to focus on making pill taking easier.</p>	<p>This pause allows the provider or counsellor to consider how to tailor the next question based on information gathered in earlier steps.</p>	<p><i>Let me think for a moment about what you have said.</i></p>
<p>Identify adherence-related needs.</p>	<p>Guide the conversation toward identifying the client’s perceptions of what would help to best integrate oral PrEP use into daily life.</p>	<p><i>Given everything going on right now, what would need to happen for it to feel a little easier to work this regimen into your daily life?</i></p>
<p>Strategize with the client on the next step.</p>	<p>Work with the client to identify one or more viable strategies for increasing effective oral PrEP use.</p>	<p><i>How could that happen? What are some ideas to approach that?</i></p>
<p>Agree on which strategy will be tried next.</p>	<p>Ask which strategy (or strategies) the client is willing to try or continue using.</p>	<p><i>Kindly, try all we have discussed.</i></p>
<p>Close and document the session</p>	<p>Summarize the discussion and thank the client.</p>	<p><i>Your feedback shows that you will try PrEP for the next one month. Thank you for talking with me, and I look forward to seeing you again.</i></p>

Below is the provider Checklist for Substantial Risk.

Engage the client in a detailed discussion of the following:

Sexual Behaviour

- How has your sexual life been in the last 3 months?
- How often did you use condoms in the last 3 months?
- What has made it easier to use condoms during sex?
- What has made it more difficult?
- What concerns do you have about your sexual activities?
- How might taking oral PrEP affect your sexual activities?

Drug Use

- Have you used any drug/s in the last 12 months? (yes/no)
- If yes, which drug/s (e.g., alcohol, opioids, stimulants, cannabis)?
- And how did you use them (smoking, orally, injecting)?
- When did you last use drugs (and which ones)?
- How often do you use drugs? Has your drug use ever been a problem for you?
- Do you think your drug use may increase your exposure to HIV?

Staying HIV and STI Negative

- In what ways are you preventing your exposure to HIV and other STIs now (e.g., abstinence, condoms, and lubricants, etc.)?
- What other ways have you considered as a measure for preventing HIV in the future?
- You are reducing your risk of getting HIV by deciding to take oral PrEP. What other ideas or plans, if any, do you have for staying HIV and STI negative?

Preparing for Effective Oral PrEP Use

- Are you taking any medication on a daily/long-term basis? (yes/no)
- If yes, what is your experience taking a medicine daily?
- How did you remember to take your medicine in the past?
- What is your plan for taking your PrEP pill daily?

Ask client what questions they have about the information presented thus far, invite participants to answer one another's questions, and complement and clarify answers as needed.

Oral PrEP Initial Visit: Adherence Counseling**Adherence Messaging for Oral PrEP Initial visit**

- Taking oral PrEP each day is easier if linked to a daily routine, such as brushing teeth or eating breakfast
- Take your pill at the same time every day. If you forget to take a pill or miss a dose, take it as soon as you remember. For example, if you usually take oral PrEP in the morning but realize at night that you forgot, it is okay to take your pill then.
- Oral PrEP can be taken at any time of the day, with or without food.

- Oral PrEP is safe and effective even if you are taking hormonal contraceptives or sex hormones.

Adherence Strategies

- Link oral PrEP to a daily routine or event.
- Use a pillbox.
- Identify significant others who can support oral PrEP adherence.
- Use reminder alarms, text messages, or a calendar.
- Have a backup supply of pills in your bag or purse.

Oral PrEP follow-up visit

This is a periodic visit by PrEP user to the service provider for continuum of care. It includes investigations and interventions undertaken at periodic visits.

The suggested follow-up visit schedule is:

- A month after initiating oral PrEP
- Every 3 months thereafter, as long as the client is on oral PrEP

In addition to regular monitoring visits, encourage clients to consult their providers if they experience adverse events, side effects, or signs or symptoms of AHI.

Services provided during Oral PrEP follow-up Visit

Procedure	Investigation/Intervention	Rationale/ Objectives
HIV Testing Services	HIV test	Assessment of HIV infection status after first one month and subsequent 3 monthly visits of oral PrEP initiation. If positive, link to ART, if negative, continue on oral PrEP
Renal assessment	<ul style="list-style-type: none"> • Urinalysis should be offered at every follow-up. <p>eGFR is recommended every 6 months after PrEP initiation.</p>	To rule-out renal impairment

STI screening and management	<ul style="list-style-type: none"> • STI screening (syndromic or aetiologic) 	To diagnose and treat STIs
Counselling	<ul style="list-style-type: none"> • 	<p>To re-enforce the following:</p> <ul style="list-style-type: none"> -Risk reduction -Condom and lubricants use -Desire and willingness to continue PrEP use -Plan for effective PrEP use, sexual and reproductive health -Reporting of Intimate Partner Violence (IPV) and GBV, substance use and mental health for possible referral • To re-assess fertility intentions and offer contraception or safer conception counselling. • To help identify possible barriers to adherence and agree on possible solutions
Adherence and side effect assessments	Adherence counseling	<ul style="list-style-type: none"> • To assess that client is following the prescription strictly • Assess to possible barriers to adherence • To assess for willingness to continue
	Side effect assessment	<ul style="list-style-type: none"> • To identify early the symptoms and signs of side effects • To reassure clients to continue on the drug • To manage appropriately if need be
PrEP re-fill		<ul style="list-style-type: none"> • To ensure client has PrEP medication at all times

Oral PrEP follow-up visit Counselling

Oral PrEP follow-up visit counseling should include the following;

- Current status of sexual health (e.g., sexual health and drug use behaviours)
- Non-PrEP sexual health preventive strategies (e.g., condom and lubricant use)
- Assessment of continued exposure to HIV and continuing need for oral PrEP
- Intention to remain on oral PrEP
- Facilitators and barriers to oral PrEP use
 - Adherence challenges
 - Common adherence strategies
 - Challenges with disclosure of oral PrEP use
- Dosing requirements for effectiveness
- What to do if a dose is missed
- How to recognize symptoms of AHI
- Side effects and their management.
- How to safely discontinue and restart oral PrEP (if appropriate)

Oral PrEP Follow-up Visit Checklist

Visit	Procedure
Visit 2 (Month 1) Counsellor/Clinician Visit	<ul style="list-style-type: none"> • Safety monitoring clinical assessment • HIV testing and counselling • STI screening and management • Adherence and risk reduction counselling • If HBsAG negative, offer HBV vaccination if available (follow HBV vaccination schedule complete series)
Visits for Months 3, 9, 15	<ul style="list-style-type: none"> • HIV testing and counselling • STI screening and management • HIV risk assessment for oral PrEP continuation • Adherence and risk reduction counselling • Assess for adverse drug reactions
Visits for Months 6, 12, 18, 24, 36	<ul style="list-style-type: none"> • HIV testing and counselling • STI screening and management • Creatinine and eGFR * • HIV risk review and assessment for oral PrEP continuation • Adherence and risk reduction counselling • Assess for adverse drug reactions

Unscheduled visits: as per need	<ul style="list-style-type: none"> • Determine if the reason for the visit is PrEP related or not (e.g., adverse events). • Assess and manage the reason for the unscheduled visit according to national guidelines (e.g., acute or chronic illnesses, worsening existing conditions). • Provide HIV risk reduction and oral PrEP adherence counselling. • Agree on follow-up schedule.
<p>During every visit: Remind oral PrEP users of the dosage of oral PrEP needed to achieve adequate levels of the ARVs in tissues to be effective and of importance of adherence. During these window periods, safer sex practices should be encouraged (including abstinence and condoms).</p>	

*This checklist can be printed as a job aid.

Assessing Oral PrEP Adherence during follow-up visit

- Ask open-ended questions.
- Be non-judgmental.
- Have a constructive discussion that can support the client in finding solutions to adherence challenges.

Examples of Open-Ended, Nonjudgmental Questions on Adherence during follow-up visits

- How has it been, taking oral PrEP?
- What side effects have you had, if any?
- What helps you remember to take your pill?
- What motivates you to continue taking oral PrEP pills?
- What challenges do you experience in taking the pills?
- When are you more likely to forget?
- What are your concerns about missing oral PrEP pills?
- What have been your experiences with missing oral PrEP doses?
- What helps or might help you to take your pills regularly?
- Has oral PrEP made you feel safer about sex? How?
- Has oral PrEP made it easier for you to take charge of your health? How?

Factors Responsible for Oral PrEP Non-Adherence

Individual	Medication-related	Facility-related	Socio-cultural
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<ul style="list-style-type: none"> • Forgetting doses • Being away from home • Changes in daily routines • Depression or other illness • Limited understanding of treatment benefits • Lack of interest in/or desire to take the medicine • Substance or alcohol abuse • Absence of supportive environment • Fear of stigma and discrimination 	<ul style="list-style-type: none"> • Adverse events following oral PrEP administration • Complexity of dosing regimens 	<ul style="list-style-type: none"> • Distance to health services • Access to pharmacies • Availability of PrEP at points of care • Long waiting time to receive care and obtain refill • Burden of direct and indirect costs of care • Poor attitude of health care providers 	<p>People with substantial risk of acquiring HIV often experience stigma from multiple sources.</p> <ul style="list-style-type: none"> • MSM, SWs, and PWID are stigmatised in many places, making them reluctant to seek HIV care. • Transgender individuals often face stigma, discrimination and violence. • Adolescents and youth often face challenges in access to SRH services (gender-based violence, age of consent, etc.).
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Factors Promoting Oral PrEP Adherence

<p>How Health Providers Can Positively Influence Adherence</p>	<p>How Peers Can Positively Influence Adherence</p>
<ul style="list-style-type: none"> • Provide accurate information and education on the benefits, efficacy and requirements of oral PrEP. • Provide accurate knowledge and understanding of medication benefits and requirements. • Express confidence in the effectiveness of oral PrEP. • Prepare the clients for and help manage side effects. • Help the client identify social support. 	<ul style="list-style-type: none"> • Peers with oral PrEP experience can be effective role models. • Peers play an important role in promoting oral PrEP, delivering accurate messaging, following up, and supporting adherence. • Peer workers are an effective ‘first line’ in introducing oral PrEP to clients at community events and outreach activities and in health facilities. • Include peers in oral PrEP discussions and trainings.

<ul style="list-style-type: none"> • Build client self-efficacy for adherence. • Encourage a routine daily schedule that includes regular pill taking. • Maintain an open line of communication with oral PrEP clients. 	<ul style="list-style-type: none"> • Clients may discuss adherence and retention challenges with peer supporters more easily than with health professionals.
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Adherence Assessments

- Discuss adherence at each visit.
- Encourage realistic, honest discussion about challenges or issues a client may be facing while using oral PrEP.
- Encourage oral PrEP clients to self-report pill taking in order to understand their experiences with adherence.
- Additional methods to monitor adherence
 - Pharmacy refill history
 - Pill count
- Ask about adherence over the last 3 days or at last potential exposure for ED-PrEP users.

Oral PrEP Discontinuation

- Starting Oral PrEP does not mean staying on Oral PrEP for life
- People often move in and out of situations of substantial risk for HIV acquisition.
- Counselling and support for ‘*safe stops*’ and ‘*restarts*’ of oral PrEP use are essential.
- Upon discontinuation of oral PrEP, the following information should be documented:
 - HIV status at the time of discontinuation
 - Reasons for discontinuation
- Ideally, clients should discuss with their service provider when they want to discontinue oral PrEP.
- Oral PrEP can be stopped for the following reasons:
 - Client request
 - Positive HIV test (clients who seroconvert while on PrEP should be linked to care and initiated on ART in line with national guidelines)
 - Renal complication, such as any form of proteinuria from urinalysis, eGFR <60mls/min
 - No longer at substantial risk of HIV acquisition
 - Persistent side effects
- A variety of other life changes may prompt a person to stop oral PrEP, including:
 - A partner with HIV on ART attains and maintains a suppressed viral load
 - A relationship becomes mutually monogamous
 - When they change the behaviour that predisposes them to HIV risk (e.g., sex work or injection drug use stops).

- Continue to take oral PrEP for 28 days after their last potential exposure to HIV (except MSM using ED-PrEP, who should continue taking one pill a day until 2 days after their last potential exposure).

Module 3 Key Points

- Prescribe oral PrEP as part of a comprehensive HIV prevention strategy.
- Confirm a negative HIV test immediately prior to initiating oral PrEP.
- Ensure there are no contraindications to oral PrEP.
- Ensure that clients have correct information about oral PrEP.
- Develop an adherence support plan with the client and monitor adherence at each visit.
- Conduct exposure-reduction counselling at each visit.

