



STANDARD OPERATING PROCEDURES

for

Oral Pre-Exposure Prophylaxis (PrEP) service delivery.

Abbreviations and Acronyms

AGYW	Adolescent girls and young women
AIDS	Acquired immune deficiency syndrome
AYP	Adolescents and young people
FSW	Female sex worker
GBV	Gender-based violence
HIV	Human immunodeficiency virus
IPV	Intimate partner violence
MSM	Men who have sex with men
OSS	One stop shop
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
SA	Sexual assault
SDC	Serodiscordant couple
SDP	Service delivery point
SOP	Standard operating procedure
STI	Sexually transmitted infection
WHO	World Health Organization

Background

This Standard Operating Procedures (SOP) is intended to be used by oral Pre-Exposure Prophylaxis (PrEP) service providers to standardize practices on oral PrEP service delivery, in line with the recommendations of the National HIV Prevention, Care and Treatment Guidelines. It contains steps for PrEP screening for substantial risk and eligibility, initiation, monitoring, follow up and GBV including IPV. This SOP has been developed to specifically guide routine implementation of oral PrEP at all levels. It also takes into account the diversity of service providers for ease of implementation in consonance with the national task-shifting policy.

Purpose To provide clear and detailed description of step-by-step routine actions of oral PrEP service provision.

For whom: Doctors, Nurses, Pharmacists, Lab personnel, Community Health Extension Workers and Community outreach workers, who have gone through the basic PrEP training.

Data Collection Tools for PrEP service Delivery:

- Request and result form
- Risk stratification form
- Client intake form
- Oral PrEP Screening and Eligibility
- Oral PrEP Care card
- Oral PrEP Register
- Oral PrEP MSF
- Combined pharmacy order form
- Lab order request form
- Referral form

Oral PrEP Messaging During HTS

Refer to job aids and flow charts for oral PrEP messaging during pre- and post-test counselling for HIV.

Note: At post-test counselling for HIV negative clients, recommend or refer for oral PrEP. For HIV positive clients, recommend that their negative partners be linked to oral PrEP.

Pre-Exposure Prophylaxis (PrEP) Screening and Eligibility Form

Purpose: Determine eligibility for PrEP

For whom: Clients tested HIV-negative

When to use: After counselling HIV-negative clients on HIV prevention methods including oral PrEP

Responsible staff: Any health service provider screening the client for oral PrEP

Source document: - Request and result form. Client intake form. Lab order request form

The oral PrEP Screening and Eligibility form is completed with the client.

1. FACILITY/OSS INFORMATION

- **Facility Name:** Name of the facility/OSS
- **Date of Initial Client Visit:** Date that the client is screened for PrEP; day (dd), month (mm), and year (yyyy), e.g. 30/04/2018
- **Person Completing Form:** First and last name of the healthcare worker screening the client for PrEP

2. CLIENT INFORMATION

- **First Name:** Client's given (first) name
- **Middle Name:** Client's middle name(s) (if any)
- **Surname:** Client's surname or family name
- **Address:** Client's current address (where the client lives now)
- **Next of Kin Contact** (Address/ Phone number)
- **Telephone #:** Client's primary telephone number
- **Client ID number:** Number assigned to the client at clinic registration

3. CLIENT DEMOGRAPHICS

- **What was your sex at birth?** Client's sex at birth. Tick Male, Female, Other (specify in the space provided), or No response.
- **What is your current gender?** Client's current gender as self-identified by the client, regardless of the client's sex at birth. If the client is transgender, tick either Transgender male to female or female to male. If Other, specify in the space provided. If the client does not respond, tick No response

- **What is your age?** Client's age at most recent birthday, in years, e.g. 25

4. **SCREENING FOR SUBSTANTIAL RISK OF HIV INFECTION**

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

A. Sexual partner risk assessment;

-Responses to questions on this part should be marked appropriately

B. Personal HIV Risk Assessment (Last 3 months)

--Responses to questions on this part should be marked appropriately

(calculate the sum of the A & B answers above to get the risk score)

