

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

**June 2022** 



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

## **Expected Training Outcomes**

After completing this training, participants will be able to:

- Identify individuals eligible for oral PrEP.
- Assess medical eligibility for oral PrEP.
- Provide adherence counselling and support to individuals eligible for oral PrEP and users.
- Prescribe oral PrEP.
- Conduct clinical, laboratory, and risk assessments during follow-up visits.
- Determine how oral PrEP monitoring and evaluation tools may be used locally.



1 Oral PrEP Basics

**Training Overview** 

- 2 Oral PrEP Eligibility Screening
- 3 Oral PrEP Initial and Follow-Up Visits
- Monitoring and Managing Oral PrEP Use: Creatinine, Seroconversion, and Stigma
- Oral PrEP Monitoring and Evaluation Tools
- 6 Event-Driven PrEP (ED-PrEP)
- Oral PrEP Demand Creation
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**Evaluation and Resources** 

#### **MODULE 1**

## Oral PrEP Basics





## **Module 1 Learning Objectives**

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#### 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 acquisition.
- Identify key populations (KPs) for oral PrEP at local level.



## **Module 1 Learning Objectives (contd.)**



- Explain the relationship between oral PrEP effectiveness and adherence.
- Understand the oral PrEP regimens currently used in Nigeria in line with World Health Organization (WHO) recommendations.
- Identify concerns regarding oral PrEP implementation.
- Explain the risks and benefits of oral PrEP.



#### **Introduction to Module 1**

- HIV prevention needs are dynamic and tend to change over time.
- Combination prevention is a mix of biomedical, behavioural, and structural interventions that decrease risk of HIV acquisition.
- Greater impact may come from combined approaches than from using a single intervention alone.
- An important additional prevention tool is provided by oral PrEP: using antiretroviral (ARV) drugs for prevention.



#### **Combination Prevention**

#### **Structural**

- Policies
- Laws
- Regulatory environment
- Culture
- Cash transfers

#### **Behavioural**

- Education
- Counselling
- Stigma reduction
- Harm reduction
- Adherence interventions

#### **Biomedical**

- HIV testing
- Condoms
- Voluntary medical male circumcision
- PMTCT
- Treatment of STIs
- Treatment as Prevention
- Post-exposure prophylaxis
- PrEP





What is pre-exposure prophylaxis (PrEP)?



## **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 Oral 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 oral PrEP recommendations in the United States



## **National Progress on Oral Prep**

- 2015-2018: PrEP Demonstration Project in Anambra, Plateau, and Cross River states
- 2016: National Guidelines for HIV Prevention, Treatment, and Care included PrEP for serodiscordant couples and key populations
- 2017-2021: PrEP included in National Strategic Framework on HIV and AIDS
- **2020:** Reviewed the National Guidelines for HIV Prevention, Treatment and Care, which included 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 Key Populations in Nigeria



## **Oral PrEP Use in Nigeria**

- A 2015–2018 demonstration project tested different models to deliver 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 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.





# What is PEP?



## **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 (e.g., through sexual intercourse).





What are some similarities and differences between 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.	





## Differences between oral PrEP and ART



### **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> <li>Are no longer at substantial risk for HIV acquisition.</li> </ul>
	<ul> <li>Decide to use other effective prevention methods.</li> </ul>



## 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 such as condoms.
- Oral PrEP reduces risk of acquiring HIV through sexual intercourse by about 99% when taken as prescribed
- Oral 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).





Who are the KPs and other populations of focus for oral PrEP in the communities you serve?



## **Key Populations and Priority Populations**

'Key populations' (KPs) are groups of people with the highest risk of HIV acquisition.

#### **Key Populations**

- Sex workers
- MSM
- Transgender people (2020 IBBSS survey)
- PWID
- People in prisons and other closed settings

#### **Priority Populations**

- HIV-negative partner in a serodiscordant relationship
- Clients of sex workers
- Exposed adolescents and young people
- Pregnant and Breastfeeding Mothers



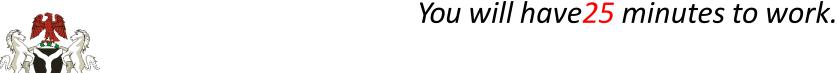
## **Evidence That Oral PrEP Works (Group Activity)**



Read this information in your participants manuals:

ARVs Used in PrEP Trials	Partners PrEP Demonstration Project
iPrEx Study	Key HIV PrEP Trials Table
PROUD: Immediate vs. Deferred PrEP	Effectiveness and Adherence in Trials
ANRS IPERGAY	

- With your group, discuss these questions:
  - From these studies, what can you conclude about oral PrEP's effectiveness?
  - In what circumstances was oral PrEP most effective?







## What is adherence?



## **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 clinic visits and observe all required protocols, including:
  - Clinic and lab assessments
  - Prescription refills



## Importance of Adherence to ARVs

Adherence to ARVs 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 ARVs 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).\*</li>
- The higher the percentage of participant samples with detectable oral PrEP drug levels, the greater the efficacy. (Refer to 'Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention' in Module 1 of the Oral PrEP Participant Manual).



<sup>\*</sup> Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV pre-exposure prophylaxis (PrEP) for all populations: A systematic review and meta-analysis. *AIDS* 2016(30):1973-1983. doi:10.1097/QAD.00000000001145.

#### **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.

#### **Oral PrEP Side Effects**

Evidence from the iPrEx open-label extension (OLE) study and randomised controlled trials (RCTs) shows that participants 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 oral PrEP

These side effects are usually mild and do not persist for more than a month.



## **Oral PrEP Side Effects** (cont.)

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 a start-up syndrome.





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



#### Risk behaviors, 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 oral PrEP implementation shows declines in selfreported 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 Oral 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 when starting oral PrEP.
- HIVDR will not occur when adherence to oral PrEP is high and HIV seroconversion does not occur.
- There can be risk of HIVDR if adherence is suboptimal and HIV acquisition 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 recognise signs and symptoms of acute HIV infection (AHI).





- Does oral PrEP prevent other STIs?
- What can people do to prevent other STIs while they are taking oral PrEP?
- What should the package of prevention services include?



#### **Does Oral PrEP Prevent Other STIs?**

- Oral 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.



# **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



# **Oral PrEP Minimum Package of Services** (cont.)

- 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 and substances affects the safety or effectiveness of oral PrEP.
- However, drugs and alcohol could make the user 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 individualised 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 with TDF-containing regimens is the current national recommendation.
- Oral PrEP should be taken with consistent and correct condoms use in addition to other prevention interventions.
- 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.



# Nigerian Example on PrEP Uptake



Click on <a href="https://youtu.be/RXgnmQkISKM">https://youtu.be/RXgnmQkISKM</a> for more information on PrEP uptake in Nigeria.



### **MODULE 2**

Oral PrEP Screening and Eligibility





# **Module 2 Learning Objectives**



After completing Module 2, participants will be able to:

- List the criteria for oral PrEP use.
- List the various entry points 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.



### Policy recommendations on oral PrEP use

#### WHO Recommendations

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.



# Policy recommendations on oral PrEP use (contd.)

# National Guidelines on HIV Prevention, Treatment and Care (2020)

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).



### **Discuss**



- Who should receive oral PrEP?
- What are the criteria for oral PrEP use?



# **Entry points for oral PrEP**

- 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)
- In-patient
- Referred from emergency room or hospital staff



### **Entry points for oral PrEP (contd.)**

- 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
- PMTCT—HIV-negative partners of HIV-positive pregnant women should be offered oral PrEP.
- PEP—Clients on repetitive PEP services should be offered oral PrEP.

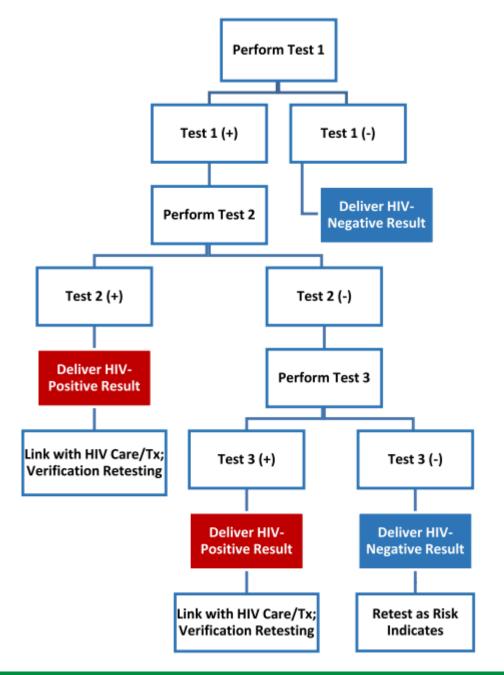
### **Criteria for Oral PrEP Initiation**

- HIV seronegative
- No suspicion of AHI
- Substantial risk of HIV acquisition
- Urinalysis to rule out proteinuria
- Willingness to use oral PrEP as prescribed



\*\*HIV testing must be done using national guidelines and algorithms

# National HIV Testing Algorithm





#### Key:

Test 1: Screening

Test 2: Confirmatory

Test 3: Tie Breaker

### **Contraindications for 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



### Contraindications for PrEP....Cont'd

- 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</li>
- Concurrent nephrotoxic medication



# **Key Points for Commencement of Oral PrEP**

- Oral PrEP is a prevention intervention for people who are HIV negative.
- All persons at substantial risk for HIV acquisition should receive HIV testing prior to oral PrEP initiation.
- HIV testing must be done using national guidelines and algorithms.
  - Ideally, use rapid HIV tests at point of care.
  - Promptly link clients who have acquired HIV to HIV treatment and care services instead of PrEP.



### **Discuss**



What is acute HIV infection?

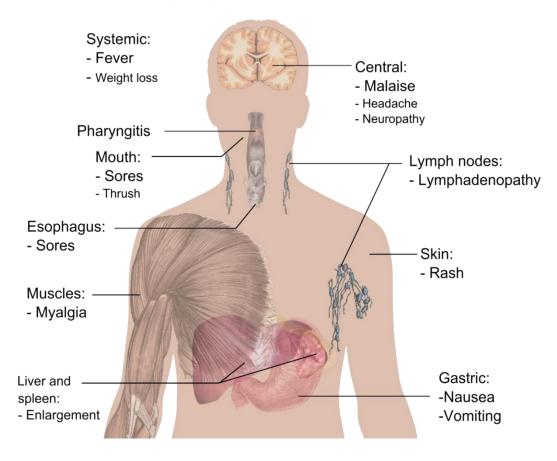


# **Acute HIV Infection (AHI)**

- AHI is the early phase of HIV disease characterised by an initial burst of viremia.
- AHI develops within 2 to 4 weeks after someone acquires HIV.
- Approximately 40–90% of AHI clients experience 'flu-like' symptoms.
  - These symptoms are not specific to HIV but occur in many other viral infections.
  - Clients with AHI can be asymptomatic.
- Never start oral PrEP if AHI is suspected.



# Main symptoms of Acute HIV infection



#### **Other Symptoms of Acute HIV Infection**

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

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



# **Diagnosis of AHI**

- During AHI, antibodies might be absent or be below the level of detection.
  - Serological testing using rapid tests might be negative.
- AHI 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.
  - Repeat the HIV serological test after 4 weeks to reassess HIV status.

<sup>\*</sup> The next slide shows the main symptoms of AHI.



### **Risk Assessment for Oral PrEP**

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.



### **Discuss**



Who has a substantial risk of HIV acquisition?



# Clients with 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



### Clients with Substantial Risk of HIV Acquisition (contd.)

- Sex partner with substantial risk for HIV acquisition
- History of an STI (based on lab test, syndromic STI treatment, or self-report)
- History of use of recurrent PEP
- 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 who has not been on effective HIV treatment.



### Clients with Substantial Risk of HIV Acquisition(contd.)

- 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.



# **Group Discussion**



- Close your participant manuals.
- In small groups, brainstorm a list of questions to screen for substantial risk of HIV acquisition.
- Keep in mind that you must ask about clients' sexual/drug use behaviours, their partners' sexual/drug use behaviours, aspects of being part of a serodiscordant couple, and other aspects of their situation—for example, their current lifestyles.



# **Group Discussion** (contd.)



- Choose one group member to record your questions on a sheet of paper.
- When you have finished brainstorming, find the list of sampled screening questions in your manuals.
- Compare your brainstormed questions to this list.
- Make a note of any questions you missed and any questions on your list that do not appear in the manual.

You will have 15 minutes to work.



# Screening for Substantial Risk of HIV Acquisition

- Frame screening questions in terms of people's behaviour rather than their identities.
- 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 a high-prevalence 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 a person when you do not know their HIV status?



# **Screening Questions** (contd.)

#### 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 for Serodiscordant Couples (contd.)

- 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 treatment?
- 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?
  - 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 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.</li>

\* 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  $[\mu mol/L]$ 



# **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.
- 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 acquisition and are motivated to take oral PrEP.



#### **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 transgender 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 result 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 two 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 result today is negative.

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



#### **Clinical Scenario 3**

Hauwa is a 30-year-old wife and mother. She 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 behavioural screening.

- Criteria for oral PrEP Use:
  - HIV seronegative
  - No suspicion of AHI
  - Has substantial risk of HIV acquisition
  - Urinalysis to rule out proteinuria
  - Willingness to use oral 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





# **Module 3 Learning Objectives**



After completing Module 3, participants will be able to:

- Understand Oral PrEP initial and follow-up visits
- Describe the content of counselling for oral PrEP initial and followup 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 it.
- Use 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.



# Procedures (minimum package) for Oral PrEP Initial Visit

Procedure	Investigation/Intervention	Rationale/ Objectives
HIV Testing Services	HIV test	Assessment of HIV infection status
PrEP Eligibility Screening	Acute HIV infection symptom checklist	To assess for AHI
	eGFR and monitoring of kidney function	To rule out renal impairment Urinalysis should be done as baseline screening. If urinalysis is abnormal, oral PrEP initiation should be delayed until creatinine results are available. eGFR should be performed after six months, followed by annually (if clinically stable, repeat at clinicians' discretion).
	NCD screening	To assess for diabetes mellitus and hypertension
	STI screening and treatment	To diagnose and treat STI Syndromic and etiological diagnosis and management



# Procedures (minimum package) for Oral PrEP Initial Visit (contd.)

Procedure	Investigation/Intervention	Rationale/ Objectives
PrEP Eligibility Screening	Discussion about pregnancy/ contraceptives	To assess need for contraceptives and/or pregnancy testing
	Brief counselling	To assess substantial risk for HIV acquisition  To assess HIV prevention options, discuss exposure- reduction, and provide condoms and lubricants  To discuss desire for oral PrEP and willingness to take oral PrEP
PrEP Initiation and Adherence Counselling	PrEP Initiation	
	Adherence Counselling	



# **Oral Prep Initial visit Counselling**

Oral PrEP Initial visit counselling is a process whereby the provider interacts and counsels a prospective client to enable the person make an informed decision:

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.



# **Oral PrEP Initial visit Counselling**(cont.)

- 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.



# Oral PrEP Initial visit Counselling(cont.)

At the beginning and end of the counselling session, the counsellor should assess client's understanding that:

- No prevention method, including oral PrEP, is 100% effective except abstinence.
- Oral PrEP does not prevent other STIs or unwanted pregnancies.
- Oral PrEP should be used as part of a package of HIV prevention services that also include condoms, lubricants, other contraceptives, exposure-reduction counselling, and STI management.



# **Oral Prep Efficacy Counselling Messaging**

- Oral PrEP 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 STIs other than HIV.
- Oral PrEP does not prevent pregnancy.
- Oral PrEP is safe.



# **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.



#### Features of Oral PrEP Counselling: Client-Centred Counselling

- The term 'client centred' refers to seeing clients as the experts on their own lives. Client-centred counselling emphasises 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 nonadherence vs. adherence.