Module 4: Monitoring and Managing Oral PrEP Use

Learning Objectives

After completing Module 4, participants will be able to:

- Explain causes and management of creatinine elevation.
- Explain how to manage seroconversion.
- Develop strategies to minimize oral PrEP stigma.

Monitoring and Managing Creatinine Elevation

Monitoring Creatinine Elevation

- Approximately 1 in every 200 oral PrEP users may develop an elevation of serum creatinine.
 - Defined as a 50% increase above baseline or an elevation above the normal range.
 - Reminder: Renal impairment is defined as having an estimated creatinine clearance of <60 ml/min.
- Creatinine elevations usually reverse after oral PrEP is stopped.
- It is important to monitor transient creatinine elevation and be alert for signs of chronic or severe renal insufficiency.

Managing Creatinine Elevation

- Stop oral PrEP if creatinine elevation is confirmed on a separate specimen on a separate day and if estimated creatinine clearance decreases to <60 ml/min.
- After oral PrEP is stopped, creatinine should be checked for another 1 to 3 months and oral PrEP should be restarted if eGFR returns to > 60 ml/min.
- Consider additional causes and management of creatinine elevations if:
 - Creatinine elevation reaches more than 3 times the baseline.
 - Renal function or creatinine elevations do not return to normal levels within 3 months after stopping PrEP.
- Common causes of chronic or severe renal insufficiency include diabetes mellitus, uncontrolled systemic hypertension, hepatitis C infection, liver failure, and preeclampsia during pregnancy

**eGFR – estimated glomerular filtration rate*

Seroconversion on PrEP

- In clinical trials, the level of effectiveness in preventing HIV acquisition was strongly correlated with adherence.
- HIV acquisition can be prevented with consistent use of oral PrEP if the exposure continues

- HIV seroconversion after starting oral PrEP can occur if oral PrEP is not used correctly or consistently or if HIV acquisition was undiagnosed at the time of oral PrEP initiation.
- Counselling should include information to help oral PrEP users recognize AHI signs and symptoms, which should prompt a clinic visit without delay.

Managing 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.
- Immediate transition from oral PrEP to HIV treatment will prevent the risk of a surge in viral load, immunological abnormalities, and secondary transmission.
- Close monitoring and tracking are important in identifying gaps and needs in care for increased oral PrEP adherence.

Oral PrEP ‘Special Considerations’

Consideration	Recommendation
Hormonal contraception	<ul style="list-style-type: none"> • Oral PrEP does not affect the efficacy of hormonal contraceptives, and hormonal contraceptives do not affect oral PrEP efficacy.
Pregnancy and breastfeeding	<ul style="list-style-type: none"> • Oral PrEP is safe in people who are pregnant and/or breastfeeding who are at continued substantial risk of HIV acquisition.
Hepatitis B infection (HBV)	<ul style="list-style-type: none"> • Oral PrEP does not affect the efficacy of HBV vaccine.
Management of recent HIV exposure with PEP	<ul style="list-style-type: none"> • People who have been exposed to HIV within 72 hours should be offered PEP. • The National Guidelines for HIV Prevention, Treatment and Care (2020) recommend a TDF/3TC/DTG (preferred) drug combination for 28 days. • PEP may be transitioned to oral PrEP after 28 days if the HIV test remains negative and there is substantial ongoing risk of HIV acquisition.

Oral PrEP and Stigma

- HIV Stigma is a negative attitude and beliefs about People living with HIV. It is also the prejudice that comes with labeling an individual as part of a group that is believed to be socially unacceptable.
- Confidentiality is essential in oral PrEP services.
- People may face stigma if their oral PrEP use becomes known.
- Oral PrEP use can be wrongly perceived as being the result of irresponsible behaviour, which may exacerbate stigmatization. Such stigma will decrease oral PrEP uptake and adherence among people who would otherwise benefit from it.

Presenting oral PrEP to your communities as a responsible choice that prevents HIV acquisition will increase the impact of oral PrEP, prevent more cases of HIV acquisition, and help reduce stigma.

Discussion (15 minutes)

Module 4 Key Points

- Oral PrEP users should be informed about how to recognize signs and symptoms of AHI.
- If someone using oral PrEP, tests positive for HIV, stop oral PrEP and start ART as soon as possible after oral PrEP has been discontinued.
- If confirmation of a positive HIV test result is delayed for more than a few hours, transition to a fully suppressive ART (TDF/3TC/DTG) according to the National Guideline for HIV Prevention, Treatment and Care (2020).
- Ideally, blood creatinine (eGFR) should be measured before starting oral PrEP and *at least every 6 months* after oral PrEP is started. Initiation of oral PrEP should not be delayed while waiting for creatinine results.

Module 5: Oral PrEP Monitoring and Evaluation

Learning Objectives

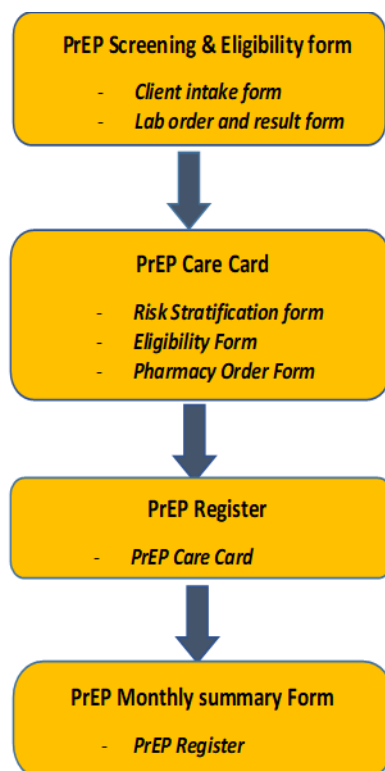
After completing Module 5, participants will be able to:

- Understand the rationale for monitoring and evaluation (M&E).
- Correctly fill out the Oral PrEP Data collection tools PrEP Eligibility Identify the correct order of the steps that health care workers should take during an initial oral PrEP visit.

Rationale For Monitoring & Evaluation

- Helps managers make informed decisions regarding ongoing programmes
- Facilitates effective and efficient use of resources
- Determines whether a programme is on track and where changes need to be considered
- Provides insight into the quality of services
- Helps stakeholders conclude whether the programme is successful or not
- Preserves institutional memory
- Serves as a means of accountability to donors and other stakeholders

National Oral PrEP Service Documentation Flow



Monitoring And Evaluation Tools

The M&E tools covered in this module are:

- Oral PrEP Screening and Eligibility form
- Oral PrEP Care Card
- Oral PrEP Register
- Oral PrEP Monthly Summary Form

Oral PrEP Screening and Eligibility Form

The Eligibility Screening Form contains the following sections:

- Demographic data
- Client biodata
- Pre-test counselling and risk assessment, which includes:
 - A. Sex partner risk assessment
 - B. Personal HIV risk assessment
 - C. Drug use history
 - D. STI screening
- Confirmation of eligibility and services received

Pre-EXPOSURE PROPHYLAXIS SCREENING AND ELIGIBILITY FORM

State: _____ LGA: _____ Facility name: _____
 Setting: _____ (CT, FP, TB, STI, Others) Source of Referral: _____ (Self, Counselor, KOL, Others -specify): _____

Client's Name Surname First): _____		Age (Years): _____		Date of visit: _____	
Unique Client's ID: _____		KP Type: _____		Sex: M F Others	
Pr/State/LGA/OSS/SN		First time visit: [No] [Yes]			
State of Residence: _____		LGA of Residence: _____		Education level: _____	
Occupation: _____		Marital status _____		No. of own children <5 years [] (If married) No. of wives []	
Sex Partners: [Male]: [Female]: [Both]:		Type of Counseling: Individual [] Couple []			

MARK with "X" the [0] if answer is No, the [1] if answer is Yes

Pre-Test Counseling/Risk Assessment																																																																					
<p>(A) Sex Partner Risk (last 3 months)</p> <p>Have you had sex with a partner who</p> <table style="width:100%;"> <tr> <td style="width: 80%;">Is HIV positive</td> <td style="width: 20%;">[0] [1]</td> </tr> <tr> <td>Injects drugs</td> <td>[0] [1]</td> </tr> <tr> <td>Has sex with men</td> <td>[0] [1]</td> </tr> <tr> <td>Is a transgender person</td> <td>[0] [1]</td> </tr> <tr> <td>Has sex with multiple partners without condoms</td> <td>[0] [1]</td> </tr> </table> <p>C) Drug use History (last 3 months)</p> <p>i) Do you use any of these drugs/substances (please tick)</p> <p>Cocaine <input type="checkbox"/> Heroin <input type="checkbox"/> Marijuana <input type="checkbox"/></p> <p>Amphetamine <input type="checkbox"/> Codeine/syrup <input type="checkbox"/></p> <p>Others <input type="checkbox"/> (Specify) _____</p> <p>Route of Administration</p> <table style="width:100%;"> <tr> <td style="width: 80%;">Inject</td> <td style="width: 20%;">[0] [1]</td> </tr> <tr> <td>Sniff</td> <td>[0] [1]</td> </tr> <tr> <td>Snort</td> <td>[0] [1]</td> </tr> <tr> <td>Smoke</td> <td>[0] [1]</td> </tr> </table> <p>ii) Have you used drugs to enhance sexual performance? <input type="checkbox"/></p> <p>Have you had HIV testing before?</p> <p>When was your last test? <1mth <input type="checkbox"/> 1-3mths <input type="checkbox"/></p> <p>4-6mths <input type="checkbox"/> >6mths <input type="checkbox"/></p> <table style="width:100%;"> <tr> <td style="width: 80%;">HIV test result at visit</td> <td style="width: 20%;">Negative [0] [1]</td> </tr> <tr> <td></td> <td>Positive [0] [1]</td> </tr> </table> <table style="width:100%;"> <tr> <td style="width: 80%;">Recommended for HIV Retest?</td> <td style="width: 20%;">[0] [1]</td> </tr> <tr> <td>Tested in certain clinical settings, such as STI clinics?</td> <td>[0] [1]</td> </tr> <tr> <td>Report ongoing HIV risk behaviors?</td> <td>[0] [1]</td> </tr> <tr> <td>Report a specific HIV exposure within the last 3 months?</td> <td>[0] [1]</td> </tr> </table> <p>If client tests HIV negative and, has signs and symptoms acute HIV infection, recommend HIV re-testing after 1 month [0] [1]</p> <p>PrEP Eligibility (Eligible if ALL criteria below are met:</p> <table style="width:100%;"> <tr> <td style="width: 80%;">HIV Negative</td> <td style="width: 20%;">[0] [1]</td> </tr> <tr> <td>HIV risk score ≥ 1</td> <td>[0] [1]</td> </tr> <tr> <td>Signs & symptoms of acute HIV infection</td> <td>[0] [1]</td> </tr> <tr> <td>Has no proteinuria</td> <td>[0] [1]</td> </tr> </table>	Is HIV positive	[0] [1]	Injects drugs	[0] [1]	Has sex with men	[0] [1]	Is a transgender person	[0] [1]	Has sex with multiple partners without condoms	[0] [1]	Inject	[0] [1]	Sniff	[0] [1]	Snort	[0] [1]	Smoke	[0] [1]	HIV test result at visit	Negative [0] [1]		Positive [0] [1]	Recommended for HIV Retest?	[0] [1]	Tested in certain clinical settings, such as STI clinics?	[0] [1]	Report ongoing HIV risk behaviors?	[0] [1]	Report a specific HIV exposure within the last 3 months?	[0] [1]	HIV Negative	[0] [1]	HIV risk score ≥ 1	[0] [1]	Signs & symptoms of acute HIV infection	[0] [1]	Has no proteinuria	[0] [1]	<p>(B) Personal HIV Risk Assessment (Last 3 months)</p> <table style="width:100%;"> <tr> <td style="width: 80%;">Unprotected Vaginal sex with casual partner:</td> <td style="width: 20%;">[0] [1]</td> </tr> <tr> <td>Unprotected Vaginal sex with regular partner:</td> <td>[0] [1]</td> </tr> <tr> <td>Unprotected Anal sex with casual partner:</td> <td>[0] [1]</td> </tr> <tr> <td>Unprotected Anal sex with regular partner</td> <td>[0] [1]</td> </tr> <tr> <td>History of STI</td> <td>[0] [1]</td> </tr> <tr> <td>Shared needles/injecting materials</td> <td>[0] [1]</td> </tr> <tr> <td>More than 1 sex partner</td> <td>[0] [1]</td> </tr> <tr> <td>Anal sex with male partner</td> <td>[0] [1]</td> </tr> <tr> <td>Anal sex with female partner</td> <td>[0] [1]</td> </tr> <tr> <td>Unprotected anal sex with male partner</td> <td>[0] [1]</td> </tr> <tr> <td>Unprotected anal sex with female partner</td> <td>[0] [1]</td> </tr> <tr> <td>Have you paid for sex in the last 6 months?</td> <td>[0] [1]</td> </tr> <tr> <td>Have you been paid for sex in the last 6 months?</td> <td>[0] [1]</td> </tr> <tr> <td>Have you experience condom breakage?</td> <td>[0] [1]</td> </tr> <tr> <td>Have you taken part in sexual orgy?</td> <td>[0] [1]</td> </tr> </table> <p>(calculate the sum of the A & B answers above) Risk score: _____</p> <p>Client is pregnant [0] [1]</p> <p>D) STI Screening</p> <p><i>Female: Complaints of vaginal discharge or burning when urinating</i> [0] [1]</p> <p><i>Female: Complaints of lower abdominal pains with or without vaginal discharge?</i> [0] [1]</p> <p><i>Male: Complaints of urethral discharge or burning when urinating?</i> [0] [1]</p> <p><i>Male: Complaints of scrotal swelling and pain</i> [0] [1]</p> <p>Genital sore +/- pains? [0] [1]</p> <p>Swollen inguinal lymph nodes +/- pains? [0] [1]</p> <p>Anal pain on stooling? [0] [1]</p> <p>Anal itching? [0] [1]</p> <p>Anal discharge? [0] [1]</p> <p>(calculate the sum of the 9 answers above) STI screening score: [0] [1]</p> <p><i>If score ≥ 1, enroll in the STI syndromic management sheet or refer</i></p> <p style="text-align: center;">Services Received by Client (Tick)</p> <p>PrEP Offered No <input type="checkbox"/> Yes <input type="checkbox"/></p> <p>PrEP Accepted No <input type="checkbox"/> Yes <input type="checkbox"/></p> <p>Client referred to other services [0] [1]</p> <p>If [1], please specify _____</p>	Unprotected Vaginal sex with casual partner:	[0] [1]	Unprotected Vaginal sex with regular partner:	[0] [1]	Unprotected Anal sex with casual partner:	[0] [1]	Unprotected Anal sex with regular partner	[0] [1]	History of STI	[0] [1]	Shared needles/injecting materials	[0] [1]	More than 1 sex partner	[0] [1]	Anal sex with male partner	[0] [1]	Anal sex with female partner	[0] [1]	Unprotected anal sex with male partner	[0] [1]	Unprotected anal sex with female partner	[0] [1]	Have you paid for sex in the last 6 months?	[0] [1]	Have you been paid for sex in the last 6 months?	[0] [1]	Have you experience condom breakage?	[0] [1]	Have you taken part in sexual orgy?	[0] [1]
Is HIV positive	[0] [1]																																																																				
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Completed by: _____ Designation _____ Sign _____ Date _____																																																																					