C. Drug use history (last 3 months)

-Responses to questions on this part should be marked appropriately

D. STI Screening

-Responses to questions on this part should be marked appropriately

Document HIV testing information appropriately

5. **PrEP ELIGIBILITY**

- Provider should establish eligibility or otherwise based on the following criteria
- HIV negative
- HIV risk score ≥ 1
- No signs and symptoms of acute HIV infection
- Has no proteinuria*
- Willingness to start oral PrEP as prescribed

** Urinalysis should be offered as baseline screening when eGFR results are delayed, or when eGFR is not available in the health care facility. Waiting for eGFR result should not delay initiation of PrEP. However, if urinalysis is not normal, PrEP initiation should be delayed until creatinine result is available. eGFR should be performed at 6 months after initiation, and then annually.*

6. **SERVICES RECEIVED BY CLIENT**

Complete this section if the client is eligible for PrEP (i.e. all boxes in the PrEP eligibility section are ticked)

- PrEP offered: If the client was offered PrEP in the PrEP eligibility section, tick the box.
- PrEP accepted: If the client accepts PrEP, tick the box.
- PrEP declined: If the client declines PrEP, tick the box.
- Reasons for Declining PrEP: If the client declines PrEP, ask the client,

“Why do you not want to take PrEP? What worries or concerns do you have?”

- Tick all reasons given by the client:
 - i. No need for PrEP
 - ii. Does not wish to take a daily medication
 - iii. Concerns about side effects
 - iv. Concerns about what others might think
 - v. Concerns about time required for clinic follow-up
 - vi. Concerns about safety of medication
 - vii. Concerns about effectiveness of medication
 - viii. Other (specify in the space provided).

- **Date eligible:** Day (dd), month (mm), and year (yyyy) that the client is eligible for PrEP based on screening using this form
- **Date initiated:** Day (dd), month (mm), and year (yyyy) that the client is initiated on PrEP. Same day initiation is recommended, but the date initiated may be different from the date eligible in some cases.
- **Referred for PEP evaluation:** If the client was referred or evaluated for PEP, tick the box.
- **Referred for PCR/HIV Ag test or follow-up HIV re-testing (if suspicion of acute HIV infection):** If the client was referred because of suspected acute HIV infection (section 6), tick the box.

FOLLOW UP VISIT

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

	<ul style="list-style-type: none"> Assess for adverse drug reactions
Unscheduled visits: as per need.	<ul style="list-style-type: none"> Determine if the reason for the visit is PrEP related or not e.g adverse events Assess and manage the reason for the unscheduled visit according to national guidelines e.g. acute or chronic illnesses, worsening existing conditions Provide HIV risk reduction and PrEP adherence counselling Agree on follow up schedule
<p>During every visit Remind PrEP users on the dosage of PrEP needed to achieve adequate levels of the ARVs in tissues to be effective. During these window periods, safer sex practices should be encouraged (including abstinence and condoms).</p>	
<p>Management of clients with inconclusive HIV test result during follow-up visit For non-pregnant or lactating clients:</p> <ul style="list-style-type: none"> Discontinue PrEP Follow the national HIV testing algorithm for clients with an inconclusive result. Only after a confirmed HIV negative result, can the client continue with PrEP Offer risk reduction counselling and strongly emphasize the importance of condoms use during the period with inconclusive HIV test results (e.g. new infection is highly infectious) 	

**creatinine clearance should be performed at 6 months, followed by annual screening.*

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) with accompanying history of “known exposure to HIV between 4 -14 days. (Defer PrEP and consider PEP counselling for clients with a history of high-risk unprotected sex in the past three days, even in the absence of symptoms of AHI).
- A client unable to commit to PrEP adherence, and to attend scheduled PrEP visits
- Drug allergy to TDF or FTC
- eGFR < 60 ml/min
- Concurrent nephrotoxic medication

PrEP Discontinuation

PrEP discontinuation Ideally, clients should inform their service provider when they want to discontinue PrEP. Health care workers should discuss the options of when to discontinue PrEP with their clients. 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)

- Safety concerns, such as eGFR

PrEP should be administered as part of the minimum prevention package intervention (MPPI).
Refer to National HIV Prevention, care and treatment guidelines, 2020.