# Features of Oral PrEP Counselling: Counselling Is About Problem Solving

- Health care workers discuss with clients their problems and ways to address them.
- Oral PrEP counselling helps clients identify factors that either facilitate access to oral PrEP or act as barriers to it.
- Oral PrEP counselling helps clients to identify the factors that influence their behaviours.



#### **Key Approaches to Promoting Oral PrEP**

#### **Motivational Interviewing**

 Explore feelings, motivations for oral PrEP use, reasons for nonadherence to medicines, and negative experiences with medicines.

#### **Informed Choice Counselling (ICC)**

 Informing the choice for oral PrEP and developing a plan for adherence

#### **Integrated Next Step Counselling (iNSC)**

This method is discussed in the next slide.



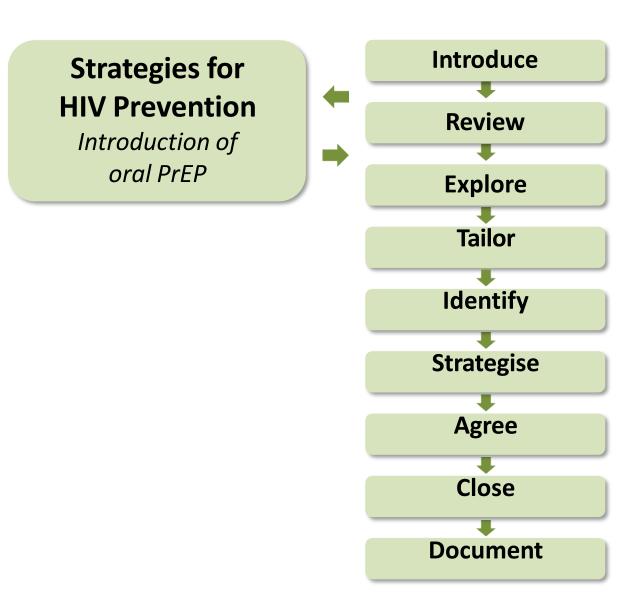
And there are others...

# **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.



# Integrated Next Step Counselling: Flow chart





# **Steps in iNSC**

iNSC Step	Critical Components	Example Prompts
<b>Introduce</b> the counselling session.	Explain what you are talking about and why. Get permission to proceed.	I would like to take a few minutes to check in with you about your goals and how to meet them. Is that okay?
<b>Review</b> the client's experiences.	Ask about what the client already knows about oral PrEP and how they learned it.	Thank you. Can you tell me a little about what you have heard about oral PrEP and about your experiences with oral PrEP?
<b>Explore</b> the context of client-specific facilitators and barriers.	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.	What seems to make oral PrEP easy to take or harder to take?
<b>Tailor</b> the discussion to focus on making pill taking easier.	This pause allows the provider or counsellor to consider how to tailor the next question based on information gathered in earlier steps.	Let me think for a moment about what you have said.



# Steps in iNSC (contd.)

iNSC Step	Critical Components	Example Prompts
Identify adherence- related needs.	Guide the conversation toward identifying the client's perceptions of what would help to best integrate oral PrEP use into daily life.	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?
<b>Strategise</b> with the client on the next step.	Work with the client to identify one or more viable strategies for increasing effective oral PrEP use.	How could that happen? What are some ideas to approach that?
Agree on which strategy will be tried next.	Ask which strategy (or strategies) the client is willing to try or continue using.	Kindly, try all we have discussed.
Close and document the session.	Summarise the discussion and thank the client.	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.



# **Steps in iNSC 1: Introduce the Counselling Session**

- Explain what you are talking about and why.
- Get permission to proceed.
  - -I would like to take a few minutes to check in with you about your life goals and how to meet them. Is that okay?



# **Steps in iNSC 2: Review the Client's Experiences**

Ask what the client already knows about oral PrEP and how they learned it.

-Thank you. Can you tell me a little about what you have heard about oral PrEP and about your experiences with oral PrEP?



# Steps in iNSC 3: Explore Client-Specific Facilitators and Barriers

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.

What seems to make oral PrEP easy to take or harder to take?



# Steps in iNSC 4: Tailor the Discussion to Focus on Pill Taking

This pause allows the provider or counsellor to consider how to tailor the next question based on information gathered in earlier steps.

Let me think for a moment about what you have said.



# **Steps in iNSC 5: Identify Adherence-Related Needs**

Guide the conversation toward identifying the client's perceptions of what would help to best integrate oral PrEP use into daily life.

-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?



# Steps in iNSC 6: Strategize with the Client on the Next Step

Work with the client to identify one or more viable strategies for increasing effective oral PrEP use.

- -How could that happen?
- -What are some ideas for how you could approach that?



# **Steps in iNSC 7: Agree on Which Strategy to Adopt**

Ask which strategy (or strategies) the client is willing to try or continue using. Refer to the HIV Exposure-Reduction Strategies to explore with the client.

-Of the things that we have talked about, which might you be willing to try between now and the next time we meet?



### **Steps in iNSC 8: HIV Exposure-Reduction Strategies**

Oral PrEP is more effective when used in combination with other prevention options. Others include:

- Abstinence
- Correct, consistent use of male condoms and lubricants/female condoms
- Diagnosis and treatment of STIs
- Mutual monogamy or reducing the number of sexual partners
- Voluntary medical male circumcision
- PEP
- Needle and syringe access programmes and opioid substitution therapy

# **Steps in iNSC 9: Close and Document**

Summarise the discussion and thank the client.

- -From your feedback, you will give oral PrEP a try between now and the next time we meet.
- -Thank you for talking with me, and I look forward to talking again.



# Clinical Scenario for Role-Play (iNSC)



Chioma, a female sex worker, is interested in starting oral PrEP. She uses condoms during sex with commercial clients but not with her long-term partner, whose HIV status is unknown. She had a negative HIV test 6 months ago and wants to avoid HIV infection. She would like to have a baby with her partner. She is using an injectable hormonal contraceptive because she used to forget to take oral contraceptives every day.

- We will now role-play this scenario. Please observe the role-play and follow along with the table of iNSC steps in your manuals.
- As you observe, think about how you might use iNSC yourself in this scenario.



# **Role-Play Debrief**



- How well did the provider follow the iNSC steps?
- What types of prompts or strategies worked best? Why?
- What were the most challenging aspects of the counselling?
- How did the provider handle the challenges?
- What other questions or comments do you have about iNSC so far?



# Oral PrEP Initial visit: Adherence Counseling



# Key Adherence Messaging for Oral PrEP Initial visit

- Taking oral PrEP each day is easier if linked to a daily routine (something else you do daily).
- 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 realise 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.



#### **Oral PrEP Initial Visit: Adherence Strategies**

- Link oral PrEP to a daily routine or event such as brushing teeth or eating breakfast.
- Take your pill at the same time every day.
- Identify what to do if a dose is missed.
- 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.



#### **Group Discussion**

- Close your participant manuals.
- Within your small group, brainstorm on one of these questions:
  - 1. What are some common reasons for poor adherence? Include both reasons associated with the individual and the medication and reasons related to the health system.
  - 2. What can providers do to promote and support adherence? Include counselling, reminder calls, and other activities.
- Choose one group member to record your questions on a flip chart.







## What is Oral PrEP follow-up visit

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



#### **Oral Prep Follow-up Visit**

- Clients on oral PrEP require regular visits to a health provider.
- Programmes should decide on the frequency of visits for monitoring oral PrEP use.
- The suggested follow-up visit schedule is:
  - A month after initiating oral PrEP
  - Every 3 months thereafter
- 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.



## Procedures (minimum package) for Oral PrEP follow-up Visit

Procedure	Investigation/Interventi on	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
Adherence and side effect assessments	Adherence counseling	<ul> <li>To assess that client is following the prescription strictly</li> <li>Assess to possible barriers to adherence</li> <li>To assess for willingness to continue</li> </ul>
	Side effect assessment	<ul> <li>To identify early the symptoms and signs of side effects</li> <li>To reassure clients to continue on the drug</li> <li>To manage appropriately if need be</li> </ul>
PrEP re-fill		To ensure client do not go out of stock



#### **Oral PrEP follow-up visit Counselling**

#### **What to Discuss During Sessions**

- 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



#### Oral PrEP follow-up visit Counselling (cont.)

#### **What to Discuss During Sessions**

- Dosing requirements for effectiveness
- What to do if a dose is missed
- How to recognise 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> <li>Safety monitoring clinical assessment</li> <li>HIV testing and counselling</li> <li>Adherence and risk reduction counselling</li> <li>If HBsAG negative, offer HBV vaccination if available (follow HBV vaccination schedule complete series)</li> </ul>
Visits for Months 3, 9, 15	<ul> <li>HIV testing and counselling</li> <li>HIV risk assessment for oral PrEP continuation</li> <li>Adherence and risk reduction counselling</li> <li>Assess for adverse drug reactions</li> </ul>
Visits for Months 6, 12, 18, 24, 36	<ul> <li>HIV testing and counselling</li> <li>Creatinine and eGFR *</li> <li>HIV risk review and assessment for oral PrEP continuation</li> <li>Adherence and risk reduction counselling</li> <li>Assess for adverse drug reactions</li> </ul>



<sup>\*</sup> Ideally, creatinine clearance performed at 6 months, followed by annual screening.

## **Oral PrEP Visit Checklist (contd.)**

Visit	Procedure	
Unscheduled visits: as per need	<ul> <li>Determine if the reason for the visit is PrEP related or not (e.g., adverse events).</li> <li>Assess and manage the reason for the unscheduled visit according to national guidelines (e.g., acute or chronic illnesses, worsening existing conditions).</li> <li>Provide HIV risk reduction and oral PrEP adherence counselling.</li> <li>Agree on follow-up schedule.</li> </ul>	
<b>During every visit:</b> 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).		
Management of clients with inconclusive HIV test result during follow-up visits	<ul> <li>For non-pregnant or lactating clients:</li> <li>Discontinue oral PrEP.</li> <li>Follow the national HIV testing algorithm for clients with an inconclusive result.</li> <li>Only after a confirmed HIV negative result can the client continue with oral PrEP.</li> <li>Offer risk reduction counselling and strongly emphasise the importance of condom use during the period with inconclusive HIV test results (e.g., new infection is highly infectious).</li> </ul>	



#### Assessing Oral PrEP Adherence during follow-up visit

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



#### Assessing Oral PrEP Adherence during follow-up visit (How to guide)

#### **Examples of Open-Ended, Nonjudgmental Questions on Adherence**

- 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?



# Assessing Oral PrEP Adherence during follow-up visit (How to guide) -contd.

## **Examples of Open-Ended Nonjudgmental Questions on Adherence**

- 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?
   Helpful strategies may include the following (next slide).



## **Discussion Prompts for Follow-Up Visits**

'Here are some strategies you could try to help with oral PrEP adherence.'

- Use a pill box.
- Take oral PrEP pills with other daily medicines.
- Use a phone alarm.
- Mark doses taken on a calendar.
- Have more support from your partner, a family member, or a friend.



What keeps you motivated to take the oral PrEP pills?

## Discussion Prompts for Follow-Up Visits (contd.)

#### **Behaviour and Activity**

- Has taking oral PrEP changed what else you do to prevent yourself from getting HIV and other STIs (for example, using condoms and lubricants, discussing HIV and other STI status and/or testing with partners)?
- 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 Poor Oral PrEP Adherence**

#### **Individual Factors**

- 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 medicines
- Substance or alcohol use
- Absence of supportive environment
- Fear of stigma and discrimination



#### Factors Responsible for Poor Oral PrEP Adherence (contd.)

#### **Medication-Related Factors**

- Adverse events following oral PrEP administration
- Complexity of dosing regimens

Oral PrEP requires taking just one tablet daily and does not mandate any dietary restrictions.



## Factors Responsible for Poor PrEP Adherence (contd.)

#### **Facility-Related Factors**

- 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



#### **Sociocultural Barriers to Uptake of Oral PrEP**

People with substantial risk of acquiring HIV often experience stigma from multiple sources.

- 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.).



## **Factors Promoting Oral PrEP Adherence**

#### **How Health Providers Can Positively Influence Adherence**

- Provide accurate information and education on the benefits, efficacy and requirements of oral PrEP.
- Express confidence in the effectiveness of oral PrEP.
- Prepare the clients for and help manage side effects.
- Help the client identify social support.
- 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.



Monitor adherence.

## **Factors Promoting Oral PrEP Adherence cont**

#### **How Peers Can Positively Influence Adherence**

- 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.
- Clients may discuss adherence and retention challenges with peer supporters more easily than with health professionals.



#### **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 visit schedule**

- At initiation, client would be given a month's prescription and scheduled for a 4-week follow-up visit.
- The follow-up visit is an ideal time to provide counselling on effective use, address any side effects, and rule out acute HIV infection at initiation.
- At 3-month follow-up visits, clients are tested for HIV to confirm HIV-negative status and 3 months of oral PrEP are prescribed.
- Schedule the client's next visit a week before the pill supply will run out.



#### **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



## **Oral Prep Discontinuation** (cont.)

- 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</li>
  - No longer at substantial risk of HIV acquisition
  - Persistent side effects



## **Oral PrEP Discontinuation (contd.)**

- A variety of other life changes may prompt a person to stop oral PrEP, including:
  - A partner with HIV on ART gets 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).



#### **Clinical Scenario**

(<del>+</del>)

Agboola has been on oral PrEP (TDF/FTC) for the last 9 months. At the follow-up visit, he is in good health, and his repeat HIV test is negative. Agboola reports recently starting a monogamous relationship with a man who tested HIV negative last year and feels he might no longer need oral PrEP.

How would you manage this case?



#### **Group Work/Discussion**

- With your small group, brainstorm responses to these question
  - —What challenges will you face when implementing oral PrEP?
  - -What strategies might you use to address these challenges?
- Choose one group member to record your responses on a sheet of notebook paper.

You will have 15 minutes to work.



## **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 Creatinine Elevation**

- Approximately one 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.</li>
- 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.</li>
- After oral PrEP is stopped, creatinine should be checked for another one to three months and oral PrEP 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 oral 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 Oral 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 recognise 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 is important in identifying gaps and needs in care for increased oral PrEP adherence.



## **Oral PrEP 'Special Considerations'**

Consideration	Recommendation
Hormonal contraception	<ul> <li>Oral PrEP does not affect the efficacy of hormonal contraceptives, and hormonal contraceptives do not affect oral PrEP efficacy.</li> </ul>
Pregnancy and breastfeeding	<ul> <li>Oral PrEP is safe in people who are pregnant and/or breastfeeding who are at continued substantial risk of HIV acquisition.</li> </ul>



## **Oral PrEP 'Special Considerations'** (cont.)

Consideration	Recommendation
Hepatitis B infection (HBV)	Oral PrEP does not affect the efficacy of HBV vaccine.
Management of recent HIV exposure with PEP	<ul> <li>People who have been exposed to HIV within 72 hours should be offered PEP.</li> <li>National Guidelines recommend a TDF/3TC/DTG (preferred) drug combination for 28 days.</li> <li>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.</li> </ul>



#### **Oral PrEP and Stigma**

HIV Stigma is a negative attitude and beliefs about People living with HIV (PLHIV). It is also the prejudice that comes with labeling an individual as part of a group that is believe to be socially unacceptable.

- Confidentiality is essential in oral PrEP services.
- People may face stigma if their oral PrEP use becomes known.



#### Oral PrEP and Stigma....Cont'd

 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.



#### **Group Discussion**



- In small groups, list possible strategies to minimise the stigma that your oral PrEP clients may face.
- Choose one group member to record your ideas on the sheet of flip chart paper.

You have 15 minutes to work.



#### **Module 4 Key Points**



- Oral PrEP users should be informed about how to recognise 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. Also, note that 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).
- Understand Oral PrEP documentation flow
- Correctly fill out the Oral PrEP Data collection tools
- Identify the correct order of the steps that health care workers should take during an initial oral PrEP visit.