Oral PrEP Care Card

This tool contains the following sections:

- Front page, which contains:
 - Demographic data
 - Client's information on initial visit
 - Biodata

Oral PrEP Care Card (Front Page)

- Oral PrEP commencement data
- Discontinuations and interruptions data
- Status at oral PrEP start (Month 0)
- Subsequent follow-up visits (1–7)
- Discontinued oral PrEP and reasons
- ART linkage

Oral PrEP Care Card (Center Page)

- Client’s encounter page, which contains the clinical assessment information
- The Oral PrEP Care Card is completed after the initial oral PrEP screening for clients who are eligible to start oral PrEP.
- The provider must ask questions of the client in order to complete the card, including test results obtained.
- Follow-up visits should be properly documented on the encounter page

E1	E2	E3	E5	E6	E7	E8	E9	E11	E10	E12	E13	E14	E15	E16	E17	E18
Visit Date	Duration (in Months) on PrEP	Weight (kg)	Blood Pressure (mmHg)	Noted Side Effects (Enter Code)	HTS Result (Enter Code)	Syndromic STI Screening (Enter Code)	Risk Reduction Services (Enter Code)	Adherence (Enter Code)	PrEP Drugs Regimen (Enter Code)	Other Drugs Prescribed	Urinalysis Upper space: Date Lower Space: Result (Enter Code)	Hepatitis Upper space: Date Lower Space: Result (Enter Code)	Syphilis Upper space: Date Lower Space: Result (Enter Code)	Other Tests Done Upper space: Date Lower Space: Result (Enter Code)	Next Appointment Date	Signature

<p>Codes E6 Noted Side Effects</p> <ol style="list-style-type: none"> No side effects Nausea/vomiting Headache Insomnia/bad dreams Fatigue/weakness Abdominal pain Diarrhea Fever Rash Anemia Stevens Johnson syndrome Hyperglycemia Others..... 	<p>Codes E7 HTS Result</p> <ol style="list-style-type: none"> HIV Positive HIV Negative Not Done <p>Codes E8 Syndromic STI Screening</p> <ol style="list-style-type: none"> No STI symptoms/signs Urethral discharge Genital Ulcers Vaginal discharge Lower Abdominal Pain Scrotal Swelling Anal Warts Genital Warts Inguinal bubo Others..... 	<p>Codes E9 Risk Reduction Plan:</p> <ol style="list-style-type: none"> Risk reduction strategies discussed Plan1 plus correct condom use demonstrated Plan1 & 2 plus lubricant provided <p>Codes E10 Regimen</p> <ol style="list-style-type: none"> TDF/FTC TDF/GTC 	<p>Codes E11 Level of Adherence</p> <p>Estimate adherence for twice daily ART using the following table:</p> <table border="0"> <tr> <td>% Missed doses per month</td> <td></td> <td></td> </tr> <tr> <td>G (Good) ≥ 95%</td> <td>≤ 2 doses</td> <td></td> </tr> <tr> <td>F (Fair) 85-94%</td> <td>3-6 doses</td> <td></td> </tr> </table> <p>Codes E12 Why Poor /Fair adherence:</p> <ol style="list-style-type: none"> Forgot Fell asleep/slept through dose Change in routine/away from home Busy/working/at school Patient moved 	% Missed doses per month			G (Good) ≥ 95%	≤ 2 doses		F (Fair) 85-94%	3-6 doses		<p>Codes E13 Urinalysis Result:</p> <ol style="list-style-type: none"> No proteinuria Proteinuria Present - One + Proteinuria Present - Two ++ Proteinuria Present - Three +++ <p>Codes E15 Syphilis Result:</p> <ol style="list-style-type: none"> Negative Positive Not Done Others 	<p>Codes E14 Hepatitis test result</p> <ol style="list-style-type: none"> Hepatitis B Positive Hepatitis B Negative Hepatitis C Positive Hepatitis C Negative
% Missed doses per month														
G (Good) ≥ 95%	≤ 2 doses													
F (Fair) 85-94%	3-6 doses													

NATIONAL ORAL PrEP INDICATORS

- i. Number of eligible people who initiated oral PrEP in the reporting month
 - ii. Number of people who received oral PrEP at least once during the reporting period.
 - iii. Number of eligible people who initiated oral PrEP in the reporting month
Number of individuals returning for oral PrEP who received repeat HIV testing in the reporting month
 - iv. Number of individuals who discontinued oral PrEP
 - o Number of individuals who received oral PrEP in the reporting month
 - v. Number of individuals returning for oral PrEP who received repeat HIV testing in the reporting month
 - vi. Number of individuals who discontinued oral PrEP
- The source document for the indicators is the PrEP Register, and these indicators are reported monthly.

Oral PrEP Indicators Reference Guide

PrEP
NEW

Number of eligible people who initiated oral PrEP during the reporting period

Program Area: ART.

DESCRIPTION: Percentage of eligible people who initiated oral PrEP during the reporting period

Purpose/Justification: The indicator measures the ongoing growth of PrEP services. This measure is critical to assess progress in the program's response to the epidemic in specific geographic areas, and the uptake and utility of PrEP among persons at substantially increased risk of HIV infection.

This indicator permits monitoring trends in PrEP / uptake uptake of PrEP. It helps managers compare the uptake of PrEP among different types of users (for example, by first-time users, age, gender, and members of priority populations). Uptake of PrEP reflects people's awareness and interest in lowering their risk for HIV through the use of antiretrovirals.

PrEP has been shown to reduce incident infections among several populations including sero-discordant heterosexual couples, MSM, FSW, and transgender people (TG). The WHO now recommends that oral PrEP containing tenofovir should be offered as an additional prevention choice for people at substantial risk, defined as HIV incidence > 3/100 person years.

Numerator: Number of people who initiated oral PrEP during the reporting period

Denominator: Number of people who are eligible for PrEP among the people screened

Disaggregation:

- Sex (Male, Female)
- Age (15–19, 20–24, 25-29, 30-34, 35-39, 40-44, 45-49, 50+ years)
- KP types (MSM, FSW, PWID, TG, Persons in Custodial Centers)
- It is also disaggregated by the type of population such as sero-discordant couples (SDC)/Partners Sex workers, injecting drug users, Individuals who engage in unprotected anal sex and exposed adolescents and young people.

The category 'other' population represents partners of key populations, other 'at risk group' (e.g. non-injection drug users, transport workers etc.) and general population who might be aware of PrEP and approach the facility to receive PrEP services.

How to measure:

The numerator is generated by counting the number of people newly enrolled on oral PrEP (including WHO specified regimens “tenofovir-containing PrEP” which could be TDF alone, TDF/FTC, or TDF/3TC) during the reporting period, in accordance with the nationally approved protocol or WHO standards.

The denominator is generated by counting the number of individuals who are eligible for PrEP in accordance with the nationally approved protocol or WHO standards. 'at risk group' (e.g. non-injection drug users, transport workers etc.) and general population who might be aware of PrEP and approach the facility to receive PrEP services.

Method of calculation: Numerator divided by the Denominator

Unit of Measurement: Percentage

Data Sources: Program monitoring tool; EMR, PrEP eligibility register; PrEP monthly summary form; PrEP enrolment register; PrEP Care card

Frequency of collection: Monthly

Frequency of reporting: Monthly

Data Sources: Program monitoring tool; EMR, PrEP eligibility register; PrEP monthly summary form; PrEP enrolment register; PrEP Care card

**PrEP
CURR**

Number of people who received oral PrEP at least once during the reporting period.

Program Area: ART.

Definition(s): Number of people who received oral PrEP at least once during the reporting period.

Purpose/Justification: Tenofovir-containing oral PrEP reduces the risk of HIV acquisition among numerous populations when taken consistently. WHO guidelines recommend offering oral PrEP to those at substantial risk of HIV infection, (incidence rate of 3 per 100 persons per year).

WHO recommends that oral PrEP containing tenofovir be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches? It recommends the use of PrEP as part of a package of comprehensive structural, biomedical and behavioral prevention services.

Monitoring the PrEP cascade will be important to understand which populations are using this prevention intervention, as well as their length of time using it and their HIV outcome. Understanding the PrEP cascade by population will help improve implementation strategies for those in highest incidence communities initiating PrEP and the strategies for supporting continuity of PrEP.

Numerator: Number of people who received oral PrEP at least once during the reporting period

Denominator: NA

Disaggregation:

- Multi-Month Dispense for One Month (MMD1), Two Months (MMD2), Three Months (MMD3)
- Sex (Male, Female)
- Age (<1, 1–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)
- KP types (MSM, FSW, PWID, TG, Persons in Custodial Centers)
- It is also disaggregated by the type of population such as sero-discordant Couples (SDC)/Partners Sex workers, injecting drug users, Individuals who engage in unprotected anal sex and exposed adolescents and young people.
- The category 'other' population represents partners of key populations, other 'at risk group' (e.g. non-injection drug users, transport workers etc.) and general population who might be aware of PrEP and approach the facility to receive PrEP services

How to measure:

- The numerator can be generated by counting the number of individuals that have received PrEP during the reporting period, in accordance with national guidelines or WHO standards,
- including both those individuals newly initiating on PrEP and those continuing to receive PrEP. PrEP_CURR reflects all persons receiving PrEP during the reporting period.
- Unlike the indicator, currently receiving ART, PrEP_CURR counts the number of individuals that received PrEP at ANY point during the reporting period, so the client does not have to be active on PrEP on the last day of the reporting period like TX_CURR.

Method of calculation: Numerator divided by the Denominator

Unit of Measurement: Percentage

Data Sources: Program monitoring tool; EMR, PrEP monthly summary form; PrEP enrolment register; PrEP Care card

Frequency of collection: Monthly

Frequency of reporting: Monthly

Location of Data Storage: Facility Medical Records Unit

PrEP
_SERO
CONVE

Number of individuals who continued oral PrEP for at least 3 consecutive months who retested and had positive HIV result during the reporting period

Program Area: ART.

Definition(s): Number of people who received oral PrEP at least once during the reporting period.

Purpose/Justification: It measures the rate at which clients who started on PrEP seroconvert to HIV positive

Numerator: Number of individuals tested positive after three months of continued oral PrEP

Denominator: NA

PREP
DISCONTI
NUATION

Number of individuals who discontinued oral PrEP during the reporting period

Program Area: ART.

Definition(s): Number of people who discontinued oral PrEP during the reporting period.

Purpose/Justification: It measures the rate at which clients who started on PrEP discontinued PrEP due to one reason or the other which are stated in the PrEP Register.

Numerator: Number of individuals who discontinued oral PrEP

Denominator: NA

Disaggregation:

- Sex (Male, Female)
- Age (<1, 1–4, 5–9, 10-14, 15–19, 20–24, 25-29, 30-34, 35-39, 40-44, 45-49, 50+ years)
- KP types (MSM, FSW, PWID, TG, Persons in Custodial Centers)
- It is also disaggregated by the type of population such as sero-discordant Couples (SDC)/Partners Sex workers, injecting drug users, Individuals who engage in unprotected anal sex and exposed adolescents and young people.

The category 'other' population represents partners of key populations, other 'at risk group' (e.g., non-injection drug users, transport workers etc.) and general population who might be aware of PrEP and approach the facility to receive PrEP services

How to measure:

The numerator can be generated by counting the number of individuals who discontinued oral PrEP during the reporting period.

This indicator counts all individuals who discontinued oral PrEP during the reporting period.

Method of calculation: Count

Unit of Measurement: Number

Data Sources: Program monitoring tool; EMR, PrEP monthly summary form; PrEP enrolment register; PrEP Care card

Frequency of collection: Monthly

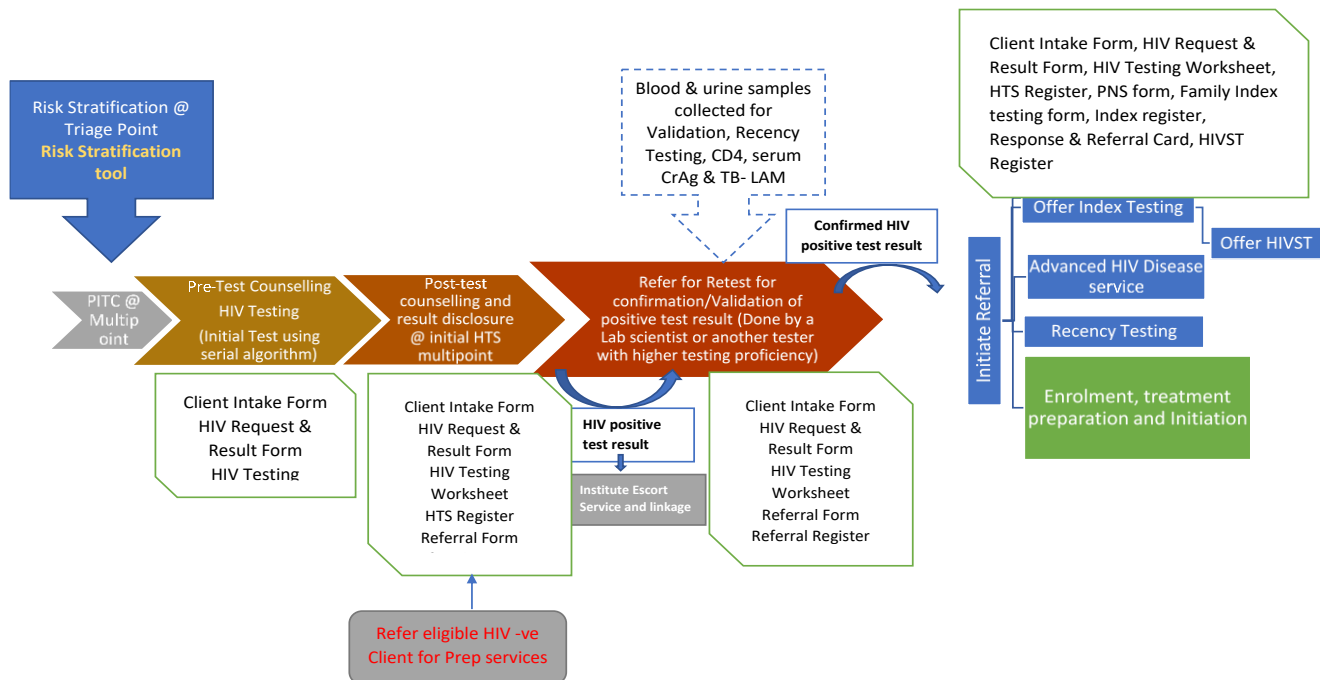
Frequency of reporting: Monthly

Location of Data Storage: Facility Medical Records Unit

Service Flow Chart

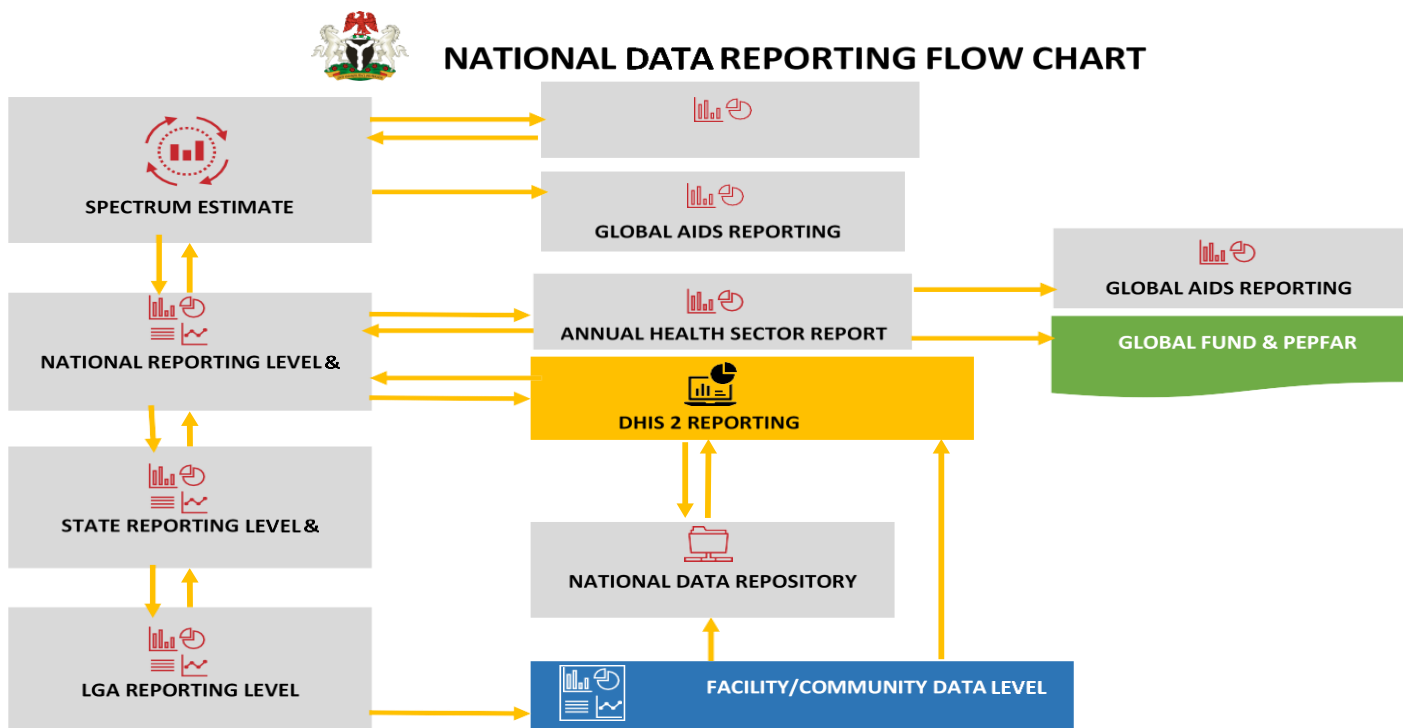
- The chart shows that HTS is the first entry point for all service delivery points at both community and facility levels. The national algorithm is followed for HTS.
- The client is to be initiated on oral PrEP if their test is negative but linked to care if the test is positive.
- Note that a client who was on PEP for 28 days can be transitioned to oral PrEP.

HTS DOCUMENTATION AND SERVICE FLOW



Ensure referrals are made and adequately documented for services not provided in initiating facility

Flow Chart for Reporting



Supply chain and Handling PrEP dugs

- Pharmacists or Providers charged with storage of PrEP drugs should ensure the following:
 - Storage at ambient temperatures of 15-30° C
 - Ensure the container bottles are tightly shut and dispense the medicines only in their original containers
 - PrEP users should be advised to retain the desiccant in the container throughout the period it is being used.
 - Ensure a 4-month supply is available for each PrEP user when initiating new users on PREP.

Module 5 Key Points

- Tracking oral PrEP screening data can inform increased outreach and education efforts and IEC materials.
- Tracking oral PrEP seroconversion data will help ensure appropriate linking and follow-up on clients diagnosed with HIV and can facilitate reporting of seroconversions for surveillance.

- Clients who present more than once for PEP may be candidates for oral PrEP. Engage these clients in sustained risk reduction and HIV prevention services, including oral PrEP.
- If your facility has multiple points of entry, consider adapting the Oral PrEP M&E tools to capture these points.

Module 6: Event-Driven PrEP

Learning Objectives

After completing Module 6, participants will be able to:

- Define event-driven PrEP (ED-PrEP)
- Consider programmatic changes needed to implement ED-PrEP.
- Identify people eligible for ED-PrEP.
- Explain how to take ED-PrEP effectively.
- Describe the advantages and disadvantages of ED-PrEP
- Identify resources for the development of ED-PrEP implementation tools.

Gender And Sexual Identity

Gender and Sexual Identity

Gender Identity: A person's deeply felt internal and individual experience of gender, which may or may not correspond with the sex assigned at birth.



Sexual Identity: Sexual identity is how one thinks of oneself in terms of to whom one is romantically and/or sexually attracted. Sexual identity may also refer to sexual orientation identity, which is when people identify or dis-identify with a sexual orientation or choose not to identify with a sexual orientation.

- **MSM:** Refers to men who have sex with men. This usually refers to cisgender men and may include men who have sex only with men (gay men), men who have sex with both men and women (bisexual men), and men who have sex with individuals of other genders.
 - Not all men who have sex with men identify as gay, so these terms should not be used interchangeably.



NATIONAL AIDS & STI CONTROL PROGRAMME (NASCP) – FEDERAL MINISTRY OF HEALTH

Gender and Sexual Identity (cont.)



- **Transgender:** An umbrella term referring to an individual whose gender identity is different from their sex assigned at birth.
- **Genderqueer or Gender nonconforming:** A person who does not identify as man or woman or may embody both or neither.

Definition of ED-PrEP

- Event-driven PrEP (ED-PrEP) involves taking a double dose (2 pills) of TDF/FTC (**Truvada**) or TDF/3TC (**Tenolam**) between 2 and 24 hours before sex is anticipated and then, if sex occurs, 1 pill 24 hours after the double dose and 1 pill another 24 hours later.
- If sex occurs several days in a row, 1 pill should be taken each day until 48 hours after the last event (WHO 2019).

Clients Eligible For ED-PrEP

Clients Eligible for ED-PrEP

Who is eligible for ED-PrEP?	Who is NOT eligible for ED-PrEP?
<p>This includes MSM, Cisgender Men, Trans Women, and Non-binary people Assigned Male At Birth (AMAB) who do not use exogenous hormones, including gender affirming hormones. Who;</p> <ul style="list-style-type: none"> • Finds ED-PrEP more convenient • Has infrequent sex (for example, sex less than 2 times per week on average) • Is 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 • Men having vaginal and/or anal sex with women

Key Takeaway: Evidence suggests ED-PrEP protects MSM from HIV transmission only during anal sex.