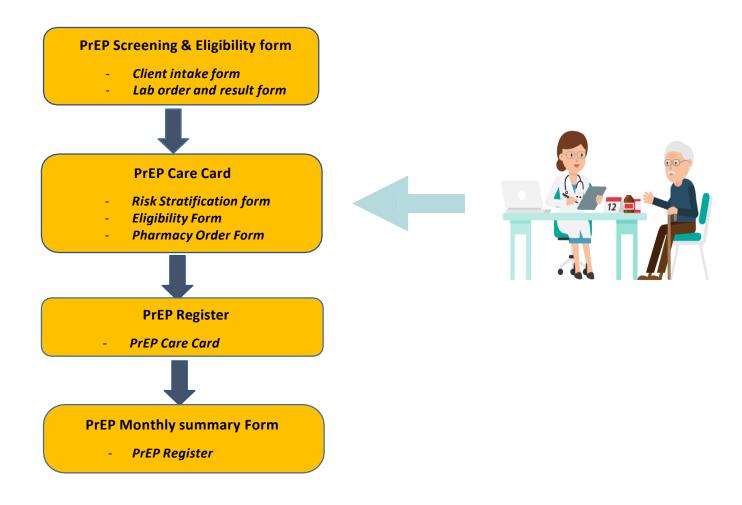


#### Rationale for Monitoring & Evaluation

- 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



#### **PrEP Service Documentation Flow**





## **Background**

Pre-exposure prophylaxis is part of an effort to scale-up HIV testing services (HTS) and prevention interventions, along with proactive referrals to antiretroviral treatment (ART).

#### **Tools used to capture PrEP intervention are:**

- Oral PrEP Screening and Eligibility form
- PrEP Card.
- PrEP Register.
- PrEP Monthly Summary Form (MSF).



## **Oral Prep Screening and Eligibility Form**

#### Pre-EXPOSURE PROPHYLAXIS SCREENING AND ELIGIBILITY FORM

State: LGA: Setting: (CT, FP, TB, STI, Others) So	ource of F	Facility name: leferral: (Self, Counselor, KOL, Others -specify):	_		
Client's Name Surname First):		Age (Years):Date of visit:			
Unique Client's ID: KP Pr/State/LGA/OSS/SN	Туре:	Sex: M F Others First time visit: [No] [Yes]			
State of Residence:		GA of Residence: Education level:			
Occupation: Marital state	25	No. of own children <5 years [ ] (If married) No. of wives [ ]	I		
Sex Partners: [Male]: [Female]: [Both]:	Type of	f Counseling: Individual [ ] Couple [ ]			
MARK with "X" the [0] if answer is No, the [1] if answer is Yes					
Pre	-Tost Co	unseling/Risk Assessment			
(A) Sex Partner Risk (last 3 months)		(B) Personal HIV Risk Assessment (Last 3 months)			
Have you had sex with a partner who		Unprotected Vaginal sex with casual partner:	[0] [1]		
Is HIV positive	[0] [1]	Unprotected Vaginal sex with regular partner:	[0] [1]		
Injects drugs	[0] [1]	Unprotected Anal sex with casual partner:	[0] [1]		
Has sex with men Is a transgender person	[0] [1]	Unprotected Anal sex with regular partner	[0] [1] [0] [1]		
Has sex with multiple partners without condoms	[0] [1]	History of STI	[0] [1]		
The sea with minips paraers without conducts	[0][1]	Shared needles/injecting materials	[0] [1]		
C) Drug use History (last 3 months)		More than 1 sex partner	oj tij		
i) Do you use any of these drugs/substances		Anal sex with male partner Anal sex with female partner	[0] [1]		
(please tick)		Unprotected anal sex with male partner	[0] [1]		
Cocaine Heroine Marijuana		Unprotected anal sex with female partner	[0] [1]		
		Have you paid for sex in the last 6 months?	[0] [1]		
Amphetamine Codeine/syrup		Have you been paid for sex in the last 6 months?	[0] [1]		
Others (Specify) Route of Administration		Have you experience condom breakage?  Have you taken part in sexual orgy?	[0] [1] [0] [1]		
Inject		(calculate the sum of the A & B answers above) Risk score:	1 (4)		
Sniff	[0] [1]	Cuttain be said by the A of D and were above, seem access.			
Snort Smoke	[0] [1] [0] [1] [0] [1]	Client is pregnant	[0] [1]		
ii) Have you used drugs to enhance sexual	[-][-]	D) STI Screening			
performance?		Female: Complaints of vaginal discharge or burning when			
Have you had HIV testing before?		urinating	[0] [1]		
When was your last test? < lmth 1-3mths		Female: Complaints of lower abdominal pains with or without	F03 F33		
4-6mths ⊃6mths		vaginal discharge?  Male: Complaints of urethral discharge or burning when	[0] [1]		
¥	202 212	urinating?	[0] [1]		
HIV test result at visit Positive	[0] [1] [0] [1]	Male: Complaints of scrotal swelling and pain	[0] [1]		
Recommended for HIV Retest?	[0] [1]	Genital sore +/- pains?	[0] [1]		
Tested in certain clinical settings, such as STI clinics?	101 [11	Swollen inguinal lymph nodes +/- pains?  Anal pain on stooling?	[6] [1]		
Report ongoing HIV risk behaviors?	[0] [1] [0] [1]	Anal itching?	ioj tij		
Report a specific HIV exposure within the last 3 months?	[0] [1]	Anal discharge?	[0][1]		
If client tests HIV negative and, has signs and	[0] [1]	(calculate the sum of the 9 answers above) STI screening score:	[0] [1]		
symptoms acute HIV infection, recommend HIV re-	[0][1]	If score ≥ 1, enroll in the STI syndromic management sheet or			
testing after 1 month		refer			
		Services Received by Client (Tick) PrEP Offered No [] Yes []			
PrEP Eligibility (Eligible if ALL criteria below		PrEP Offered No [] Yes []			
are met:	[0] [1]	PrEP Accepted No [] Yes []			
HIV risk score ⊇l					
Signs & symptoms of acute HIV infection	[o] [i]	Client referred to other services [0] [1]			
Has no proteinuria	[0] [1]	If [1], please specify			
Completed by: Design:	ation	Sign_ Date	_		



#### **Demographic Section**

#### Pre-EXPOSURE PROPHYLAXIS SCREENING AND ELIGIBILITY FORM

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

**State**: Write the state in which the health facility is located

**Facility:** Write the name of the health facility.

Source of referral: Write the specific source of referral (self, counsellor, KOL, Others)

**LGA:** Write the local government area (LGA) in which the health facility is located.

**Setting:** Write the specific SDP (CT,FP,TB,STI, Others).



#### **Bio Data Section**

Client's Name Suman	First)		Age (Yean):	Dess of visit	
Unique Client's ID	bis/LGA/OSS	ID Ty	e:Sex: M F Other	es First time visit: [No] [	Yes]
State of Residence:	THE DOME COM	The second of the second	LGA of Raudence:	Education level:	
Occupation:		Marital status	_No. of own children =7 ye	surs [ ] (If married) No. of	ouble-
Sen Pertners: [Male]	[Female]:	[Both]: T	rps of Counseling: Individual [ ]	Couple[]	liou

**Age**: Write the age of the client in this format (....years)

KP Type: Write the exact KP type (MSM, TG, FSW, PWIDs) and Others (SDPs &AGYW)

Type of counselling:

Specify the type of counselling (individual/couple)

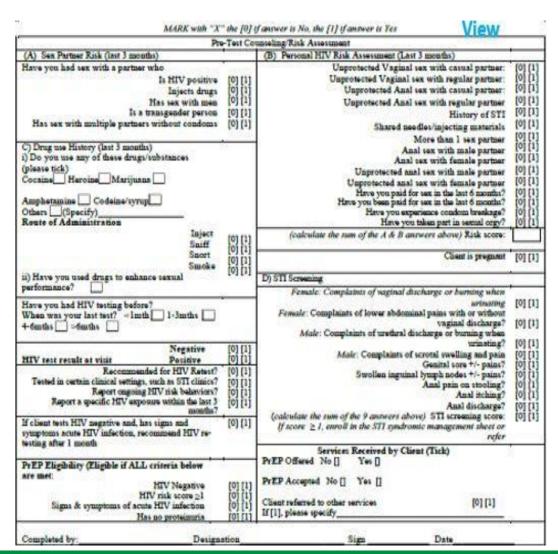
Sex Partners: Write the exact number of sexual partners a client have(male/ female or both sex



#### Pre-test counselling and risk assessment

A.
Pre-test counselling
(Assess partner's
risk)

STI Screening



В.

Pre-test counselling
(Assess Personal HIV Risk)
Document pregnancy status
for female clients

Post-test counselling (Provide HIV Test result)

Confirmation of eligibility and services received





#### **Completing the Pre-Exposure Prophylaxis Card**

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

#### **Objectives**

At the end of this session, participants should be able to:

- Understand the PrEP Card.
- Effectively complete the PrEP Card.
- Use the PrEP Card to document Patient data.



#### **Oral PrEP Care Card Sub-sections**

- PrEP CARD The Demographic Section
- PrEP CARD The Commencement Section
- PrEP CARD Discontinuations and Interruptions
- PrEP CARD Key definitions





#### **PrEP CARD - The Demographic Section**

Medical records
personnel/data clerk fills
in the demographic
information (elements 1 –
13) at the initial visit.

#### 1. Hospital number -

Write the hospital number of the client in the space provided.

PrEP CARD	FACILITY NAME:	1. Hospital number	
INITIAL VISIT			
2. Unique PrEP ID:	3	. Date enrolled in Prl 4. Partner ANC	/Unique ART No
5. Surname:	Other Names:	(dd/mm/yyyy) 6. Address:	7b. Educational Level: 1. None 2. Primary
7a. Occupation:	7b. Educational Level:	7c. Telephone No:	3 Secondary
7d. Sex: M F	7e. Age: (Yrs) 7f. DOB:	: 7g. Marital Status: (dd/mm/yyyy)	7g. Marital Status:  1. Single
8. PrEP Supporter:	9. Relationship: 1	0. Telephone No. (PrEP Supporter):	Married     S. Divorced     Seperated     Cohabiting
11. HIV Testing Po	12. Date of Last HIV Negative T		6. Widow/er
13. Date Referred for PrEP:	<b>1</b> . nm/yyyy)	(dd/mm/yyyy) 3b. PrEP Risk Type:	11. HIV Testing Point:  1 = Facility 2 = Community 3 = Others



- 2. Unique Clients ID Write the client's Unique PrEP ID in the boxes provided. A unique ID is assigned when the patient is newly enrolled in PrEP care
- **3. Date enrolled in PrE**P Write the date enrolled in PrEP in the dd/mm/yy format. This is the day the client was first enrolled in PrEP care in the health facility

PrEP CARD	FACILITY NAME:	1. Hospital number_	
INITIAL VISIT			
2. Unique PrEP ID:	3. Date enrolle	led in Prl 4. Partner AN	IC/Unique ART No
		(dd/mm/yyyy)	7b. Educational Level:
5. Surname:	Other Names: 6.	Address:	1. None
7a. Occupation:	_ 7b. Educational Level: 7c	Telephone No:	2. Primary
7d. Sex: M F	7e. Age: (Yrs) 7f. DOB: (dd/mm/yyyy)	7g. Marital Status:	7g. Marital Status: 1. Single
8. PrEP Supporter:	9. Relationship: 10. Telephone	e No. (PrEP Supporter):	2. Married 3. Divorced
11. HIV Testing Po	12. Date of Last HIV Negative Test:		4. Seperated 5. Cohabiting 6. Widow/er
	(dd/mm/y	)yyy)	11. HIV Testing Point:
13. Date Referred for PrEP:(dd/mm/t		k Type:	1 = Facility 2 = Community 3 = Others

**4. Partner ANC/Unique ART No -** Write the client's partner's ANC numBER if pregnant and registered for ANC services or client's Unique ART number.

- **5. Client Name -** Write the client's names (surname and other names), including alias.
- Obtain this from the client directly
- check against the names written on the hospital card.
- Note differences
- Determine actual

PrEP CARD	FACILITY NAME:	1. Hospital number	
INITIAL VISIT			
2. Unique PrEP ID:			RT No
Surname:0	ther Names: 6. Address:	hmmlyyyy)	7b. Educational Level: 1. None 2. Primary
7a. Occupation:7	b. Educational Level:7c. Telephone	e No:	3. Secondary 4. Tertiary
7d. Sex: M F 7	e. Age: (Yrs) 7f. DOB: 7g. (dd/mm/yyyy)	Marital Status:	7g. Marital Status:  1. Single
8. PrEP Supporter:9	. Relationship: 10. Telephone No. (PrEP	Supporter):	Married     Divorced     Seperated     Cohabiting
11. HIV Testing Po 1	2. Date of Last HIV Negative Test:  (dd/mm/yyyy)		6. Widow/er  11. HIV Testing Point:
13. Date Referred for PrEP:(dd/mm/yyyy			1 = Facility 2 = Community 3 = Others

**6. Address -** Write the descriptive address of the client in a manner that will ensure that the client can be traced if necessary.

**7a Occupation** Enter the client's occupation in the space provided

**7b. Educational Status** Enter the code appropriate for the client's educational status.

**7c Telephone Number** Request all contact telephone numbers from the client.

Verify the validity of the phone number at the point of enrolment.

PrEP CARD	FACILITY NAME:	1. Hospital number	
INITIAL VISIT			
2. Unique PrEP ID:	3. Date enrolled in Prl	4. Partner ANC/Unique A	RT No
5. Surname:Oth	(dd er Names: 6. Address: _	łmmłyyyy)	7b. Educational Level: 1. None 2. Primary
7a. Occupation:7b.	Educational Level:7c. Telephone	e No:	3 Secondary 4. Tertiary
7d. Sex: M F 7e.	Age:(Yrs) 7f. DOB: 7g.	. Marital Status:	7g. Marital Status:
8. PrEP Supporter: 9. R	elationship: 10. Telephone No. (PrEP	Supporter):	Married     Divorced     Seperated     Cohabiting
11. HIV Testing Po 12.	Date of Last HIV Negative Test: (dd/mm/yyyy)		6. Widow/er
13. Date Referred for PrEP:(dd/mm/yyyy)			11. HIV Testing Point:  1 = Facility 2 = Community 3 = Others



7d Sex - This should be obtained by simple observation. Mark the 'F' box for females and the 'M' box for males

**7e Age -** Obtain this from the client directly and check against the figures written on the hospital card (where applicable). Note any differences and the actual age determined.

PrEP CARD	FACILITY NAME: _	1. Hospita	al number	
INITIAL VISIT	·			
2. Unique PrEP ID:		3. Date enrolled in Prl	4. Partner ANC/Unique A	RT No
5. Surname:	Other Names:	(dd/mm/yyyy) 6. Address:		7b. Educational Level: 1. None 2. Primary
7a. Occupation:	7b. Educational Level:	7c. Telephone No:		3. Secondary 4. Tertiary
7d. Sex: M F	7e. Age:(Yrs) 7f.	DOB: 7g. Marital S	itatus:	7g. Marital Status:  1. Single 2. Married
		10. Telephone No. (PrEP Supporter	r):	3. Divorced 4. Seperated 5. Cohabiting 6. Widow/er
11. HIV Testing Po	12. Date of Last HIV Nega	tive Test: (dd/mm/yyyy)		11. HIV Testing Point:
13. Date Referred for PrEP:(dd/mm		13b. PrEP Risk Type:		1 = Facility 2 = Community 3 = Others



7f DoB (Date of Birth) This should be obtained from the client directly and checked against the figures written on the hospital card (where applicable).