Policy Considerations

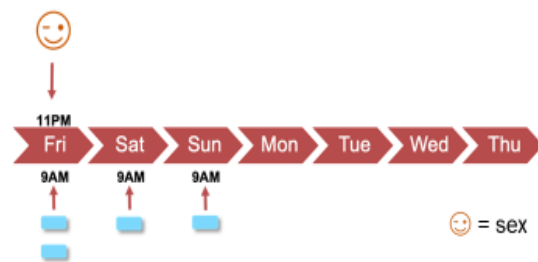
- The World Health Organization (WHO) issued a [technical brief](#) in July 2019 to update the dosing considerations of oral PrEP for MSM.
- ED-PrEP is included in the National Guidelines for HIV Prevention, Treatment and Care 2020.
- WHO update on ED -PrEP 2022

How To Take ED-PrEP Effectively

How to Take ED-PrEP Effectively

Event-Driven PrEP (ED-PrEP) is an additional dosing regimen for men who have sex with men (MSM) only where:

- Two pills of TDF/FTC (or TDF/3TC) are taken 2 to 24 hours before sex (the loading dose) followed by
- One pill 24 hours after the loading dose (the 3rd pill), followed by
- One more pill 24 hours after the 3rd pill (the 4th pill)*



ED-PrEP may also be referenced as 'on-demand', 'event-based', or 'intermittent' PrEP, or '2+1+1'



* If a client has sex on the days following the loading dose, the client should continue taking one pill each day until two days after the last potential sexual exposure.

Evidence For ED-PrEP Efficacy and Implementation

Evidence for ED-PrEP Efficacy and Implementation

Author, Year	Setting	Key Findings
Molina et al., 2015 IPERGAY RCT	France and Canada	<ul style="list-style-type: none"> Likelihood of HIV acquisition was reduced by 86% among men randomised into the ED-PrEP group. Likelihood of HIV acquisition was reduced by 97% during the open-label extension.
Molina et al., 2017 Prevenir observational study	France	<ul style="list-style-type: none"> No new HIV acquisitions were reported in the ED-PrEP group and the daily oral PrEP group. More than half (53%) of MSM preferred ED-PrEP over daily PrEP.
Cornelisse et al., 2019 PrEPX Australian demonstration study	Australia	<ul style="list-style-type: none"> High level of interest in ED-PrEP was strongly associated with having sex infrequently and concerns about long-term toxicity.
Zimmermann et al., 2019 Jongen et al, 2020 Amsterdam PrEP demonstration project (AMPrEP)	The Netherlands	<ul style="list-style-type: none"> MSM have a number of motives for choosing a regimen to meet their priorities and needs for prevention, including changing exposure contexts, perceived or actual self-efficacy around adherence, and effects of oral PrEP on well-being. Adherence to ED-PrEP was significantly higher for sexual encounters with casual sex partners, suggesting that MSM use ED-PrEP when they are most likely to be exposed to HIV.



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Drug Regimen For ED-PrEP

The required combinations for ED-PrEP include:

- TDF/FTC (Truvada)
- TDF/3TC (Tenolam)

Advantages of ED-PrEP

- May require the client to take fewer pills.
- May be more convenient for clients who have potential exposures which are typically planned or irregular.
- May make it easier to keep using or oral PrEP.

Disadvantages of ED-PrEP

- Planning before sex is needed.
- Clients 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 they start ED-PrEP during acute HIV infection.
- No evidence ED-PrEP prevents HIV transmission during any other potential exposures.

ED-PrEP should not be the ONLY option available for MSM.

Stopping and Starting Oral PrEP (MSM only)

Starting and Stopping Oral PrEP (MSM only)

- ▶ **Daily PrEP:** Start with a loading dose of two pills*
- ▶ **ED-PrEP:** Start with a loading dose of two pills each time two to 24 hours before sex

■ **Daily and ED-PrEP:** Stop by taking a pill each day for two days after the last time having sex

🔄 ED-PrEP users should repeat this process for each period of potential exposure to HIV.



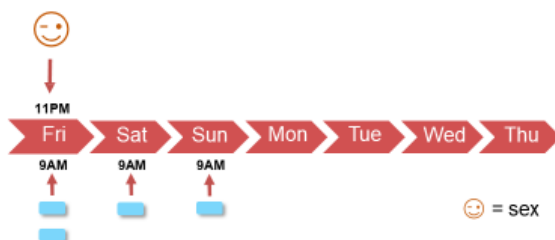
* This represents new guidance on daily oral PrEP for MSM which can be found in the 2+1+1 Guidance from WHO.

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Dosing Scenarios 1–3

Dosing Scenario 1 – Sex One Time

Femi lives in Lagos. On Friday night, Femi plans to invite someone he met on Grindr over to his place and plans to have anal sex. He takes two pills (the loading dose) of PrEP Friday morning at 9am and has sex Friday night at 11pm. He takes a third pill on Saturday at 9am and a fourth on Sunday at 9am.



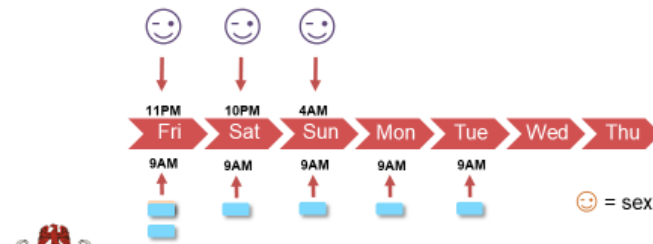
Note: MSM should take 2 pills 2-24 hours before having sex and take 1 pill each day for the 2 days following sex.



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Dosing Scenario 2 – Sex on Multiple Consecutive Days

Audu lives in Abuja. His wife is going to Akwa Ibom to visit her family on Friday and will return on Sunday night. Audu sometimes has sex with his male friends who he is planning to hang out with on Friday and Saturday nights. Audu takes 2 pills (the loading dose) on Friday morning. He has sex Friday night and takes 1 pill on Saturday morning. Saturday night he has sex again, and then again early Sunday morning. Audu takes 1 PrEP pill each morning on Sunday, Monday, and Tuesday at 9am.



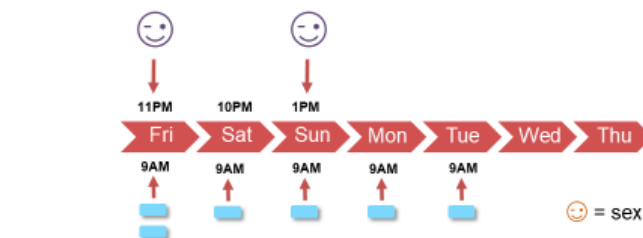
Note: MSM who have sex over multiple days should continue taking 1 pill each day for 2 days after the last time they had sex.



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Dosing Scenario 3 – Sex on Multiple Non-Consecutive Days

Chike is gay and lives in Imo. Chike has a date on Friday night and hopes to have sex. He uses ED-PrEP. He takes 2 pills Friday morning before having sex on Friday night. On Saturday and Sunday, he takes another pill each day. On Sunday, he meets up with his date again and they have unplanned sex, so he continues taking a pill each day on Monday and Tuesday.

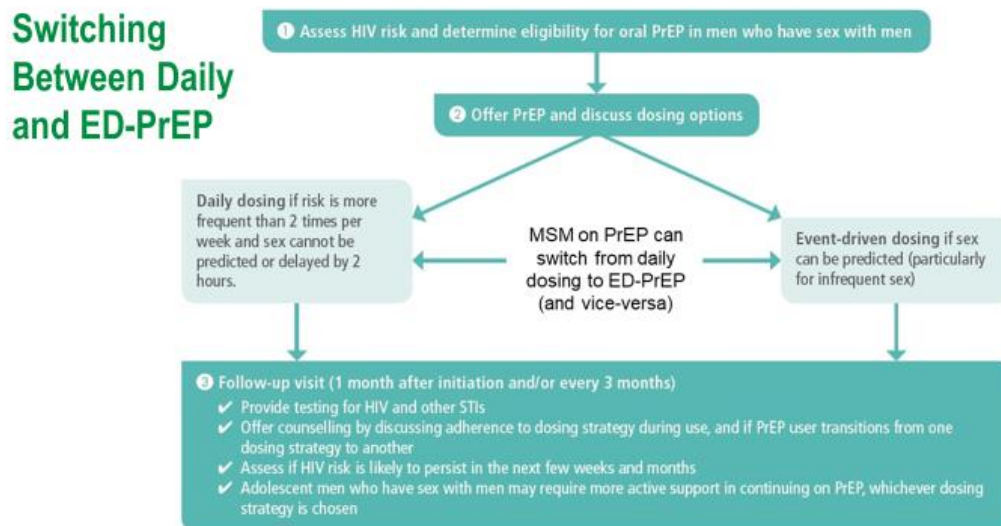


Note: MSM who have sex on non-consecutive days while still taking ED-PrEP should continue taking 1 pill each day for 2 days after the last time they had sex.



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Switching Between Daily and ED-PrEP

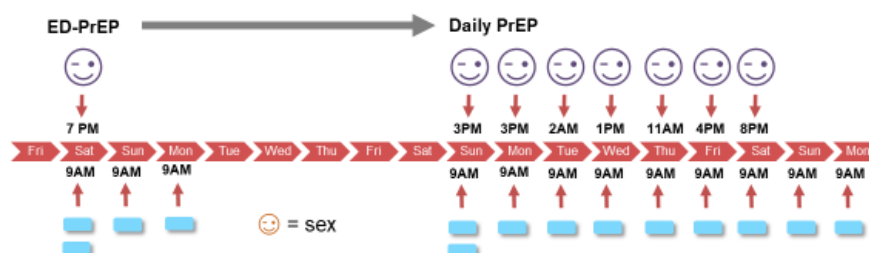


Source: What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: Update to WHO's recommendation on oral PrEP. Geneva: World Health Organization; 2019 (WHO/CDS/HIV/19.8).

Dosing scenarios 4–5

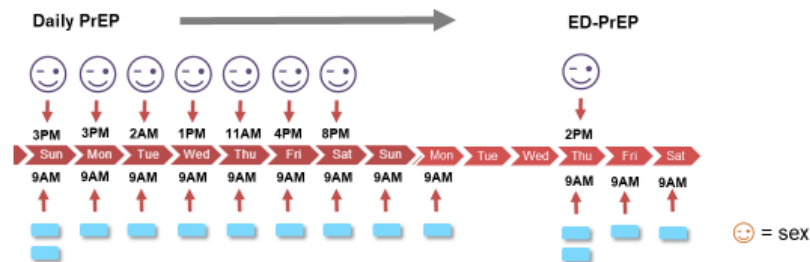
Dosing Scenario 4 – Switching from ED-PrEP to Daily PrEP

Akpan has been taking ED-PrEP for several months. Next week he plans to go to a nearby city to sell sex and make some money at a popular holiday location. Akpan is not always able to negotiate condoms with his clients, so he decides to switch to daily PrEP. Akpan takes 2 pills (loading dose) of PrEP on Sunday, and then continues taking a pill each day he is working. He has sex several times throughout the week with different clients. On Saturday night, Akpan has sex and on Sunday he heads home. Akpan takes PrEP on Sunday and Monday, and then can stop taking PrEP if he wants.



Dosing Scenario 5 – Switching from Daily PrEP to ED-PrEP

Back at home, Akpan plans to meet up with a regular partner on Thursday afternoon and is switching back to ED-PrEP. He takes 2 pills Thursday morning at 9am and 1 pill each day on Friday and Saturday mornings, and then can stop taking PrEP until he thinks he will have sex again.



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Considerations For Monitoring Visits For ED-PrEP Clients

Considerations for Monitoring Visits for ED-PrEP Clients



Frequency of visits

- Visits should follow the same frequency and procedures as anyone taking daily oral PrEP.



Prescriptions and Refills

- TDF combined with FTC or 3TC is recommended for ED-PrEP.
- Clients may not need a refill at each monitoring visit.
- Clients should have enough pills between visits to use oral PrEP daily if they wish.



Counselling

- In some settings, it may be valuable to educate all men about ED-PrEP, especially in settings where MSM are unlikely to disclose same-sex activities.
- Inform women that ED-PrEP is not effective for them.



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Module 6 Key Points

- The evidence shows ED-PrEP is effective and safe when taken as prescribed.
- ED-PrEP provides an additional dosing option for MSM, which may increase oral PrEP uptake and continuation.
- ED-PrEP is appropriate for sexual exposures for all people Assigned Male At Birth (AMAB) who are not taking exogenous hormones including gender affirming hormones. This refers to cisgender men, trans women and non-binary people AMAB who are not taking hormones (WHO update 2022)
- ED-PrEP can be used by people with chronic hepatitis B infection (WHO update 2022)
- Education on ED-PrEP is key to its effective implementation.