**7g Marital Status** Write the code appropriate for the client's marital status.

PrEP CARD	FACILITY NAME:	1. Hospital number	
INITIAL VISIT			
2. Unique PrEP ID:	3. Date enrolled in Prl	4. Partner ANC/Unique Af	RT No
5. Surname:Ot		d/mm/yyyy)	7b. Educational Level: 1. None 2. Primary
7a. Occupation: 7b	. Educational Level:7c. Telephon	e No:	Secondary     Tertiary
7d. Sex: M F 7e	e. Age: (Yrs) 7f. DOB: 7g	. Marital Status:	7g. Marital Status:  1. Single
8. PrEP Supporter: 9.	Relationship: 10. Telephone No. (PrEP	Supporter):	2. Married 3. Divorced 4. Seperated 5. Cohabiting
11. HIV Testing Po 12			6. Widow/er
13. Date Referred for PrEP:(dd/mm/yyyy)			11. HIV Testing Point:  1 = Facility 2 = Community 3 = Others



**8 Prep Supporter -** Obtain Prep supporter's information from the client. This should be somebody the Prep client is comfortable disclosing their status to.

**9 Relationship of PrEP supporter -** Confirm and write the relationship of the PrEP supporter to the client, e.g., spouse, son, daughter, etc.

**10 Telephone Number of PrEP supporter -**Obtain the telephone number of the client's supporter.

PrEP CARD	FACILITY NAME:	1. Hospita	al number
INITIAL VISIT			
2. Unique PrEP ID:	3.	. Date enrolled in Prl	4. Partner ANC/Unique ART No
	Other Names: 7b. Educational Level:	(dd/mm/yyyy)6. Address: 7c. Telephone No:	2. Primary
7d. Sex: M F F		7g. Marital St (dd/mm/yyyy) 0. Telephone No. (PrEP Supporter	1. Single 2. Married
11. HIV Testing Po	12. Date of Last HIV Negative T	est: (dd/mm/yyyy)	5. Cohabiting 6. Widow/er  11. HIV Testing Point:
13. Date Referred for PrEP:(dd/mi	1. π/yyyy)	3b. PrEP Risk Type:	1 = Facility 2 = Community 3 = Others



#### PrEP CARD - The Demographic Section ...... cont

11 HIV testing point - Write the appropriate HIV testing point code from the list of "HIV testing points" provided. For example, in the case of a client tested at the facility, write "1" for the facility.

12 Date of last HIV negative test Write the date (dd/mm/yy) the client was last confirmed HIV negative. Obtain this information from the lab tests results and not verbally. If no test result exists, refer the patient for re-testing.

PrEP CARD	FACILITY NAME:	1. Hospital number_	
INITIAL VISIT			
2. Unique PrEP ID:	3. Date enrolled in Pri	4. Partner ANC/Unique A	ART No
5. Surname:	Other Names: 6. Address	(dd/mm/yyyy)	7b. Educational Level: 1. None 2. Primary
7a. Occupation:	b. Educational Level:7c. Telepho	one No:	Secondary     Tertiary
7d. Sex: M F	7e. Age: (Yrs) 7f. DOB: (dd/mm/yyyy)	7g. Marital Status:	7g. Marital Status:  1. Single 2. Married
8. PrEP Supporter:	). Relationship: 10. Telephone No. (Pri	EP Supporter):	Divorced     Seperated     Cohabiting
1. HIV Testing Po	2. Date of Last HIV Negative Test:  (dd/mm/yyyy)		6. Widow/er  11. HIV Testing Point:
13. Date Referred for PrEP:(dd/mm/yy			1 = Facility 2 = Community 3 = Others



13a Date referred for PrEP Write the date (dd/mm/yyyy)
the client was referred for PrEP
at the health facility.

**13b PrEP Risk Type**- Write the code of the client eligibility for PrEP services.

PrEP CARD	FACILITY NAME:		1. Hospital number	_
INITIAL VISIT				
2. Unique PrEP ID:		3. Date enrolled in Prl	4. Partner ANC/Unique	ART No
5. Surname:		6. Address: _	e No:	7b. Educational Level: 1. None 2. Primary 3. Secondary 4. Tertiary
7d. Sex: M F	7e. Age: (Yrs) 7f. DOE	3: 7g	. Marital Status:	7g. Marital Status: 1. Single
8. PrEP Supporter:			Supporter):	2. Married 3. Divorced 4. Seperated 5. Cohabiting 6. Widow/er
11. HIV Testing Po		Test: (dd/mm/yyyy)  13b. PrEP Risk Type:		11. HIV Testing Point:  1 = Facility 2 = Community 3 = Others



#### **PrEP CARD - Commencement Section**

Prep Commencement			
14. Date Initial Adherence Counseling (dd/mm/yyyy)	15. Date PrEP started (dd/mm/yyyy)	16. PrEP Regimen	
17. Weight(kg) 18. Height(m)	19. BMI (kg/m2)	20. Pregnant Breastfeeding 24. Why STOP Codes:	
21. History of drug allergies:		1 Toxicity/side effects 2 Pregnancy 3. Client preference	
22. Urinalysis Result	23. Referred Yes No	24. Date referred:	

The attending physician or ART nurse should complete the PrEP commencement information



#### PrEP CARD - Commencement Section..... (contd.)

1	Prep Commencement			
	14. Date Initial Adherence Counseling (dd/mm/yyyy)	15. Date PrEP started (dd/mm/yyyy)	16. PrEP Regimen	
	17. Weight(kg) 18. Height(m)  21. History of drug allergies:	19. BMI (kg/m²)		24. Why STOP Codes: 1 Toxicity/side effects 2 Pregnancy 3. Client preference
	22. Urinalysis Result	23. Referred Yes No	24. Date referred:	4. HIV positive

14 Date Initial Adherence

Counselling Completed - Write the date (DD/MM/YYYY) the client completes initial adherence counseling.

15 Date PrEP started - Write the date (DD/MM/YYYY) the first PrEP prescription was given to the client.

16 PrEP regimen - Write the PrEP regimen or regimen code for the first PrEP regimen that the client begins with.



## PrEP CARD - Commencement Section (contd.)

Prep commencement				
14. Date Initial Adherence Coun	nseling	15. Date PrEP started (dd/mm/yyyy)	16. PrEP Regimen	
17. Weight(kg) 18	. Height(m)	19. BMI (kg/m2)	20. Pregnant Breastfeeding	24. Why STOP Codes: 1 Toxicity/side effects
21. History of drug allergies:				2 Pregnancy 3. Client preference
22. Urinalysis Result		23. Referred Yes No	24. Date referred:	4. HIV positive

17 Weight (kg) - Write the weight of the client, measured in kilograms (kg), at the start of PrEP. This is obtained from item16 of the PREP commencement section.

18 Height(m) - Write the height of the client, measured in metres (m) at the start of PrEP. This is obtained from item17 of the PREP commencement section.

19 BMI (kg/m2) - The Body Mass Index (BMI) is a calculated indicator field of nutritional status. The clinical staff should determine the BMI for the clients.



#### **PrEP CARD - Commencement Section (contd.)**

Prep commencement		
14. Date Initial Adherence Counseling (dd/mm/yyyy)	15. Date PrEP started 16. PrEP Regimen	
17. Weight(kg) 18. Height(m)	19. BMI (kg/m2) 20. Pregnant Breastfeeding 24. Why TOP Codes:	$\overline{}$
21. History of drug allergies:	1 Toxicity/side effects 2 Pregnancy 3. Client preference	
22. Urinalysis Result	23. Referred Yes No 24. Date referred:	

20 Pregnant/ Breastfeeding - If the client is female, obtain and write the information on pregnancy or breastfeeding status from the client.

21 History of drug allergies -Confirm and write the history of drug allergies of the client. **22 Urinalysis result -** Write the urinalysis result of the client.



#### **PrEP CARD - Commencement Section (contd.)**

Prep Commencement			
14. Date Initial Adherence Counseling (dd/mm/yyyy)	15. Date PrEP started (dd/mm/yyyy)	16. PrEP Regimen	
17. Weight(kg) 18. Height(m)	19. BMI (kg/m2)	20. Pregnant Breastfeeding	24. Why STOP Codes: 1 Toxicity/side effects
21. History of drug allergies:			1 Toxicity/side effects 2 Pregnancy 3. Client preference
22. Urinalysis Result	23. Referred Yes No	24. Date referred:	4. HIV positive

**23 Referred -** Mark either **Yes** or **No** to indicate if the client was referred to the facility from another facility or service delivery area for PrEP

**24 Date referred -** Write the date the client was referred to the facility



#### **Prep CARD - Discontinuations and Interruptions**

					DISCONTINUATIONS & INTERRUPTIONS		
25. PrEP Interruptions					26. Date client referred-out:	27. Facility referred to:	
Default (D) Date Why		Date of restart if placed back on medication	28. Date client died:(dd/mm/yyyy)	29. Cause of Death:			
S	D				30. Source of death information		
S	D						
S	D						
S	D						
S	D						
S	D						

**25 PrEP Interruptions** - The attending physician or ART nurse should determine whether they have voluntarily stopped PrEP or defaulted from the client.

#### The information should contain:

- 1. when the interruption happened (Date)
- 2. the reason for the interruption (Why)

Record the date and the code for the reason why client stopped. The *reason codes* are listed on the card.

If PrEP is restarted, record the date of Restart in the space provided.



## PrEP CARD - Discontinuations and Interruptions (contd.)

DISCONTINUATIONS & INTERRUPTIONS								
25. PrEP Interruptions				26. Date client referred-out:	27. Facility referred to:			
Stopped (S)  Default (D) [circle as appropriate]		Why Date of restart if placed back on medication		28. Date client died:	29. Cause of Death:			
S D				30. Source of death information				
S D								
S D								
S D								
S D								
S D								

**26 Date client referred out -** If the client is referred out of the health facility, write the date client was referred out in the space provided.

**27 Facility referred to -** Write the name of the health facility to which the client is being referred for the continuation of PrEP.



#### **Prep Card** - Discontinuations and Interruptions

	DISCONTINUATIONS & INTERRUPTIONS								
25. PrE	P Interru	ıptions			26. Date client referred-out:	(dd/mm/vvvv)	27. Facility referred to:		
Stoppe Defaul [circle a appropr	t (D)	Date	Why	Date of restart if placed back on medication	28. Date client died:	(dd/mm/yyyy)	29. Cause of Death:		
S	D				30. Source of death information	on			
S	D								
S	D								
S	D								
S	D								
S	D								

28 Date client died - In the event of death, enter the date the client died or the date when the news of the death reached the facility (i.e., if the date of death cannot be ascertained). Write the date in DD/MM/YYYY format.

29 Cause of death - Write the source from which the notification of death was obtained. This includes family, neighbors, workmates, death certificates, hospital workers, etc.



#### **PrEP CARD - Discontinuations and Interruptions**

25. PrE	P Interru	ptions			26. Date client referred-out: [dd/mm/www]	27. Facility referred to:
Stoppe Defaul [circle a appropr	t (D) s	Date	Why	Date of restart if placed back on medication	28. Date client died:(dd/mm/yyyy)	29. Cause of Death:
S	D				30. Source of death information	
S	D					
S	D					
S	D					
S	D					
S	D					

30 Source of death information -

Write the cause of death of the client.



# **PrEP CARD - Key definitions**

DEFAULT	Missed one or two appointments or PrEP drug pick- ups.
STOP	Client or provider-initiated intentional treatment interruption.
Restart	Client starts PrEP again after treatment interruption (STOP or defaulted).



#### **PrEP CARD: Encounter Pages**

Encounter page of the PrEP Card captures the details of the client's status at each clinical visit

E1	E2	E3	E4	E5	E6	E7
Visit Date dd/mm/yyyy	Duration on PrEP (Months)	Weight (kg)	Blood Pressure (mmHg)	HTS Result (Enter Code)	Noted Side Effects (Enter Code)	Syndromic STI Screening (Enter Code)

Status Codes guiding use of this tool is at the bottom of this page

E8	E9	E10	E11	E12	E13	
Risk	Adherence	PrEP Drugs	Other Drugs	Urinalysis Upper space: Date	Hepatitis	
Reduction Services (Enter Code)	(Enter Code)	Regimen (Enter Code)	Prescribed	Lower Space: Result (Enter Code)	Upper space: Date Lower Space: Result (Enter Code)	

ART Nurse completes this section.

E13	E14	E15	E16	E17
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 dd/mm/yyyy	Signature



**E1 Visit date -** Write the date (DD/MM/YYYY) of the visit into this column.

# E2 Duration on PrEP (usually documented in months)

Write the number of months since the commencement of PrEP.

The month of PrEP commencement should be documented as month '0'

/E1	E2	E3	E4	<b>E</b> 5
Visit Date dd/mm/yyyy	Duration on PrEP (Months)	Weight (kg)	Blood Pressure (mmHg)	HTS Result (Enter Code)

E3 Weight (kg) - Write the client's weight in kilograms (kg).

**E4 Blood Pressure -**Write the Blood
Pressure of the client.

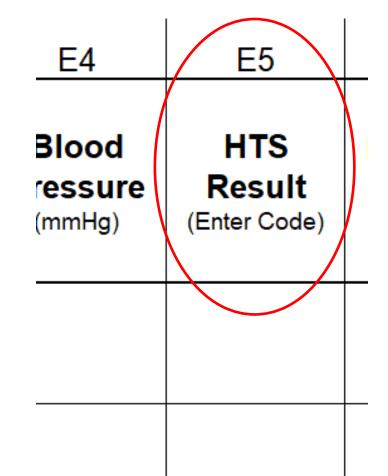
E1	E2	/E3	E4	<b>E</b> 5	
Visit Date dd/mm/yyyy	Duration on PrEP (Months)	Weight (kg)	Blood Pressure (mmHg)	HTS Result (Enter Code)	



**E5 HTS Result -** Write the appropriate HTS result.

#### Use Code Provided.

For example, write
'1' if the client is HIV positive,
'2' if HIV negative,
'3' if HIV test not done.



# Codes E5 HTS Result

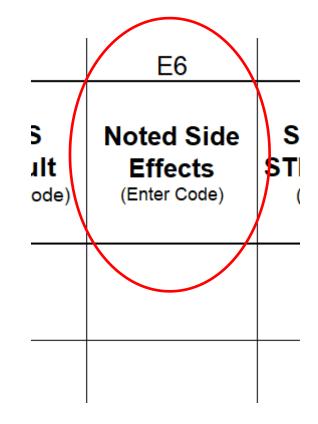
- 1. HIV Positive
- 2. HIV Negative
- 3. Not Done



#### **E6 Noted Side Effects -**

Write the code (1, ...,12) that corresponds to the client's noted side effects.

Refer to noted side effects status codes.



## Codes E6 Noted Side Effects

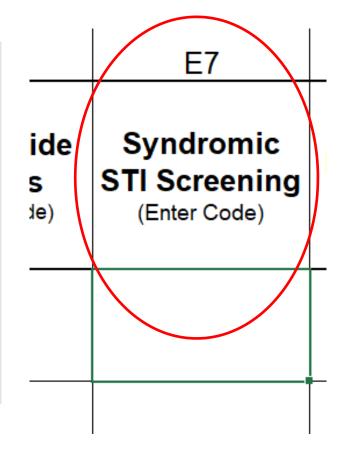
- 0. No side effects
- 1.Nausea/vomiting
- 2. Headache
- 3.Insomnia/bad dreams
- 4 Fatigue/weakness
- 5. Abdominal pain
- 6. Diarrhea
- 7.Fever
- 8.Rash
- 9.Anemia
- 10.Stevens Johnson syndrome
- 11.Hyperglycemia
- 12. Others



#### **E7** Syndromic STI screening -

Write the code (1, 2, 3, 4, 5, 6, 7, 8, 9) that corresponds to the client's syndromic STI screening status.

Refer to syndromic STI screening status codes.



# **Codes E7 Syndromic STI Screening**

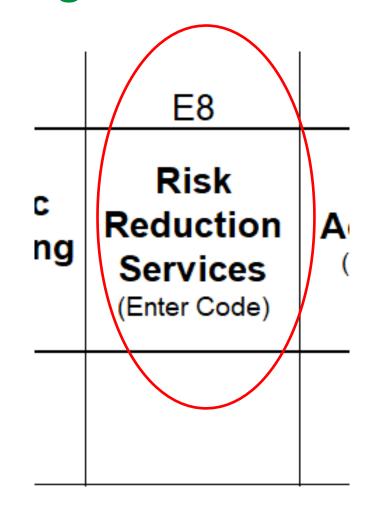
- 1. No STI symptoms/signs
- 2. Urethral discharge
- 2.Genital Ulcers
- 3. Vaginal discharge
- 4. Lower Abdominal Pain
- 5. Scrotal Swelling
- 6. Anal Warts
- 7. Genital Warts
- 8. Inguinal bubo
- 9. Others



#### **E8 Risk Reduction Services -**

Write the code (1, 2, 3) that corresponds to the risk reduction service provided to the client during the clinic visit.

Refer to risk reduction services codes.



# Codes E8 Risk Reduction Plan:

- Risk reduction strategies discussed
- Plan 1 plus correct condom use demonstrated
- 3. Plan1&2 plus lubricant provided



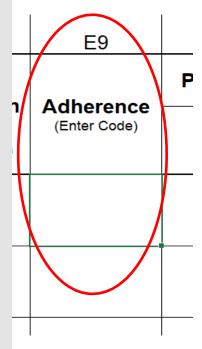
**E9 Adherence -** Write the code corresponding to the client's level of adherence to PrEP at the time of the visit, e.g., 'G' or 'F' or 'P'

#### Note:

For documentation of the adherence, use the codes from the Level of Adherence and Why.

If the adherence is poor or fair, enter the code for the reason, e.g., if the client is judged to have a fair adherence due to a change in routine, write "**F(3)**" in the adherence cell.

Refer to adherence codes.



#### Codes E9

#### **Level of Adherence**

Estimate adherence for once daily PrEP using the following table:

% Missed doses per month

 $G (Good) \ge 95\% \le 1 doses$ F (Fair) 85-94% 2-5 doses

P (Poor) < 85% ≥ 6 doses

#### Codes E9a

#### Why Poor /Fair adherence:

- 1 Forgot
- 2 Fell asleep/slept through dose
- 3 Change in routine/away from home
- 4 Busy/working/at school
- 5 Patient moved
- 6 Ran out of medications
- 7 Drug stock-out
- 8 Not able to pay
- 9 Partner Influence
- 10. Others



E10 - PrEP drugs and regimen -

Write the code (1, 2) that corresponds to the regimen provided to the client during the clinic visit.

Refer to regimen code.

E11 Other drugs prescribed -

Document any other drugs prescribed for the client during the clinic visit.

Attending Physician/ART Nurse

E10	E11
PrEP Drugs	Other Drugs
Regimen (Enter Code)	Prescribed

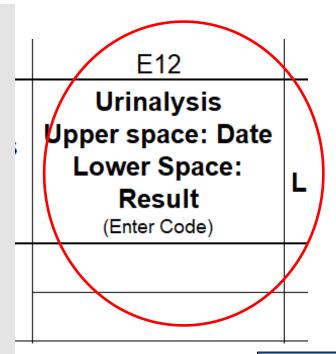
Codes E10 Regimen 1.TDF/FTC 2. TDF/3TC



E12 Urinalysis - (Date and Result) - Write the date that the urinalysis test was done for the client in the upper space of the urinalysis column.

Write the code (1, 2, 3, 4) that corresponds to the urinalysis test result of the client on the lower space of the urinalysis column during the clinic visit.

Refer to the urinalysis test result codes.



#### Codes E12 Urinalysis Result:

- 1. No proteinuria
- 2. Proteinuria Present One +
- 3. Proteinuria Present Two ++
- 4. Proteinuria Present Three +++

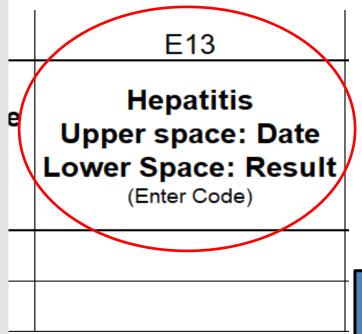


#### **E13 Hepatitis (Date and Result)**

Write the date that the hepatitis test was done for the client on the upper space of the hepatitis column.

Write the code (1, 2, 3, 4, 5, 6) that corresponds to the client's hepatitis test results in the lower space of the hepatitis column during the clinic visit.

Refer to hepatitis test result codes.



# Codes E13 Hepatitis test result

1 = Hepatitis B Positive

2 = Hepatitis B Negative

3 = Hepatitis C Positive

4 = Hepatitis C Negative

5 = HIV/HBV Coinfected

6 = HIV/HCV Coinfected

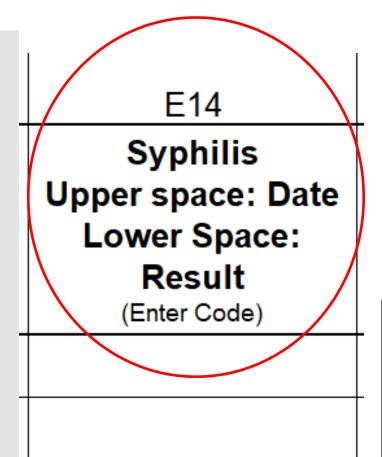


#### E14 Syphilis (Date and

**Result) -** Write the date that the syphilis test was done for the client in the upper space of the syphilis column.

Write the code (1, 2, 3, 4) that corresponds to the syphilis test result of the client on the lower space of the syphilis column during the clinic visit.

Refer to syphilis test result codes.



# Codes E14 Syphilis Result:

- 1. Negative
- 2. Positive
- 3. Not Done
- 4. Others



**E15 Other tests (Date and Result) -** Write the date that any other test was done for the client in the upper space of the other test column.

Document the result of other tests done by the client on the lower space of the other test column during the clinic visit.

Other Tests Done
Upper space: Date
Lower Space: Result
(Enter Code)

#### Codes E15 Other Tests

- 1. HB/PCV
- 2. WBC + Diff
- 3. ALT
- 4. AST
- 5. Creatinine
- 6. Lipid Profile
- 7. HBsAg
- 8. Urinalysis
- 9. Sputum AFB
- 10. Chest Xray
- 11. Other (specify)



E16 Next Appointment Date - The attending physician should indicate the period in which the client will return for a follow-up visit.

Medical Records should translate that period into a date.

The date in this column will be used to determine if a visit is scheduled for the client.





**E17 Signature -** The attending physician/ART nurse during the client's clinic visit should sign in this column.

## **Case Study**

On the 10<sup>th</sup> August, 2020, Mr Obi Chukwu received his first PrEP service at Jollad hospital, Gbagada. He tested HIV Negative on this date, his Partner's ART Unique ID is **0018**.

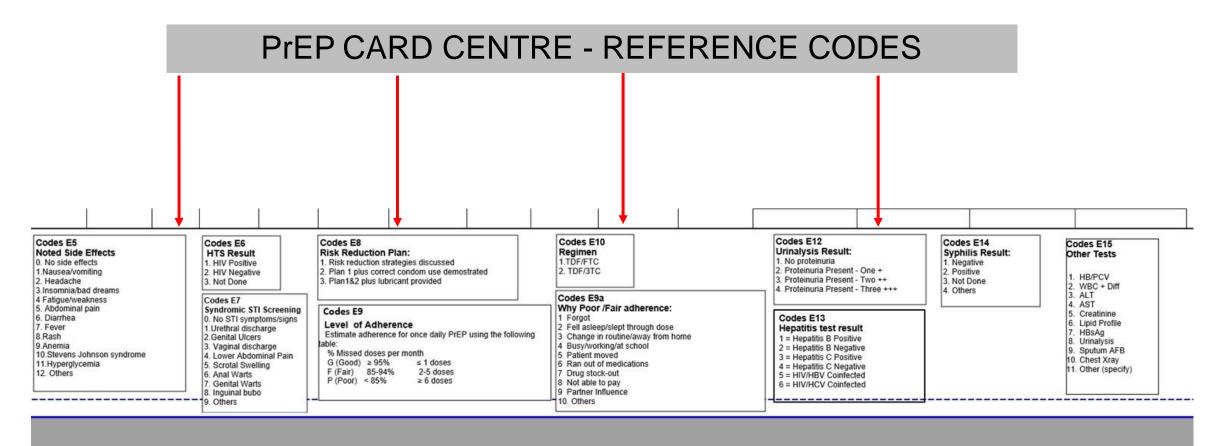
On his 1<sup>st</sup> follow up visit (September 9<sup>th</sup> 2020), he tested HIV negative, however, he takes his drugs regularly but his STI Screening shows he has *Lower Abdominal Pain*.

On the 12th of October, 2020, Mr Obi tested HIV positive, and was subsequently linked to ART

#### **Activity:**

- Complete the PrEP Card and Register.
- Show this information on the PrEP MSF in October 2020 reporting period)







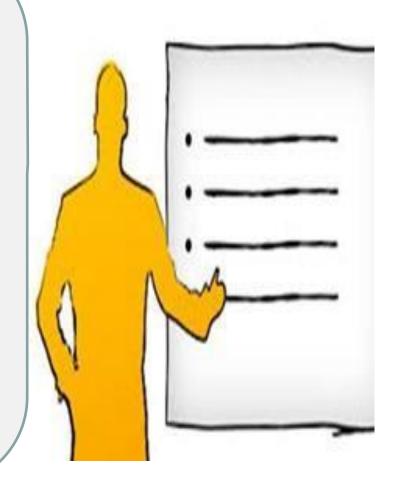


## Completing the Pre-Exposure Prophylaxis register

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

### **Outline**

- > Training Objective
- Objective of the Tool (Register)
- Background Information
- > PrEP Service Documentation Flow
- > The Header Section
- The Client Registration Section
- > Status at PrEP
- ➤ The Follow-up Visit
- The PrEP Discontinuation and Linkage to ART
- Case study
- > Appendix



## **Training Objectives**

By the end of the training session, all participants will:

- Be familiar with the PrEP register.
- > Understand the importance of collecting data using the PrEP register.
- > Be able to fill the PrEP register correctly.



# Objective of the Tool (PrEP Register)

- > To document PrEP clients' information.
- To Monitor respective client on the uptake of PrEP services.
- > To provide aggregated data on the PrEP monthly summary form.



# **Background Information**

Pre-exposure prophylaxis is part of an effort to scale-up HIV testing services (HTS) and prevention interventions, along with proactive referrals to antiretroviral treatment (ART).

Tools used to capture PrEP intervention are:

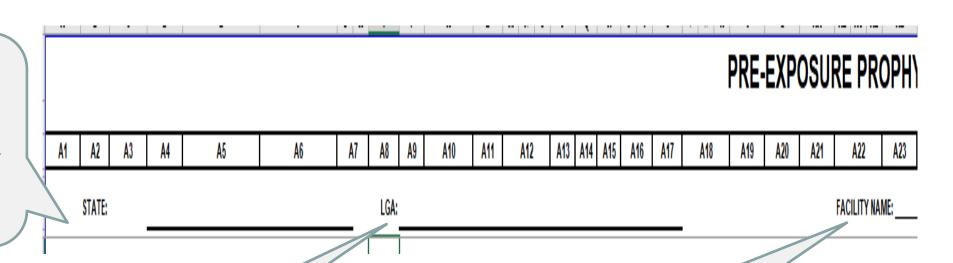
- > PrEP Card
- ➤ PrEP Register
- ➤ PrEP Monthly Summary Form (MSF)

**PrEP Register** – Documents PrEP clients' information from the PrEP Card on a daily basis, and monitor the respective client on the uptake of PrEP services



### The header section

State: Write the state in which the health facility is located



LGA: Write the local government area (LGA) in which the health facility is located.

**Facility:** Write the name of the health facility.



## The header section (Contd.)

#### PRE-EXPOSURE PROPHYLAXIS (PIEP) REGISTER



FACILITY NAME: \_\_\_\_\_ MONTH: \_\_\_\_\_ YEAR:

Month: Write the month that the clients started PrEP. Each sheet documents only clients registered within that month. Every new month should start on a new page.

**Year**: Write the year that the clients started PrEP.

# **The Clients Registration Section**

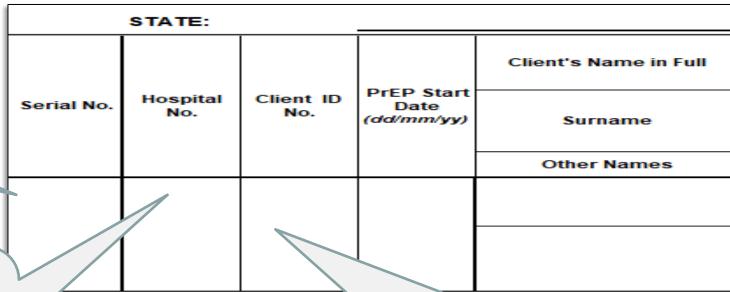
	Registration and Personal Information																									
			PrEP Start	Client's Name in Full	Risk Type								Se	ex											Transfer In (Tick if	
Serial No.	Hospital No.	Client ID No.	Date (dd/mm/ yy)	Surname	(Descriptive)	PrEP High		М			F						sni	Age	Partner ANC/Uniqu e ART No.	patient was						
				Other Names	See code 1	15-19	20-24	25-29	30-34	35-39 4	0-44	45-49	50+	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+				facility)	

This section collects personal and demographic information of the clients. *The details required to complete this section can be sourced from the 'Initial visit' section of the PrEP card* 



# The Client Registration Section (Contd.)

A1- Serial number: Write the serial number. Serial number should begin from '1' each month.



A2- Hospital number: Write the client's hospital number.

Obtain this from item 1 of the PrEP card (above the initial visit section).

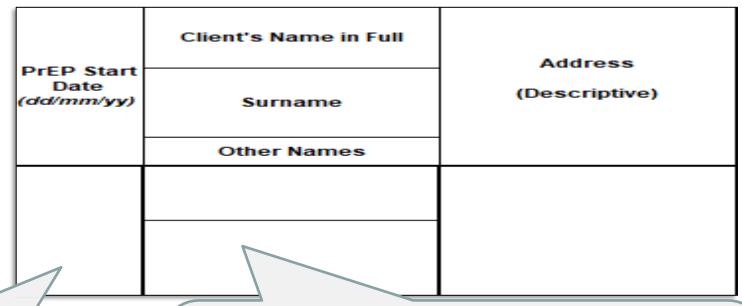
A3- Client ID No: Write the client's unique PrEP ID number. Obtain this from item 2 on the initial visit section of the PrEP card.



# The Client Registration Section (Contd.)

A4- PrEP start date: Write the date that the client started PrEP in the dd/mm/yy format.

This is obtained from Item 15 in the PrEP commencement section of the PrEP card.



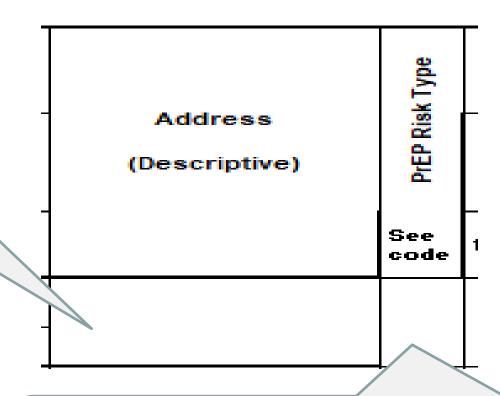
A5- Name (Surname, other names):

Write the client's surname in upper case (capital letters) in the upper section and first name and other names in lower case (small letters) in the lower section.