Module 7: Oral PrEP Demand Creation

Learning Objectives

After completing Module 7, participants should be able to:

- Define ARVs and its use
- Understand the concept of Demand Creation for Oral PrEP
- Utilize demand creation strategies for improved Oral PrEP services
- Know how to plan demand creation interventions for Oral PrEP services

Concept of Oral PrEP Demand Creation

Demand creation for Oral PrEP is the process of eliciting buy-in, uptake, or consumption of PrEP services by an identified target audience. Oral PrEP demand creation activities are designed to create awareness, desire, and motivation, as well as an enabling environment, for the uptake and effective use of oral PrEP among those with increased likelihood of HIV acquisition

Steps in planning Oral PrEP Demand Creation

Implementation of demand creation activities will follow a defined pathway, as follows:

- Situation analysis:
- Identification of oral PrEP target audience
- Identification of appropriate approaches and types of social and behaviour change communication materials to reach oral PrEP target audience
- Development and production of relevant print, electronic, interpersonal communication (IPC), and social media materials for health talks, informational sessions, community dialogues, social media, focus group discussions, and town hall meetings
- Rollout of messages through appropriate approaches
- Monitoring, supportive supervision and evaluation

Strategies/ Approaches for Oral PrEP Demand Creation

Demand creation approaches	Audience(s)
Interpersonal communication (where possible, engage trained oral PrEP ambassadors as facilitators)	FSW, MSM, PWID, TGP, HIV negative individuals in SDCs, persons in custodial centres, AGYW and their partners, adults
Peer group education (physical and virtual)	BBFSW, MSM, PWID, persons in custodial centres
Social media (Facebook, Twitter, Grindr, Tinder, WhatsApp, closed chatrooms, YouTube, etc.)	AGYW and their partners, young people, adults, MSM, FSW, TGP
Prints (posters, stickers, handbills, flyers, etc.)	PWID, BBFSW, MSM, TGP, persons in custodial centres, AGYW and their partners, young people, adults
Priority for Local AIDS Control Effort (PLACE) (venue outreach facilitators)	NBBFSW and adult men (busy during day)

Outreaches and roadshows	FSW, MSM, PWID, SDC, persons in custodial centres, adolescents, adults
Electronic media (TV and radio)	FSW, MSM, PWID, SDC, AGYW and their partners, young people, adults
Focus Group Discussions	BBFSW, MSM, PWID, SDC, persons in custodial centres, AGYW and their partners, adults
Short message services	BBFSW, MSM, PWID, SDC, AGYW and their partners, adults

(Reference: National HIVST and PrEP communication strategy, 2021)

Community Mobilization and Engagement for Oral PrEP

Community Mobilization and Engagement for Oral PrEP is a process of identifying, harnessing and utilizing relevant available structures, human and material resources in the community to support PrEP interventions. This allows for ease of implementation, ownership and promotes sustainability of PrEP interventions.

Steps for Stakeholder Mobilization and Engagement

1. Identification and social mapping of relevant stakeholders working on PrEP program
2. Collaboration with stakeholders on the harmonization of oral PrEP demand creation activities
3. Conduct of a joint oral PrEP demand creation planning meeting where stakeholders will be assigned roles and responsibilities

Advocacy for Oral PrEP

Advocacy for Oral PrEP is the process of soliciting support from relevant identified influential targets/persons for oral PrEP intervention.

PrEP is the use of ARVs which are HIV prevention medicines by people who are HIV negative, to prevent the acquisition of HIV *before* exposure to the virus. PrEP is used as long as the person is at on-going risk of HIV infection.

Antiretrovirals (ARVs) are medicines used to treat HIV. They can also be used to prevent HIV infection among persons who are not HIV positive, but are at high risk of contracting HIV eg negative partners in sero-discordant relationships, sexually active adolescents and young women, key populations (SW, PWID, MSM, TG).

Steps for conducting advocacy for Oral PrEP

1. Identify the advocacy issues or problems
2. Analyze and gather information on the advocacy issue
3. Determine objectives for the advocacy project
4. Identify advocacy target audience
5. Identify allies and build support for the advocacy project
6. Develop advocacy strategies
7. Create an advocacy action plan
8. Develop advocacy kits

9. Plan advocacy meetings and other relevant advocacy activities
10. Conduct advocacy meetings and other relevant advocacy activities
11. Follow up to ensure that expected action is taken to establish the support promised

Targets for advocacy and how to support oral PrEP intervention

Targets	Areas of support
Political Leaders (<i>e.g. State Governors, State House of Assemblies, Commissioners of health, LGA Chairmen, Councilors, LGA Health Supervisors</i>):	<ul style="list-style-type: none"> • Facilitate support of oral PrEP interventions in the community (promotion, enforcement of necessary policies for oral PrEP interventions, allocation and approval of budgets, and release of funds) • Canvass for more private sector investors for oral PrEP private sector intervention.
Religious Leaders:	<ul style="list-style-type: none"> • Support awareness creation about oral PrEP • Encourage service uptake among their congregations. • Facilitate the mobilization of resources among their congregations to support oral PrEP interventions.
Traditional rulers:	<ul style="list-style-type: none"> • Support in awareness creation about oral PrEP • Encourage service uptake among their subjects. • Support the mobilization of available resources in their communities to support oral PrEP interventions.
Media organizations/individuals (<i>TV, radio, social media influencers, journalists etc.</i>):	<ul style="list-style-type: none"> • Support the promotion and uptake of oral PrEP services as part of their corporate social responsibility or at a discounted price, • Support the airing and disseminating oral PrEP information
Opinion leaders/Influencers/young professional groups (<i>youth leaders, celebrities, women leaders, male social group leaders, oral PrEP ambassadors, young pharmacist groups, etc.</i>).	<ul style="list-style-type: none"> • Support awareness creation and facilitation of oral PrEP uptake among their peers and followers.
Healthcare professional groups and leadership:	<ul style="list-style-type: none"> • Strengthening access to oral PrEP interventions. • Encourage group members to buy-in to PrEP promotion and services delivery

Other organizations and well-to-do persons: <i>(Both corporate organizations and individuals)</i>	<ul style="list-style-type: none"> • Donate resources for oral PrEP interventions. • Take ownership to ensure continuity and sustainability of the entire project.
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Interpersonal Communication/Enhancing Provider-Client Interaction: Empathy Building for Oral PrEP-

***EMPATHWAYS:** an empathy-building card activity developed to support health care providers counseling interactions with young clients. This version has been adapted for PrEP and ART service delivery.

Empathways takes users on a journey from thinking about their own experiences, to understanding their partner’s experiences and then working together to improve Pre-Exposure Prophylaxis (PrEP) service delivery for Adolescent Girls and Young women (AGYW).

The objective is to forge greater empathy between these groups, and then for providers to apply this empathy to improve PrEP and other sexual and reproductive health service delivery to AGYW.

Empathways can be used in provider trainings, during program or research design, and more. It is adapted for use in pairs of AGYW and PrEP service providers. Light facilitation is recommended, particularly to ensure respectful conversations, keep the activity to time, introduce and conclude sessions, and share experiences between each of the three rounds.

Empathways includes three rounds with one card deck for each round

Round 1: OPEN UP: To help participants develop rapport

Round 2: DISCOVER: To explore the factors that impact provider’s attitudes and PrEP service delivery for AGYW

Round 3: CONNECT: To reflect on service delivery scenarios and invite providers to commit to improving PrEP service delivery to AGYW.

Card review:

- When planning your session, consider your participants’ needs and readiness to talk about Reproductive Health, HIV & AIDS, HIV prevention interventions including PrEP.

Review all cards in the deck below and consider if any will be counterproductive to your activity. If you wish to skip or remove any cards, consider using the printable version of the deck.

Participants:

- The deck is designed/adapted to be used with adolescent girls and young women, who are somewhat familiar with reproductive health, HIV & AIDS and PrEP services, and with providers who are interested to better understand adolescent and young clients. Consider reaching out to local youth associations to help you plan the activity, invite young people, to even co-facilitate sessions with you.

Facilitation:

- When planning, think about how participant literacy, age and gender dynamics might impact the activity. During the session, pay attention to body language to ensure participants feel safe and comfortable - and that facilitators are prepared to intervene if needed to ensure participant well-being.

Room setup:

- Empathways is designed for use between pairs of young people and providers. Placing a small table between the young person and the provider might make each feel more comfortable and focused. They have somewhere to lean, personal space, and somewhere to put their belongings. Each pair should be spaced far enough away from other pairs to allow for some privacy
- See below Facilitator's guide (Deck) ; This is what is required to effectively conduct the

Empathways session.

Empathways






1

The Pledge

Both participants must read this aloud to one another

- ◆ I commit to an open, honest and respectful dialogue
- ◆ I pledge to truly see you and hear you
- ◆ I will keep what you tell me private & confidential
- ◆ I will keep an open mind to understand and respect you as a whole person

2



**Open
Up**


Get to know each other

Where did you grow up?

What kinds of things do you enjoy doing?

Both participants should answer

3



**Open
Up**


Goals

Name two things you would like to achieve in the next two years.

What, if anything, would stop you from achieving them

Both participants answer

4




Inspiration

Who in your life inspires you, and why?

Both participants should answer

5



Relationships

How should a partner who loves you, show you they love you?

Both participants should answer

6



**Open
Up**


Sex & HIV

Why might a young woman worry about getting HIV?

How is this the same or different for young men?

Both participants should answer

7



**Open
Up**


Consent

Do you think it can be unsafe for a young woman to say "no" to sex?

If yes, in what situation?

Both participants answer; young person first

8



Religion

How does religion affect your relationships?

How does it impact your your thoughts about PrEP / ART / FP?

Both participants answer

9




Relationships

Who first talked to you about things like relationships, sex, HIV/ AIDS, condoms?

What did you think of their advice?

Both participants answer

10




Your best experience

What was the best health care experience you've ever had?

What made it so good?

Both participants answer

11



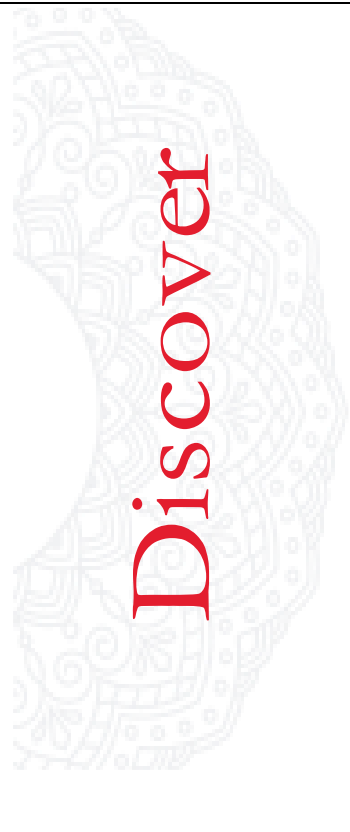
Your worst experience

What was the worst health care experience you've ever had?

How did it make you feel?

Both participants answer

12




Family and Friends

What do your family members
& friends think of PrEP?

Do you agree with them?

Both participants answer

13




Health care Decisions

If you choose to go to a
health center, who is
involved in the decision?

Both participants answer

14

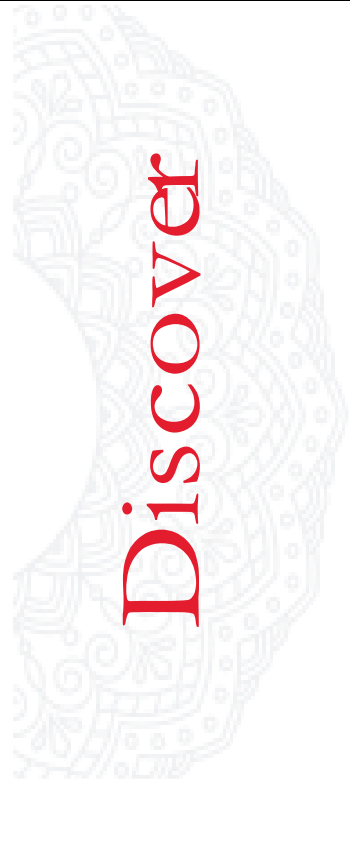


Seeking Information

At their best, what are a healthcare provider's goals and duties to a client during a visit?

Only you ng person answers

15




Healthcare Providers' Goals

If you had questions about PrEP who would you ask?
Where would you go first?
Why?

Bo th participants answer

16




PrEP services

After a visit to a PrEP healthcare facility, how should a client feel when they are leaving the room?

Both participants answer

17




Youth-friendly services

When you were younger, did you feel comfortable going to a health center or pharmacy?
Why or why not?