# The Clients Registration Section (Contd.)

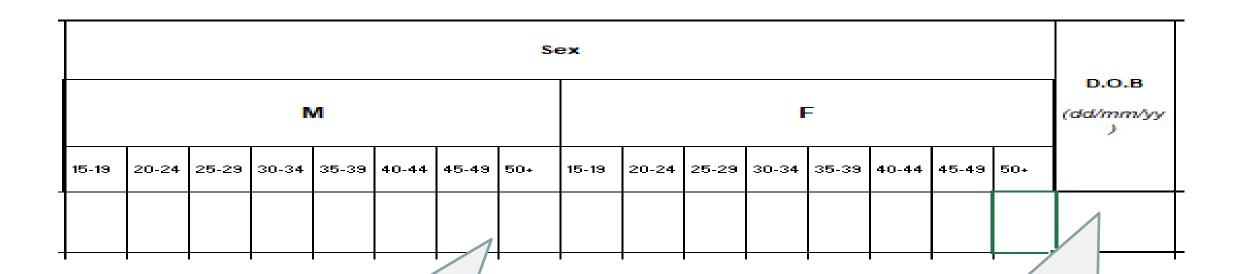
Address: Write the client's descriptive address. (Use landmark). This is obtained from item 6 in the initial visit section of the PrEP card.



PrEP Risk Type: Write the code of the client eligibility for PrEP services.see code at the bottom of the register.



## The Clients Registration Section (Contd.)



**Sex**: Mark "X" for the sex of the client in the disaggregated column..

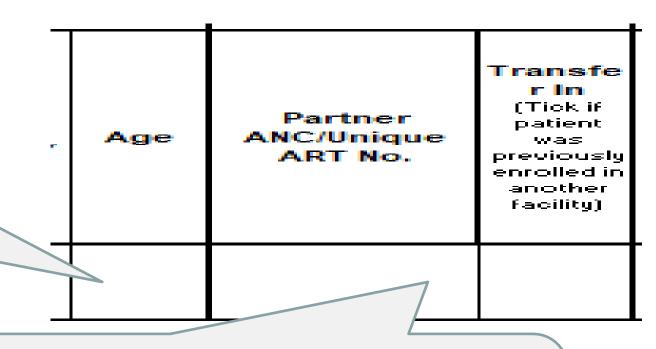
**DOB:** Write the client's date of birth (DOB) in the format dd/mm/yy.

This is obtained from item 7f in the initial visit section of the PrEP card.



# The Client Registration Section (Contd.)

Age: Write the client's age in years at the start of PrEP. Obtain from item 7e in the initial visit section of the PrEP card.



Partner ANC/Unique ART number: If the client has a partner who is HIV-positive and either enrolled in the PMTCT or ART program, write the partner's ANC number for those enrolled in the PMTCT program or the Unique ART number. *Obtain this from item 4 on the initial visit section of the PrEP card.* 



## The Clients Registration Section (Contd.)

**Transfer-in**: Mark' X' Transfe r In to indicate if the (Tick if Partner | patient client was previously ANC/Unique Age was ART No. previously enrolled in another enrolled in l another facility for PrEP facility) services.



### **Status at PrEP Start**

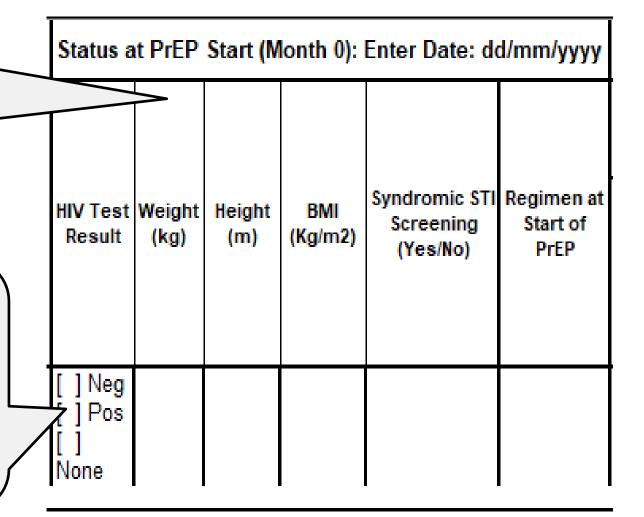
Introduction: This section captures information on the client's clinical status at the time of PrEP initiation. It should be completed using the PrEP card (PrEP commencement section of the PrEP card or the encounter page of the PrEP card).

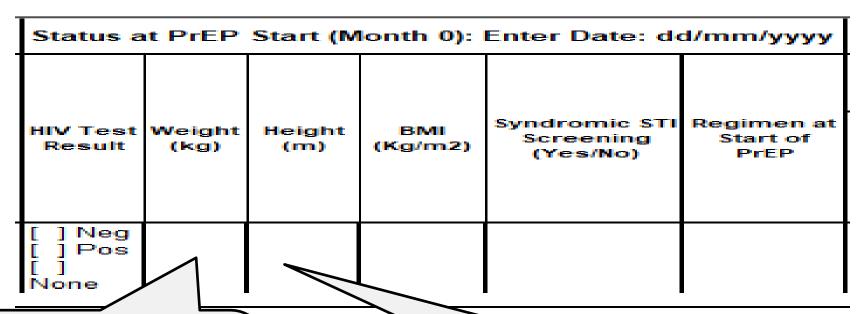
Status a	Status at PrEP Start (Month 0): Enter Date: dd/mm/yyyy											
HIV Test Result	Weight (kg)	Height (m)	BMI (Kg/m2)	Syndromic STI Screening (Yes/No)	Regimen at Start of PrEP							
[]Neg []Pos [] None												



Month 0: Enter month and year of PrEP start to indicate month 0. This applies to all the clients on this page of the register since they are all in the same cohort.

HIV Test Result: Mark' X' against the client's corresponding HIV test results at the start of PrEP. This is obtained from item 12 in the initial visit section and item E5 (for the first visit date) on the encounter page of the PrEP card





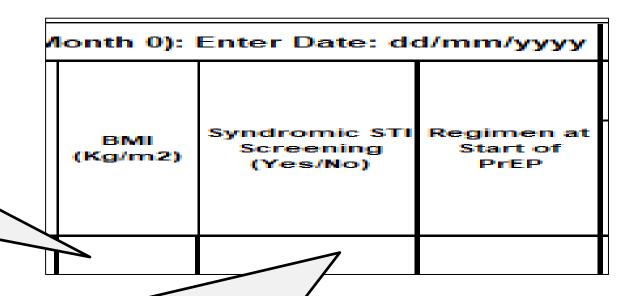
Weight: Write the client's weight in "Kg" at the start of PrEP. This is obtained from item 17 in the PrEP commencement section of the PrEP card.

Height: Write the client's height in meters (M) at the start of PrEP. This can be obtained from item 18 in the PrEP commencement section of the PrEP card



**BMI**: Write the client's BMI in kg/m2 at the start of PrEP.

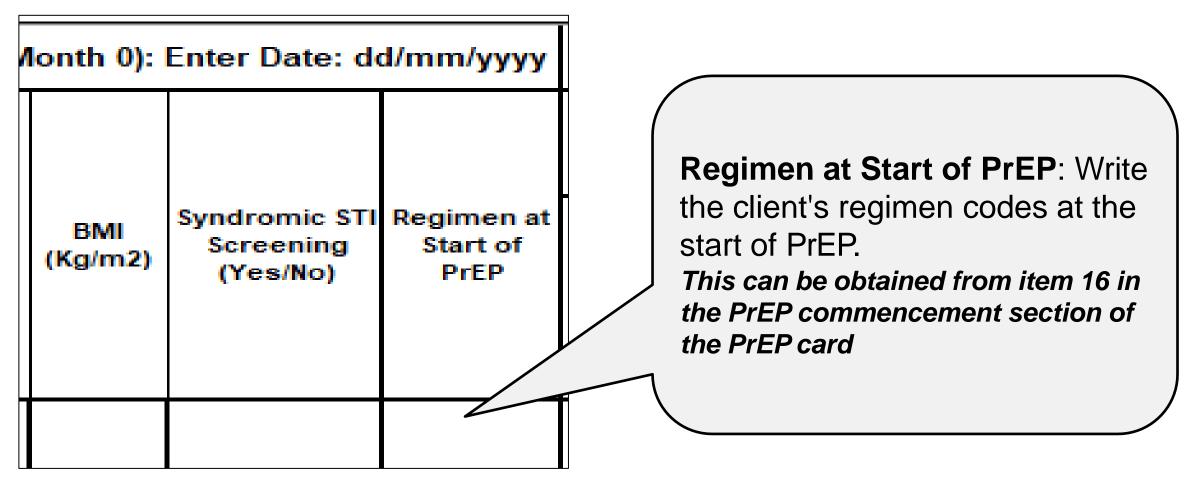
This can be obtained from item 19 in the PrEP commencement section of the PrEP card.



#### **Syndromic STI Screening:**

If the client had syndromic STI screening at the start of PrEP, write Yes; if the client was not provided with syndromic STI screening at the start of PrEP, write 'No'. "This can be obtained from item E7 (for the first visit date) on the encounter page of the PrEP card".







## The Follow Up Visit Section

				Syndromic Bogimon		1st Follow up Visit						
HIV Test Result	Weight (kg)	Height (m)	BMI (Kg/m2)	STI Screening (Yes/No)	Regimen at Start of PrEP	HIV Result (mark X)	Adherence	STI Screening	PrEP Given (MMD type) Date (dd/mm/yy)			
[]Neg []Pos []None						[]Neg []Pos []None						



This section is used to document PrEP given over the period of three months.

## The Follow Up Visit Section (Contd.)

### 1st follow up visit

Under the "1st followup visit" section, document:

- the next month and year (mm/yyyy)
- > HIV Test Result
- > Adherence
- > STI Screening
- PrEP Given (Enter date –dd/mm/yy).

	1st Follow Up Visit Enter Date: MM/YYYY										
HIV Result			Adherence	STI	PrEP Given						
Non e	Non Nea Pos		Adherence	Screening	(Enter date - dd/mm/yy)						

#### 2<sup>nd</sup> follow up visit

Under the "2nd follow-up visit" section, document:

- the next month and year (mm/yyyy)
- > HIV Test Result
- > Adherence
- > STI Screening
- > Proteinuria
- PrEP Given (Enter date dd/mm/yy).

	211	ıd Foll	low Up Visit	Enter Date: MM/YYYY						
HIV	/ Res	ult	Adherence	STI	Droteinuria	PrEP Given				
Non e	Neg	Pos	Adiiciciicc	Screening	Totomaria	dd/mm/yy)				
	81	th Foll	ow Up Visit	Enter	Date: MM/YY	YY				
	Non	HIV Res	HIV Result  Non e Neg Pos	HIV Result    Adherence   Pos	HIV Result  Adherence STI Screening	Non e Neg Pos Adherence STI Screening Proteinuria				

#### 3<sup>rd</sup> follow up visit

Under the "3<sup>rd</sup> follow-up visit' section, document:

- the next month and year (mm/yyyy)
- > HIV Test Result
- > Adherence
- > STI Screening
- > Proteinuria
- PrEP Given (Enter date dd/mm/yy).

1	3r	d Foll	ow Up Visit	Enter Date: MM/YYYYY						
HIV	V Result		Adhoronoo	STI	Drotoinurio	PrEP Given				
Non e	Neg	Pos	Adherence	Screening	Proteinuria	dd/mm/yy)				
9th Follow Up Visit				Enter Date: MM/YYYY						

1.HIV Test Result: Document the client's HIV test result at the time of the clinic visit by ticking the appropriate cell. This is obtained from item E5 (for the specific visit date) on the encounter page of the PrEP card.

1st Follow Up Visit Enter Date: MM/YYYY HIV Result PrFP Given Adherence (Enter date -Screening dd/mm/vv) Non Neg Pos

2.Adherence: Write the level of adherence to PrEP for the client at the time of the clinic visit, e.g., 'G' or 'F' or 'P'. This is obtained from item E9 (for the specific visit date) on the encounter page of the PrEP card. In addition, refer to adherence codes at the bottom of the register.



3. STI screening: Write the result of the Syndromic STI screening at the time of the clinic visit. Refer to syndromic STI screening codes at the bottom of the register.

STI
Screening
Proteinuria
PrEP
Given
(MMD type)
Date
(dd/mm/yy)

4. Urinalysis: Write the code (1, 2,

3, 4) that corresponds to the urinalysis test result of the client at the time of the clinic visit. Refer to urinalysis test result codes at the bottom of the register.

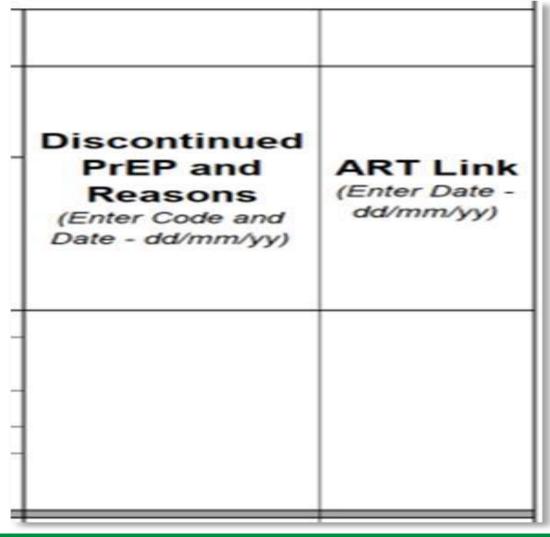
5. PrEP given

(Date): Write the date that PrEP was given to the client during the clinic visit.



### The PrEP Discontinuation and Linkage to ART Section

This section is filled when there is a reason to discontinue the provision of PrEP or when the client has seroconverted requiring ART

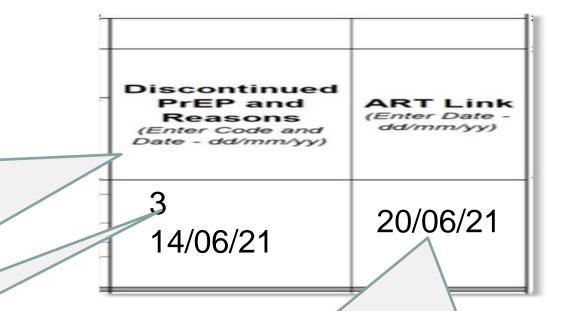




# The PrEP Discontinuation and Linkage to ART Section (Contd.)

#### **Discontinued PrEP and Reasons:**

If the PrEP client discontinues PrEP, write the code (1, 2, 3, 4, 5, 6, 7) that corresponds to the client's reason for PrEP discontinuation at the time of the clinic visit. Refer to the discontinued PrEP and reasons codes at the bottom of the register.



The date PrEP is discontinued is also filled into this section.

ART Link: If the PrEP client is linked to ART, write the date that the client commenced ART. The date of ART commencement should be the same as on the ART register.



#### Who fills the tool

To be completed by the health care worker (ART Nurse or Clinician) providing the PrEP service.





### When to fill the tool

The PrEP register is filled at the completion of each clinic day at the facility



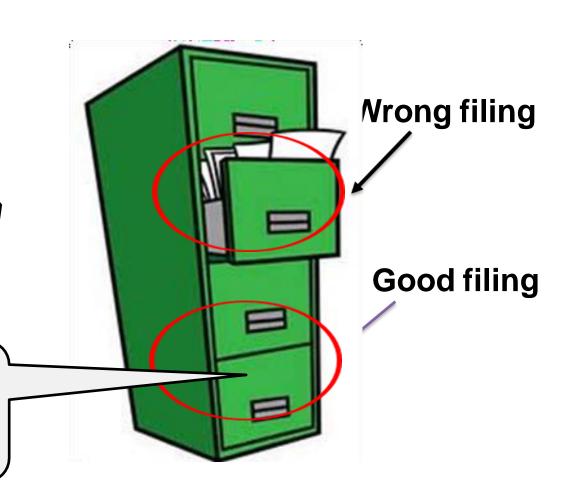


# Where to keep the tool

The PrEP register will be domiciled wherever PrEP services are rendered at

the health facility.

It should always be kept safely in a cabinet.





### **Sources of Information**

PrEP card

PrEP CARD	FACILITY NAME	1. Hospital number	
INITIAL VISIT			
2. Unique Client's	3. Date enrolled in PrEP:	4. Partner ANC/Unique	e ART No
	es:6. Address:7c. Telephone		7b. Educational Level: 1. None 2. Primary 3. Secondary 4. Tertiary
7d. Sex: M F 7e. Age  8. PrEP Supporter:	(dd/mm/yyyy)  9. Relationship:	7g. Marital Status	7g. Marital Status: 1. Single 2. Married 3. Divorced 4. Seperated 5. Cohabiting 6. Widow/er
12. Date of last HIV Negative test	13. Date Referred for PrEP:		11. HIV Testing Point:  1 = Eacility 2 = Community 3 = Others

## Case Study 1

The table below shows the example of the cohort of patients starting PrEP in Nov 2020. Also it shows example of months in follow up section. What are the corresponding calendar months?

Follow Up Section	<b>Corresponding Month</b>
Month 0	
Month 1	
Month 2	
Month 3	



# Case Study 2

1.On the 10<sup>th</sup> August, 2021, Mr Obi Chukwu received his first PrEP service at Jollad hospital. He tested HIV Negative on this date, his Partner's unique ID is 0018

2.In September 9<sup>th</sup> 2021, on his 1<sup>st</sup> follow up visit, he tested HIV negative, however, he takes his drugs regularly but with symptoms in his STI screening.

3.On the 12th of October, 2021, Mr Obi tested HIV positive, and was subsequently linked to ART



Activity: Complete the various PrEP monitoring tools.

### **Comments/Questions**





### **Appendix: Refer to Codes**

### Codes E10 Regimen

- 1.TDF/FTC
- 2. TDF/3TC

#### **Syndromic STI Screening**

- 1. Urethral discharge
- 2.Genital Ulcers
- 3. Vaginal discharge
- 4. Lower Abdominal Pain
- 5. Scrotal Swelling
- 6. Anal Warts
- 7. Genital Warts
- 8. Inguinal bubo
- 9. Others (specify)-----

#### **Reason for Discontinuation**

- 1.Dead
- 2. Stopped
- 3. Seroconverted
- 4. Transfer out
- 5. Loss to follow up
- 6. Adverse drug reaction
- 7.No longer at substantial risk



# **Appendix: Refer to Codes (contd.)**

#### **Level of Adherence**

Estimate adherence for twice daily ART using the

following table:

% Missed doses per month

G (Good)  $\geq 95\%$   $\leq 3$  doses

F (Fair) 85-94% 4-8 doses

P (Poor) < 85% ≥ 9 doses





# **Completing the PrEP MSF**

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

#### **Outline**

- Objective
- Brief overview of Steps in PrEP Cascade
- Introduction
- Purpose of the PrEP MSF
- PrEP MSF Header
- PrEP MSF Body
- Indicators on the PrEP MSF
- Completing indicator disaggregation, Sex, Age and totals
- Authentication
- Key Notes



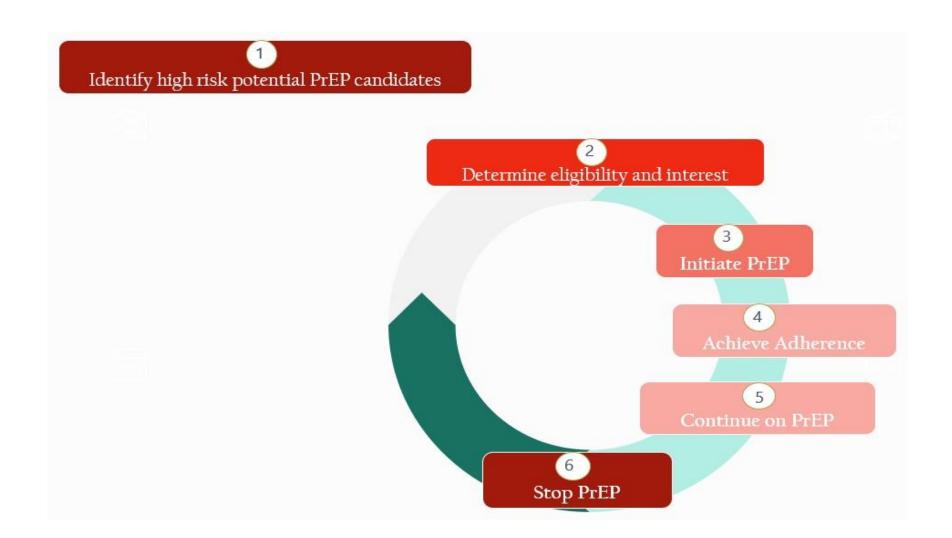


### **Objectives**





### **Steps in Oral PrEP Cascade**





#### Introduction

- The PrEP MSF is designed to summarize PrEP clients' information and for PrEP performance monitoring and reporting.
- The PrEP Monthly Summary Form (MSF) is a 1-page document
- Has 2 sections
  - Header
- **Body** PrEP Service Delivery components disaggregated by data elements that includes the **indicators**, **target beneficiaries**, **Sex and Age**.





# Indicators on the PrEP MSF

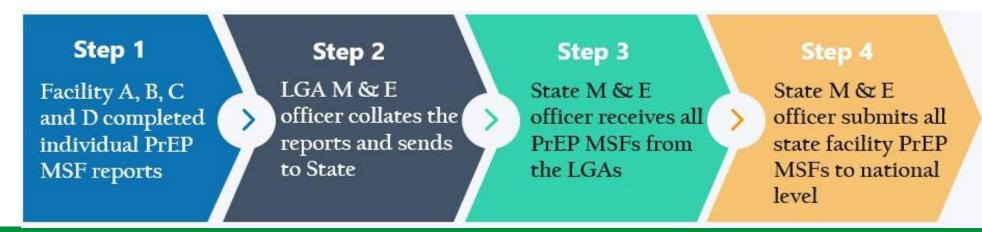
Indicators	Disaggregation by Beneficiary
Number of eligible people who initiated oral PrEP in the reporting month	<ul><li>Serodiscordant Couples(SDC)</li><li>Sex Workers</li><li>Partners of Sex Workers</li></ul>
Number of individuals who received PrEP in the reporting month	<ul> <li>Injecting Drug Users</li> <li>Individuals who engage in anal sex on a prolonged and regular</li> </ul>
No. of individuals returning for PrEP who received repeat HIV testing in the reporting month	<ul> <li>basis</li> <li>Exposed adolescents and young people</li> <li>Transgender</li> </ul>
Number of individuals who discontinued PrEP	Other population



### Purpose of the PrEP Monthly Summary Form

- At facility level
  - The form summarizes and reports the required data elements and indicators for PrEP services
- LGA, State and National Level
  - Reports from lower levels are aggregated up to the national

#### **Process Flow Chart**





### **PrEP MSF - Header**

PrEP Mo	nthly Summary Form
Facility Name	
State	
LGA	
Month	
Year	Level Primary Secondary Tertian
Reporting Officer	Type of Facility Public Private

Name of Facility	State	LGA	Month and Year	Level of Facility	Type of Facility
Write the name of the facility submitting the monthly report e.g., National Hospital Abuja	Write the State in which the facility is located e.g., FCT	Write the LGA in which the facility is located e.g., AMAC	Write the Month and Year for which the report is being submitted	Indicate the level of the facility i.e., primary, secondary, or tertiary	Write the Month and Year for which the report is being submitted
Step 1	Step 2	Step 3	Step 4	Step 5	Step 6



### **PrEP MSF Body**

The body of the form includes the *PrEP services delivery components*:

- The indicator
- Sex disaggregation Male, Female

Indicator

- Age disaggregation <1,1-4, 5-9, 10-14, 15-19, 20-24, 25-49, 50+</li>
- Totals for indicator and age disaggregation
- Source of information e.g., PrEP Register

	PrEP Service Delivery																	
					Ma	ale							Fen					+
S/No.	Indicators	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	Total
3	No. of individuals who were eligible and started PrEP in the reporting month																	
	-		4					-			_		_					



Male and Age disaggregation

Female and Age disaggregation

Totals for indicator

#### Completing Indicator disaggregation, Sex, Age and Totals

					Ma	ale							Fen	ıale				
S/No.	Indicators	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	Total
3	No. of individuals who were eligible and started PrEP in the reporting month																	
	Serodiscordant Couples(SDC)																	
	Sex Workers									-								
	Injecting Drug Users																	
	Individuals who engage in anal sex on a prolonged and regular basis				<b>→</b> }	<p td="" ty<=""><td>polo</td><td>gies</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></p>	polo	gies										
	Exposed adolescents and young people					<u> </u>	<u> </u>											
4	Number of individuals who received PrEP in the reporting month																	
	Serodiscordant Couples(SDC)																	
	Sex Workers																	
	Partners of Sex workers																	
	Injecting Drug Users																	
	Individuals who engage in anal sex on a prolonged and regular basis																	
	Exposed adolescents and young people																	
	Other population						_											

- Indicators are disaggregated by target beneficiaries, sex, age and totals.
- Data source is *PrEP register* 
  - Count of all patients documented each month
  - Care must be taken in filling the forms to make sure that the sex and age disaggregates for each target beneficiary align



#### **Authentication**

Complted by:		Date (dd/mm/yyyy)
Name	Signature	
Checked by:		Date (dd/mm/yyyy)
•		
Name	_ Signature	

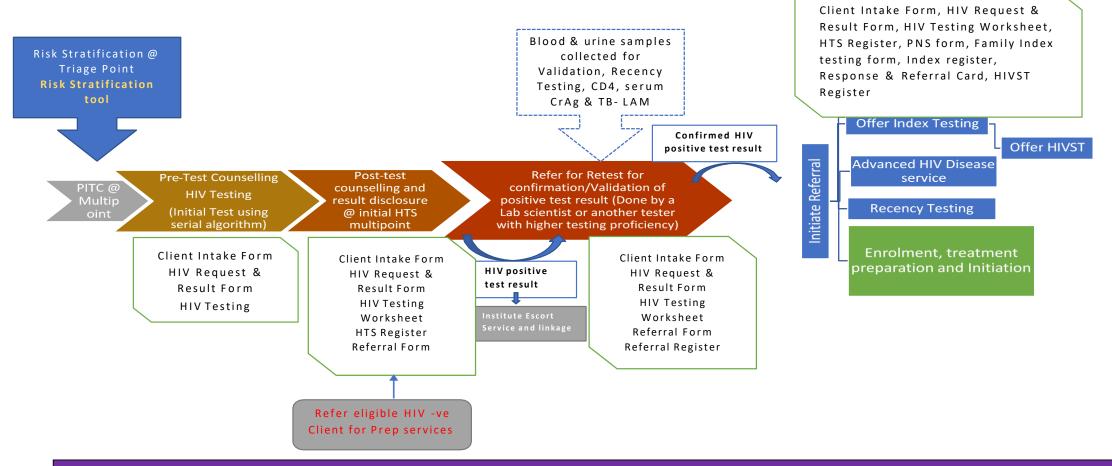
- The tail end of the form is for authentication.
- The officer that compiles the data for the MSF and the one that verifies the data, fill this section
- Completing officers must remember to date the forms





#### **Service Flow Chart**

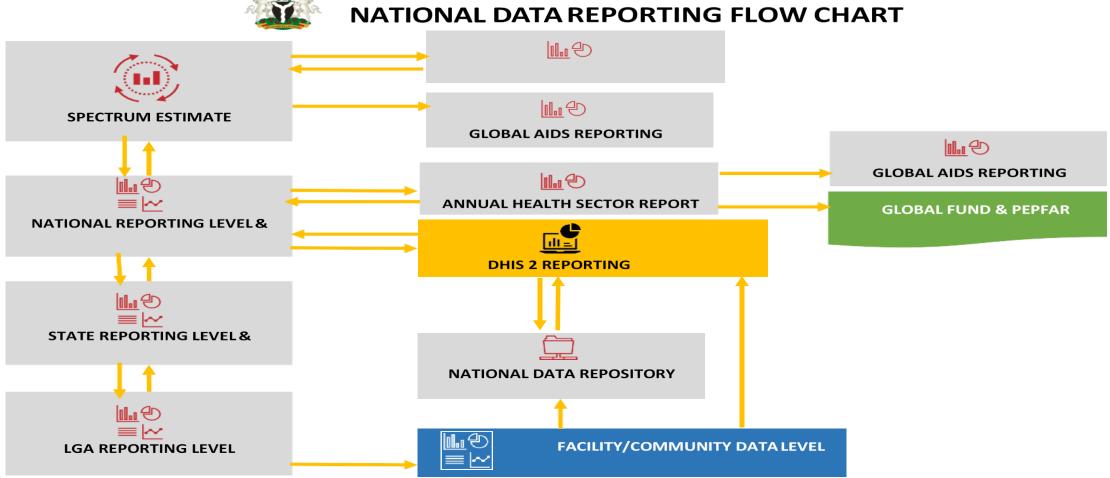
#### HTS DOCUMENTATION AND SERVICE FLOW



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



### Flow Chart for Reporting



### **Key Notes**



#### Purpose of the tool

PrEP MSF is designed to summarize PrEP clients' information and for PrEP performance monitoring and reporting



#### Source of information

PrEP register



#### Who Fills The Tool?

The PrEP MSF is filled by the facility Health Information Management staff/Data Clerk/ or designated PMM/PME staff and submits to the LGA M&E unit



#### When To Fill The Tool

It should be filled at the end of every reporting period



### 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 four month supply is available for each PrEP user when initiating new users on PREP.



# Thank you



#### **MODULE 6**

### **Event-Driven PrEP (ED-PrEP)**







### **Module 6 Learning Objectives**

After completing Module 6, participants will be able to:

- Understand gender and sexual identity in the context of ED-PrEP.
- 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 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 disidentify 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.



### Gender and Sexual Identity (contd.)



- 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 Event-Driven 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**

### Who is eligible for ED-PrEP?

MSM which includes, Cisgender Men, Trans Women, and Non-binary people Assigned Male At Birth (AMAB) who do not use exogenous hormones, including gender affirming hormones. Who;

- 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

### Who is **NOT** eligible for ED-PrEP?

- 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**

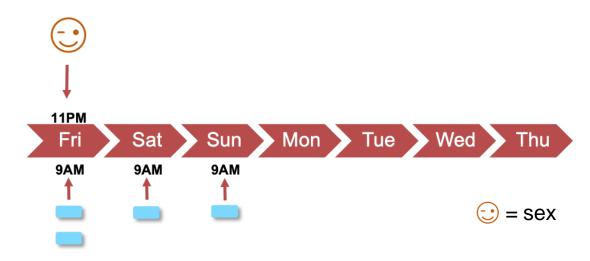
- The World Health Organization (WHO) issued <u>a technical brief</u> in July 2019 to update the dosing considerations of oral PrEP for MSM.
- ED-PrEP is included in the National Guidelines for HIV Prevention, Treatment and Care 2020.
- WHO update on ED PrEP November 2021



### **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:

- <u>Two</u> 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 3<sup>rd</sup> pill (the 4<sup>th</sup> 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**

Author, Year	Setting	Key Findings
Molina et al., 2015 IPERGAY RCT	France and Canada	<ul> <li>Likelihood of HIV acquisition was reduced by 86% among men randomised into the ED-PrEP group.</li> <li>Likelihood of HIV acquisition was reduced by 97% during the open-label extension.</li> </ul>
Molina et al., 2017 Prevenir observational study	France	<ul> <li>No new HIV acquisitions were reported in the ED-PrEP group and the daily oral PrEP group.</li> <li>More than half (53%) of MSM preferred ED-PrEP over daily PrEP.</li> </ul>
Cornelisse et al., 2019 PrEPX Australian demonstration study	Australia	<ul> <li>High level of interest in ED-PrEP was strongly associated with having sex infrequently and concerns about long-term toxicity.</li> </ul>
Zimmermann et al., 2019 Jongen et al, 2020 Amsterdam PrEP demonstration project (AMPrEP)	The Netherlands	<ul> <li>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.</li> <li>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.</li> </ul>



### **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 PrEP.

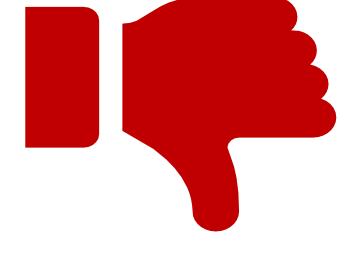




### **Disadvantages of ED-PrEP**

- 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 PrEP during acute HIV infection.
- No evidence ED-PrEP prevents HIV transmission during any other potential exposures.