Provider should answer

18



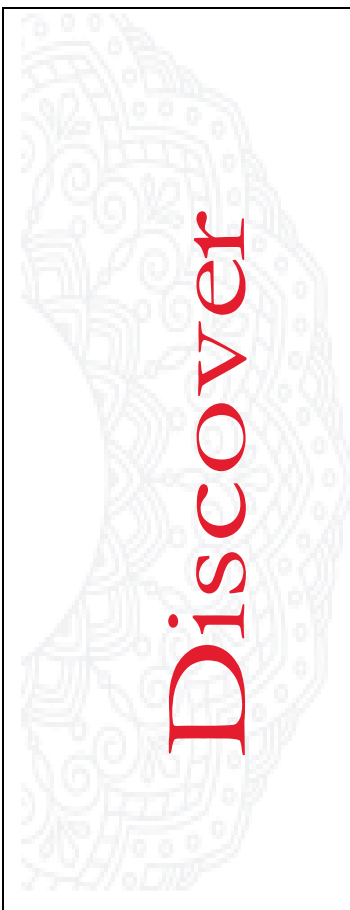
Discover

Serving young clients

Are there challenges providing services like PrEP or family planning to young people?
What are they?

Provider should answer

19




Discover

Your health care experience

What questions do you wish a provider would and would not ask during a visit? Why?

Young person should answer

20



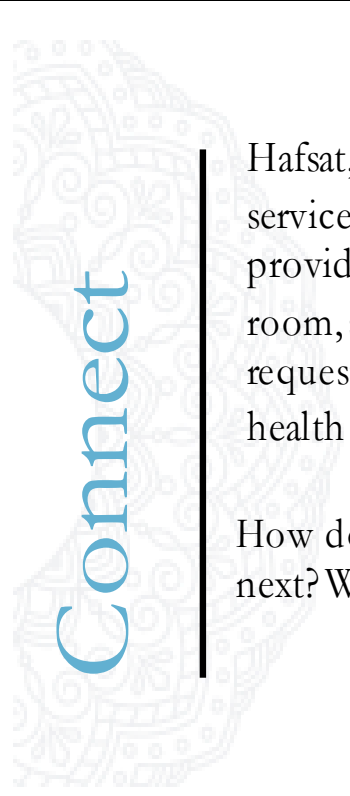
Discover

Youth-friendly services

Give three words or elements that define "youth-friendly health services."

Both participants answer

21



Connect

Hafsat, 19 goes to a health facility to learn about PrEP services. While in the waiting area she hears a health care provider shouting at a young woman in the consultation room, saying the girl must be ‘promiscuous’ to be requesting for PrEP at her age. Hafsat decides to leave the health centre.

How does Hasfat feel? What might happen to Hasfat next? What could have gone differently?

Both participants answer

22


 The logo for 'Connect' is written vertically in a blue, serif font. To its right is a vertical black line. The background of the entire page is a faint, light blue pattern of interconnected lines and dots, resembling a network or a map.

Sarah, 19 is fun-loving and adventurous. She usually goes to party with her friends, and recently she narrowly escaped being raped, but two of her friends were raped.

They all feared they could have been infected with HIV. However, Sarah doesn't think that's something to stop her from having fun and making the most of her moments.

They all decide to go to a health center to seek advice.

What should the provider who meets with Sarah and her friends do? How should Sarah and her friends feel leaving the health center?

Both participants answer

23

The trainer will provide copies of the Post-Training Assessment and the Training Evaluation forms.

Oral PrEP Resource Materials for Providers

- Centers for Disease Control and Prevention. *Pre-Exposure Prophylaxis (PrEP)*. <http://www.cdc.gov/hiv/risk/prep/>. Accessed 11 January 2019.
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- UNAIDS. *ME&E Guidelines: ME&E of Key Populations at Higher Risk for HIV*. Geneva: UNAIDS; 2018. https://www.unaids.org/en/dataanalysis/monitoringandevaluationguidance/ME_keypops. Accessed 29 July 2021.

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- Centers for Disease Control and Prevention. Pre-exposure Prophylaxis (PrEP). <https://www.cdc.gov/hiv/risk/prep/index.html>. Accessed 1 March 2021.
- Centers for Disease Control and Prevention. Prep: An HIV Prevention Option. Video. <https://www.youtube.com/watch?v=TR8-3uAuZGo>. Accessed 1 March 2021.
- PleasePrEPMe.org. What Is PrEP? <http://www.PleasePrEPMe.org/resources>. Accessed 11 January 2021.
- PrEP Project. What Is Prep? <http://www.whatisprep.org>. Accessed 11 January 2021.
- PrEPWatch. PrEP Basics. <https://www.prepwatch.org/about-prep/basics/>. 1 Accessed March 2019.
- Terrence Higgins Trust. What Is PrEP? <http://www.iwantprepnw.co.uk>. Accessed 11 January 2021.

Nigeria Oral PrEP Resource Materials

- Federal Ministry of Health. *National Guidelines for HIV Prevention, Treatment and Care*. Abuja: National AIDS & STI Control Programme (NASCP), Federal Ministry of Health; 2020.
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Appendix

- A. Pre-and Post-Training Assessment
- B. Materials in Participant Folders
- C. PrEP Clinical Pathway
- D. Screening for Substantial Risk of HIV infection
- E. Provider Checklist for Initial PrEP Visit
- F. Provider Checklist for Follow-Up PrEP Visit
- G. Provider Checklist for Substantial Risk
- H. Frequently Asked Questions about PrEP

A. Pre- and Post-Training Assessment for PrEP Training For Providers In Clinical Settings

Please tick the correct answer to each question below:

1. Is the following statement true or false? 'Pre-exposure prophylaxis (PrEP) is a medication you take for life.'
 - a) True
 - b) False
2. Counselling to support PrEP use and adherence may be provided by:
(Select all that apply.)
 - a) Pharmacists
 - b) Nurses
 - c) Lay counsellors
 - d) Peer workers
3. Which of the following are WHO-recommended regimens for PrEP?
(Select all that apply.)
 - a) Tenofovir/emtricitabine (TDF/FTC)
 - b) Tenofovir/emtricitabine + efavirenz (TDF/FTC) +(EFV)
 - c) Tenofovir/lamivudine (TDF/3TC)
 - d) Zidovudine/lamivudine (AZT/3TC)
4. Is the following statement true or false? 'PrEP is safe to use during pregnancy and breastfeeding.'
 - a) True
 - b) False
5. PrEP is safe to use with:
(Select all that apply.)
 - a) Hormonal contraception
 - b) Recreational drugs
 - c) Alcohol
 - d) Antibiotics
6. PrEP should be discontinued if:
(Select all that apply.)
 - a) The health care worker decides it is no longer right for the client
 - b) The estimated creatinine clearance decreases to <60 ml/min
 - c) The client reports headaches and stomach upset
 - d) The client tests HIV positive

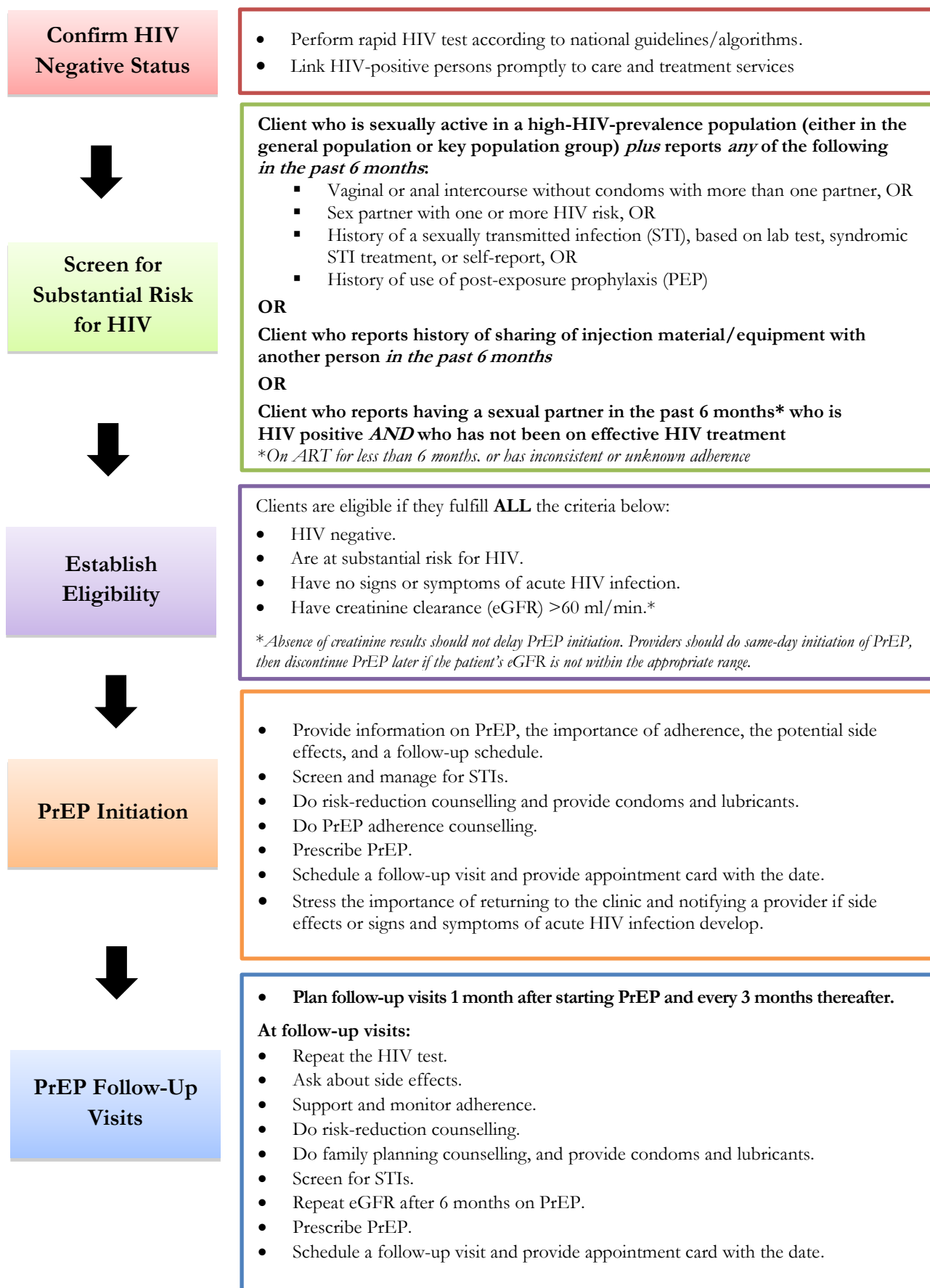
- 7.** Is the following statement true or false? ‘PrEP and post-exposure prophylaxis (PEP) are both used by HIV-negative persons to prevent HIV acquisition’
- a) True
 - b) False
- 8.** PrEP can be offered as part of a comprehensive HIV prevention package for:
(Select all that apply.)
- a) Men who have sex with men
 - b) Individuals with potential HIV exposure in the last 72 hours
 - c) People who inject drugs
 - d) Serodiscordant couples
- 9.** Is the following statement true or false? ‘PrEP is protective against a variety of sexually transmitted infections.’
- a) True
 - b) False
- 10.** Counselling to support PrEP adherence should include:
(Select all that apply.)
- a) A client-centered approach
 - b) Identification of barriers to taking PrEP
 - c) Identification of client-specific strategies to use PrEP effectively
 - d) Integration of condom use

B. Materials Needed for Participant Folders

Each participant folder should include:

1. Pre-Training Assessment
2. Post-Training Assessment
3. Training Evaluation Form
4. PrEP Job Aids
 - a. PrEP Clinical Pathway
 - b. Screening for Substantial Risk of HIV Infection Chart
 - c. Provider Checklist for Initial PrEP Visits
 - d. Provider Checklist for Follow-Up PrEP Visits
 - e. Provider Checklist for Substantial Risk
 - f. Frequently Asked Questions about PrEP
5. The PrEP M&E Tool Package, including:
 - a. Oral PrEP Eligibility Screening Form
 - b. Oral PrEP Care Card
 - c. Oral PrEP Register
 - d. Oral PrEP Monthly Summary Form

C. PrEP Clinical Pathway



D. Screening for Substantial Risk of HIV Infection

(based on history in the past 6 months)

- **Client who is sexually active in a high HIV prevalence population (either in the general population or key population group) PLUS reports **ANY** of the following in the past 6 months:**
 - Vaginal or anal intercourse without condoms with more than 1 partner, OR
 - Sex partner with one or more HIV risk, OR
 - History of an STI (based on lab test, syndromic STI treatment, self-report), OR
 - History of use of post-exposure prophylaxis (PEP)