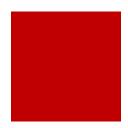




### Starting and Stopping Oral PrEP (MSM only)



- 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



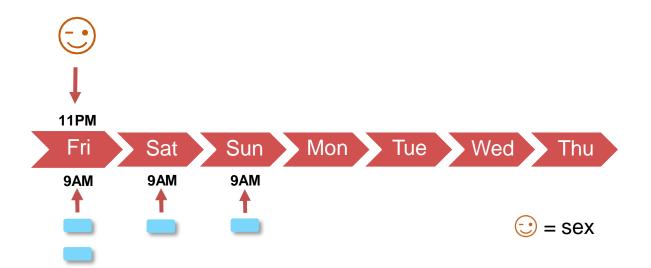
ED-PrEP users should repeat this process for each period of potential exposure to HIV.



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

### **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.

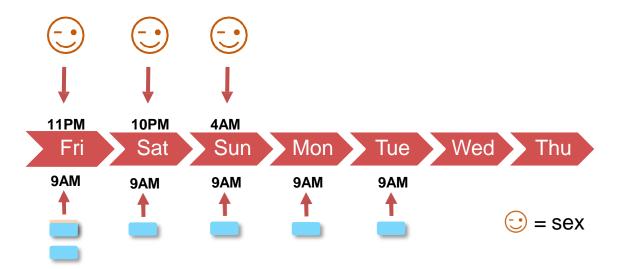


Note: MSM should take 2 pills 2-24 hours before having sex and take 1 pill each day for the 2 days following sex.



### **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.

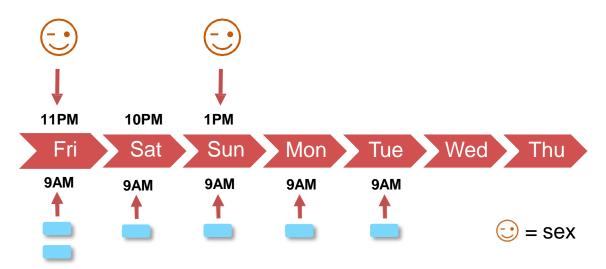


Note: MSM who have sex over multiple days should continue taking 1 pill each day for 2 days after the last time they had sex.



### **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 nonconsecutive days while still taking ED-PrEP should continue taking 1 pill each day for 2 days after the last time they had sex.



### Switching Between Daily and ED-PrEP

1 Assess HIV risk and determine eligibility for oral PrEP in men who have sex with men

2 Offer PrEP and discuss dosing options

Daily dosing if risk is more frequent than 2 times per week and sex cannot be predicted or delayed by 2

hours.

MSM on PrEP can switch from daily dosing to ED-PrEP

Event-driven dosing if sex can be predicted (particularly for infrequent sex)

- 3 Follow-up visit (1 month after initiation and/or every 3 months)
  - Provide testing for HIV and other STIs
  - Offer counselling by discussing adherence to dosing strategy during use, and if PrEP user transitions from one dosing strategy to another
  - ✓ Assess if HIV risk is likely to persist in the next few weeks and months
  - Adolescent men who have sex with men may require more active support in continuing on PrEP, whichever dosing strategy is chosen

(and vice-versa)

Source: What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men:

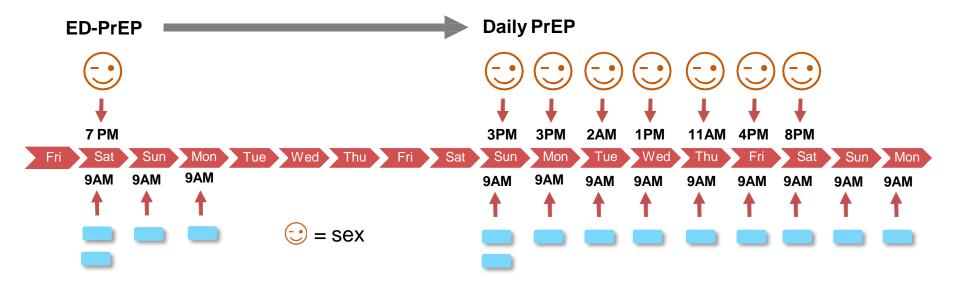
Update to WHO's recommendation on oral PrEP. Geneva: World Health Organization; 2019 (WHO/CDS/HIV/19.8).



### **Dosing 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.

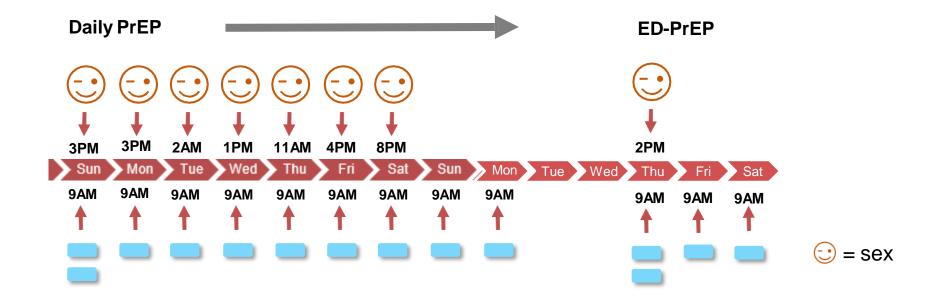
He has sex several times throughout the week with different clients. On Saturday night, Akpan has sex and on Sunday he heads home. Akpan takes PrEP on Sunday and Monday, and then can stop taking PrEP if he wants.





### **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.





### **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.



### **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
- ED-PrEP can be used by people with chronic hepatitis B infection
- Education on ED-PrEP is key to its effective implementation.



### **MODULE 7**

### **Oral PrEP Demand Creation**





### **Learning Objectives**

After completing Module 7, participants will be able to:

- Understand differences between ART, PrEP and PEP
- Understand the concept of Demand Creation for Oral PrEP
- Utilize demand creation strategies for improved Oral PrEP services
- Plan demand creation interventions for Oral PrEP services



### **ARVs (ART, PrEP and PEP)**

- Antiretrovirals (ARVs) are medicines used to treat HIV(ART), or to prevent HIV (PrEP and PEP).
- ART is the use of a combination of three or more ARVs to treat HIV in order to achieve viral suppression.
- PrEP is the use of ARVs or HIV prevention medicines by people who are HIV negative, to prevent the acquisition of HIV before exposure to the virus. PrEP is used for as long as the person is at on-going risk of HIV infection.
- PEP is the short term (28 days) use of ARVs to prevent HIV infection, in persons accidentally exposed to a potential risk of acquiring HIV infection.



### **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**

Demand creation approaches	Audience(s)
Interpersonal communication	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	AGYW and their partners, young people, adults, MSM, FSW, TGP
Prints (posters, stickers, handbills, flyers,	PWID, BBFSW, MSM, TGP, persons in custodial centres, AGYW
etc.)	and their partners, young people, adults
Priority for Local AIDS Control Effort (PLACE)	NBBFSW and adult men (busy during day)
(venue outreach facilitators)	



### **Strategies/ Approaches for Oral PrEP Demand**

Demand creation approaches	Audience(s)
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



### **Introduction to Empathways**

- Empathways is designed to forge greater empathy between Providers and Adolescent Girls and Young Women (AGYW), towards improving Pre-Exposure Prophylaxis (PrEP) and other sexual and reproductive health service delivery to AGYW.
- 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.



### How to use Empathways (contd.)

Empathways includes three rounds with one card deck for each round.

The cards are in numbered order and should be discussed one at a time.

Round 1: **OPEN UP-** The questions in this round are to help participants develop rapport: between provider and young client.

Eq. Who in your life inspires you, and why?

Round 2: **DISCOVER**-The questions here are to explore the factors that impact provider's attitudes and PrEP service delivery for AGYW.

E.g. What do your family members and friends think about PrEP? Do you agree with them?

Round 3: **CONNECT-** This round is to reflect on service delivery scenarios and invite providers to commit to improving PrEP service delivery to AGYW.

E.g. Sarah's story(See the Facilitator's deck/guide) in the following slides



# Empathways



**HIV Negative Generation** 





### The Pleage

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

### Get to know each other



Where did you grow up?

What kinds of things do you enjoy doing?



### Goals





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

What, if anything, would stop you from achieving them



### Inspiration



Who in your life inspires you, and why?

### Relationships

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







### Sex & HIV



How is this the same or different for young men?



Why might a young woman worry about getting HIV?



### 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



### Religion

How does religion affect your relationships?





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



### Relationships

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

What did you think of their advice?



## 

### Your best experience

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

What made it so good?



# 0

## Your worst experience

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

How did it make you feel?



Both participants answer

# OVE

## Family and Friends

What do your family members & friends think of PrEP?

Do you agree with them?

Both participants answer



## 

### **Healthcare Decisions**

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



## **Seeking Information**

# 0

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



## **Healthcare Providers' Goals**

# O (P)

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



### **PrEP services**

# 0

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



Both participants answer

# 0

## 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

## Serving young clients

# 

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



Provider should answer

## Your healthcare experience

# 

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



## Youth friendly services

# 

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



## U

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?

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

### **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 engenders sustainability of PrEP interventions.



### Steps for Stakeholder Mobilization and Engagement

- Identification and social mapping of relevant stakeholders working on PrEP
- Networking and harmonization of oral PrEP demand creation activities among the stakeholders
- 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



### Steps for conducting advocacy for Oral PrEP

- Identify the advocacy issues or problems
- Analyse and gather information on the advocacy issue
- Determine objectives for the advocacy project
- Identify advocacy target audience
- Identify allies and build support for the advocacy project
- Develop advocacy strategies
- Create an advocacy action plan



### Steps for conducting advocacy for Oral PrEP (contd.)

- Develop advocacy kits
- Plan advocacy meetings and other relevant advocacy activities
- Conduct advocacy meetings and other relevant advocacy activities
- Follow up to ensure that expected action is taken to establish the support promised



### Targets audiences for advocacy and how to support oral PrEP intervention

Targets	Areas of support
Political Leaders	<ul> <li>facilitate support of oral PrEP interventions in the community (promotion, enforcement</li> </ul>
	of necessary policies for oral PrEP interventions, allocation and approval of budgets, and
	release of funds)
	<ul> <li>canvass for more private sector investors for oral PrEP private sector intervention.</li> </ul>
Religious Leaders:	<ul> <li>support awareness creation about oral PrEP</li> </ul>
	<ul> <li>encourage service uptake among their congregations.</li> </ul>
	• facilitate the mobilisation of resources among their congregations to support oral PrEP
	interventions.
Traditional rulers:	<ul> <li>support in awareness creation about oral PrEP</li> </ul>
	<ul> <li>encourage service uptake among their subjects.</li> </ul>
	• support the mobilisation of available resources in their communities to support oral PrEP
	interventions.



### Targets for advocacy and how to support oral PrEP intervention

Targets	Areas of support
Media organisations/ individuals  Opinion leaders/Influencers	<ul> <li>support the promotion and uptake of oral PrEP services as part of their corporate social responsibility or at a discounted price,</li> <li>support the airing and disseminating oral PrEP information</li> <li>support awareness creation and facilitation of oral PrEP uptake among their peers and followers.</li> </ul>
Healthcare professional groups and leadership:	<ul> <li>strengthening access to oral PrEP interventions.</li> <li>encourage group members to buy-in to PrEP promotion and services delivery</li> </ul>
Other organisations and well-to-do persons: (Both corporate organisations and individuals)	<ul> <li>donate resources for oral PrEP interventions.</li> <li>take ownership to ensure continuity and sustainability of the entire project.</li> </ul>



### **MODULE 8**

### **Evaluation and Resources**





### **Post-Training Assessment**

- The objective of this post-training assessment is to find out what you have understood about providing oral PrEP services and how much your knowledge have improved.
- The results of the pre-training and post-training assessments will help improve future trainings.
- Remember to write your name on your post-test questionnaire.
- We will discuss the correct answers to the questions after the assessment.



You have 15 minutes to complete the assessment.

### **Training Evaluation**

- Please take a few minutes to complete this Training Evaluation Form.
- We welcome your honest feedback to help us improve future trainings.
- Your evaluation will be confidential. You do not need to include your name.



### **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.
- Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. *AIDS*. 2016;30(12):1973-1983. doi:10.1097/QAD.00000000001145
- Glidden DV, Amico KR, Liu AY, et al. Symptoms, side effects and adherence in the iPrEx open-label extension. *Clin Infect Dis.* 2016; 62(9):1172-1177. <a href="https://doi.org/10.1093/cid/ciw022">https://doi.org/10.1093/cid/ciw022</a>.
- Mofenson LM; for the World Health Organization. Review: Safety of Tenofovir PrEP in Pregnant and Breastfeeding HIV-Uninfected Women and Their Infants.
   https://www.childrenandaids.org/sites/default/files/2018-05/PrEP%20in%20Pregnancy%20Review%20Presentation 11%20August%202016.pdf. Accessed 11 January 2019.
- PrEP Watch. <a href="http://www.prepwatch.org/">http://www.prepwatch.org/</a>. Accessed 11 January 2019.



### **Oral Prep Resource Materials for Providers (cont.)**

- UNAIDS. M&E Guidelines: M&E of Key Populations at Higher Risk for HIV. Geneva: UNAIDS; 2018.
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### Nigeria Oral PrEP Resource Materials (contd.)

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### WHO/Jhpiego Oral PrEP eLearning Course Includes ED-PrEP

- The Oral PrEP
   eLearning course
   created through a
   collaboration
   between WHO and
   Jhpiego is a self paced, free eLearning
   course available at
   www.hivoralprep.org.
- The training prepares clinicians to provide both daily oral PrEP and ED-PrEP.

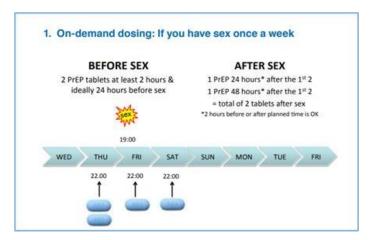




### Resources on ED-PrEP – International Examples













Resources shown here are not necessarily endorsed by PEPFAR, in alignment with WHO recommendations, or aligned with national recommendations and guidance but can serve as examples of resources which may be useful in tool development.

### **Video from the Netherlands**







Resources shown here are not necessarily endorsed by PEPFAR, in alignment with WHO recommendations, or aligned with national recommendations and guidance but can serve as examples of resources which may be useful in tool development.

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### List of contributing organizations









































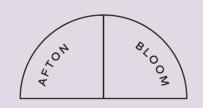


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