OR

- **Client who reports history of sharing of injection material/equipment with another person in the past 6 months**

OR

- **Client who reports having a sexual partner in the past 6 months* who is HIV positive **AND** who has not been on effective HIV treatment**
 - *On ART for less than 6 months, or has inconsistent or unknown adherence

E. Provider Checklist for Initial PrEP Visit

- Conduct HIV testing (using the algorithm in the national HIV testing guidelines).
Assess on HIV infection status.
- Exclude acute HIV infection.
 - Ask about the last potential exposure to HIV.
 - Ask about and look for flu-like symptoms.
- Screen for substantial risk for HIV.
- Screen for signs and symptoms of kidney disease.
To identify potential pre-existing renal impairment if lab results are not available on the day of testing.
- Conduct serum creatinine testing (calculate eGFR).
Absence of creatinine results should not delay PrEP initiation. Providers should do same-day initiation of PrEP, then discontinue PrEP if a patient's eGFR is not within the appropriate range.
- Screen for hepatitis B (HBsAg).
 - To identify undiagnosed hepatitis B (HBV) infection.
 - To identify those eligible for vaccination against hepatitis B.
- Screen for sexually transmitted infections (STI).
 - Perform syndromic and etiological STI testing (depending on local guidelines).
 - Rapid plasma reagin test (RPR) for syphilis (if available).
- Conduct risk reduction counselling.
 - Refer clients based on needs (i.e., for social support, harm reduction, gender-based violence programs, etc.).
- Counsel on family planning.
 - Perform a pregnancy test for women.
 - Provide condoms and lubricants.
 - Provide other contraception.
- Provide information on PrEP, including potential side effects; schedule a follow-up visit.
- Conduct PrEP adherence counselling.
- Prescribe PrEP.
- Schedule the next PrEP follow-up appointment and provide an appointment card.

**This checklist to be aligned with national guidelines on PrEP.*

F. Provider Checklist for Follow-Up PrEP Visits

- Brief PrEP Counselling
 - Ask about signs and symptoms of acute HIV infection.
 - Assess for substantial ongoing risk for HIV.
 - Confirm the client wishes to remain on PrEP.
 - Review facilitators and barriers to PrEP use.
- Adherence Counselling
 - Assess adherence and adherence challenges.
 - Provide adherence counselling.
 - Discuss the importance of effective use of PrEP.
- Assessment and Management of Side Effects
 - Ask about and manage side effects.
- Confirmation of HIV-Negative Status
 - Repeat HIV test 1 month after starting PrEP, then every 3 months thereafter.
- Calculation of Estimated Creatinine Clearance (eGFR): Recommended Frequencies
 - At least every 6 months—*more frequently* if there is a history of conditions affecting the kidney (e.g., diabetes, hypertension, any chronic nephropathy).
 - Check creatinine test results, calculate creatinine clearance, and add the results to the appropriate forms.
- Screening for Sexually Transmitted Infections (STIs)
- Risk Reduction Counselling
 - Refer clients based on their specific needs (i.e., for social support, harm reduction, gender-based violence programs, etc.).
- Counselling on Family Planning
 - Perform a pregnancy test for women, if indicated.
 - Provide condoms and lubricants.
 - Provide other contraception.
- PrEP Prescribed
- Schedule next appointment, and provide appointment card

STOP PrEP
when a client using PrEP tests positive for HIV
and link promptly to treatment and care services.
Start ART for HIV infection immediately.

** Checklist to be aligned with national guidelines on PrEP **

G. Provider Checklist for Substantial Risk

Providers should assess for a client's substantial risk at each PrEP follow-up visit by asking the questions below. *If at least one item is ticked, the client is at substantial risk.*

Have you...

- Had vaginal sexual intercourse with more than one partner of unknown HIV status in the past 6 months?
Y N (If *yes*, tick substantial risk.)
- Had vaginal sex without a condom in the past 6 months?
Y N (If *yes*, tick substantial risk.)
- Had anal sexual intercourse in the past 6 months?
Y N (If *yes*, tick substantial risk.)
- Had sex in exchange for money, goods or a service in the last 6 months?
Y N (If *yes*, tick substantial risk.)
- Injected drugs in the past 6 months?
Y N (If *yes*, tick substantial risk.)
- Been diagnosed with a sexual transmitted infection (STI) more than once in the past 12 months?
Y N (If *yes*, tick substantial risk.)
- Taken post-exposure prophylaxis (PEP) for exposure to HIV in the past 6 months?
Y N (If *yes*, tick substantial risk.)
- Do you have a partner who is living with HIV?
Y N Don't know (If *no* or *don't know*, continue to Client Risk Classification.)
- Is your HIV-positive partner on ART?
Y N Don't know (If *no* or *don't know*, tick substantial risk.)
- Has your HIV-positive partner been on ART for at *less than* 6 months?
Y N Don't know (If *no* or *don't know*, tick substantial risk.)

Client Risk Classification

- SUBSTANTIAL RISK (*At least one item indicating substantial risk is ticked above*)
 NOT AT SUBSTANTIAL RISK (*If none of the substantial risk items above are ticked*)

H. Frequently Asked Questions about Oral PrEP

What is oral PrEP?

PrEP stands for pre-exposure prophylaxis. Oral PrEP is a single daily pill that protects you from getting infected with HIV. It works when you take it before you are exposed to HIV.

Who should use oral PrEP?

Oral PrEP is for anyone (both men and women) who is at substantial risk of acquiring HIV. It is for situations and times when you may have a substantial risk of HIV infection.

Is oral PrEP a new drug?

No. Oral PrEP is not new. Oral PrEP is made of antiretroviral drugs (HIV medication) used to help treat people living with HIV and for preventing mother-to-child HIV transmission (PMTCT).

When and how do I use oral PrEP?

- See a health care provider to find out if you are eligible for oral PrEP.
- If you are prescribed oral PrEP, you must take 1 pill every day.
- You can take oral PrEP any time of day and at different times on different days, as long as you take 1 pill every day.
- You can take oral PrEP with or without food.
- When starting or re-starting oral PrEP, you must take it every day for at least 7 days before you are protected.
- You must see your health care provider for regular follow-up visits while on oral PrEP.
- While taking oral PrEP, you must test for HIV every 3 months to be sure you are still HIV-negative.

How long do I use oral PrEP?

Oral PrEP is recommended as added protection for people who are at substantial and ongoing risk for HIV infection. For most people, oral PrEP will not be a lifelong medication. It is for a time in your life when you feel you are regularly or frequently at risk for HIV. As part of your follow-up care for oral PrEP, your health care provider will help you assess your risk and decide whether or not oral PrEP is still appropriate for you. If you wish to stop PrEP, talk to your health care provider about how to safely stop.

How well does oral PrEP work?

PrEP does not provide 100% protection, but it is highly effective and provides a great deal of protection against HIV. Among clients who take oral PrEP consistently, as prescribed, oral PrEP reduces the risk of HIV acquisition during sex by over 90%.

What if I miss a dose?

If you miss a dose, just take it when you remember. For example, if you usually take oral PrEP in the morning, but one day realize at 10 in the evening that you forgot, it is okay to take 1 pill then and resume your usual morning schedule the next day. Remember, oral PrEP is effective when taken every day.

Is oral PrEP an HIV vaccine?

No. oral PrEP is not an HIV vaccine. Oral PrEP is a pill that works only when taken consistently and correctly—1 pill every day. Unlike a vaccine, oral PrEP stops working once you stop taking it.

Will I have side effects while taking oral PrEP?

You may experience some side effects—such as nausea, vomiting, or abdominal pain—but these usually stop within the first weeks of starting oral PrEP.

Will oral PrEP affect my liver?

No. Several studies have shown that oral PrEP medication does not affect the liver. However, the same medication used for oral PrEP is also used to treat hepatitis B (a liver disease), so before you start oral PrEP, you should first be screened for hepatitis B to make sure your liver is okay.

Will oral PrEP affect my kidneys?

For some clients, oral PrEP can affect the kidneys. It is important for oral PrEP clients to have their kidneys checked regularly by a health care provider, using a creatinine test, because kidney problems caused by oral PrEP may not be obvious or show any symptoms.

Can I take oral PrEP if I use alcohol or drugs?

Yes. Oral PrEP works if you drink alcohol and/or use recreational drugs. However, alcohol and drug use can cause you to forget to take oral PrEP. See your provider if you need help with alcohol or drug use.

Will oral PrEP work if I am HIV positive?

No. Oral PrEP is only for HIV-negative people. You must be tested regularly for HIV while taking PrEP.

I just had sex without a condom with someone who is HIV positive. Should I take oral PrEP?

No. Oral PrEP works only when it is taken before you are exposed to HIV. If you have sex with someone whom you believe may be HIV positive, go immediately to a health care provider and ask for PEP (post-exposure prophylaxis).

If I take oral PrEP every day, can I stop using condoms?

No. Oral PrEP does not protect against other sexually transmitted infections (STIs) or pregnancy, as condoms do. Condoms also provide additional protection against HIV. You should use condoms even when taking oral PrEP.

Can I use oral PrEP and hormonal contraception (e.g., oral, injectable, implants) at the same time?

Yes. It is safe to use oral PrEP and hormonal contraception (i.e. birth control) at the same time. Taking them together does not make them less effective.

Do I have to tell my partners that I am taking oral PrEP?

No. Oral PrEP can be private. You do not have to tell anyone that you are taking oral PrEP unless you want to. However, people sometimes find it helpful to tell a partner, friend or family member that they are taking oral PrEP so that people can help support their oral PrEP use.

Will oral PrEP cause erectile dysfunction, “loss of manpower,” sterility, or infertility?

No. Over several years, men who have taken oral PrEP have not had any of these problems.

Can I use oral PrEP if I am pregnant or breastfeeding?

Yes. It is safe to use PrEP during pregnancy and breastfeeding.

Can I take 2 oral PrEP pills just before having sex to avoid getting HIV?

No. To avoid possible side effects, you should take your oral PrEP medication every day as prescribed.

Can both my partner and I take oral PrEP?

Yes. Oral PrEP is for all people at substantial risk of HIV.

Can I give oral PrEP to my children if they are sexually active?

No. To ensure proper screening and follow-up, oral PrEP can be given only by professional health care workers. If you think your child is at substantial risk for HIV infection, seek services at a clinic.

When and how can I stop oral PrEP?

Starting oral PrEP does not mean taking oral PrEP for the rest of your life. You may stop if you are no longer at substantial risk for HIV infection. However, after your last potential HIV exposure, you should keep taking oral PrEP for 7 more days. If you want to stop oral PrEP, see your health care provider.

What else can I do to stay HIV negative?

- Use oral PrEP together with other ways of preventing HIV including:
 - Use condoms every time you have sex.
 - Get regular HIV testing for yourself and your partners.
 - Get screened and treated for STIs.
 - Get counselling and support to reduce behaviours that put you at risk for HIV.

How does oral PrEP compare to PEP (post-exposure prophylaxis)?

- You take oral PrEP before you are exposed to HIV; you take PEP after you are exposed to HIV.
- Oral PrEP is taken as long there is substantial risk for HIV infection.
PEP is taken for only 28 days after exposure to HIV.
- Both are given by health care providers to HIV-negative people to keep from getting HIV.
- Both must be taken correctly and consistently to work well.
- Both use HIV treatment medication to help stop HIV infection in those exposed to HIV.

What other countries are using oral PrEP?

The medication in oral PrEP has been approved in the United States, South Africa, Brazil, Peru, Kenya, Canada, Australia, Belgium, Botswana, Czech Republic, Denmark, United Kingdom, France, Lesotho, Namibia, Netherlands, Taiwan, Thailand, Zambia, Zimbabwe, and others.

REMEMBER

- Oral PrEP is a pill you take once a day to prevent HIV infection.
- Oral PrEP works best if you take it every day as prescribed.
- If you take oral PrEP as prescribed, it will stop you from acquiring HIV.
- Oral PrEP does not protect against other STIs or pregnancy.
- Oral PrEP is private. You do not have to tell anyone you are using it.
- Oral PrEP is safe. Mild side effects, which some people experience, usually go away after the first few weeks.
- You must take oral PrEP under the care of a health care provider and go to the clinic for regular follow-up visits.

- Oral PrEP is not a lifelong medication. It is for a time of life when you feel at substantial risk of HIV exposure.

Do you have more questions about oral PrEP?
Come see us to learn more!

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