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# National Standard Operating Procedure for Implementation of Oral HIV Pre-exposure Prophylaxis in Nepal

March 2022


Government of Nepal
Ministry of Health and Population
National Centre for AIDS and STD Control
Teku, Kathmandu

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**Disclaimer:**

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# List of acronyms

| | |
|---|---|
| AE | Adverse Event |
| AHI | Acute HIV Infection |
| AIDS | Acquired Immuno - Deficiency Syndrome |
| ANC | Antenatal Care |
| ART | Antiretroviral Therapy |
| ARV | Antiretroviral |
| CBO | Community-Based Organization |
| CBS | Community-Based Supporters |
| CHBC | Community- and Home-Based Care |
| DHIS | District Health Information System |
| EpiC | Meeting Targets and Maintaining Epidemic Control |
| FSW | Female Sex Worker |
| HA | Health Assistant |
| HCWM | Healthcare Waste Management |
| HIV | Human Immunodeficiency Virus |
| HMIS | Health Management Information System |
| HTC | HIV Testing and Counseling |
| IBBS | Integrated Biological and Behavioral Surveillance |
| ICH GCP | International Council of Harmonization, Good Clinical Practice |
| IEC | Information, Education and Communication |
| KP | Key Population |
| MoHP | Ministry of Health and Population |
| MSM | Men Who Have Sex with Men |
| MSW | Male Sex Worker |
| NCASC | National Center for AIDS and STD Control |
| NGO | Non-Governmental Organization |
| NPHL | National Public Health Laboratory |
| OST | Opioid Substitution Therapy |
| ONHIS | One National HIV Information System |

| | |
|---|---|
| PEP | Post-Exposure Prophylaxis |
| PEPFAR | President's Emergency Plan for AIDS Relief |
| PN | Peer Navigators |
| PP | Priority Population |
| PrEP | Pre-Exposure Prophylaxis |
| PSI | Population Services International |
| PWID | People Who Inject Drugs |
| RPR | Rapid Plasma Reagin |
| SAE | Severe Adverse Effects |
| SBCC | Social and Behavior Change Communication |
| SOP | Standard Operating Procedure |
| STI | Sexually Transmitted Infections |
| TDF | Tenofovir disoproxil fumarate |
| UNAIDS | Joint United Nations Programme on HIV and AIDS |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |

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# Content

# Content

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**Foreword**

Nepal is a country with a concentrated epidemic of HIV. So far, there is a limited means of HIV prevention for key populations at higher risk of acquiring and transmitting HIV infection. Therefore, there is a need of additional method of prevention other than condom use. Considering this, National Centre for AIDS and STD Control (NCASC) is in the process of initiating and expanding oral HIV pre-exposure prophylaxis (PrEP) from government-supported facilities. In this regard, it is my pleasure to present National Standard Operating Procedures (SOP) for Implementation of Oral HIV Pre-exposure Prophylaxis (PrEP) in Nepal 2021.

This SOP includes clinical set ups, and conditions to be considered while providing PrEP, flow charts of PrEP services, approaches for initiating PrEP, counseling, drugs and regimen used in PrEP, monitoring and evaluation, recording and reporting and logistics management of PrEP medicines.

Oral HIV PrEP was introduced in Nepal as part of demonstration study in November 2018 to June 2019 conducted by United States Agency for International Development (USAID)- and The U.S. President's Emergency Plan for AIDS Relief (PEPFAR)-supported LINKAGES Nepal project in collaboration with NCASC and National Public Health Laboratory (NPHL). Based on the findings and recommendations of the study, National HIV Testing and Treatment Guidelines 2020 recommended PrEP as an alternative approach of HIV prevention. PrEP services is currently being provided from USAID-/PEPFAR-supported nongovernment organization (NGO) sites.

I would like to acknowledge the technical support provided by USAID-/PEPFAR-supported EpiC Nepal project for coordinating and drafting this SOP. I would also like to acknowledge the contribution of the participants of the workshop for finalization of the SOP organized on August 12, 2021, in Dhulikhel. I would also like to acknowledge the contribution from World Health Organization (WHO), Joint United Nations Program on HIV/AIDS (UNAIDS), Global Fund and AHF Nepal in the SOP development process.

I encourage all partners working in the field of HIV in Nepal to use the SOP appropriately, and together Fast-Track towards ending the AIDS HIV epidemic as a public health threat in Nepal by 2030.

Dr. Sudha Devkota
Director,
National Centre for AIDS and STD Control

# 1. Introduction

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral (ARV) drugs before HIV exposure by people who are not infected with HIV, in order to block the acquisition of HIV. In the 2016 consolidated HIV guidelines, the World Health Organization (WHO) recommended oral PrEP containing tenofovir disoproxil fumarate (TDF) as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches. Consolation gudiline 2016 this recommendation was based on a systematic review of 12 trials that addressed the effectiveness of oral PrEP and were conducted among serodiscordant couples, heterosexual men, women, men who have sex with men (MSM), people who inject drugs (PWID)and transgender women. The review showed that, where adherence was high, significant levels of efficacy were achieved, demonstrating the value of this intervention as part of combination prevention approaches[1]. A systematic review and meta-analysis of PrEP trials containing TDF demonstrated that PrEP is effective in reducing the risk of acquiring HIV infection. The level of protection did not differ by age, sex, regimen (TDF versus Emtricitabine (FTC) + TDF) and mode of acquiring HIV (rectal, penile or vaginal)[2]. The level of protection was strongly correlated with adherence**.** Parenteral exposure to HIV was not analyzed separately because only one study explicitly included PWID, and their exposure to HIV arose from sexual practices and incomplete access to sterile injection equipment[3].

When used as directed, PrEP can reduce the risk of HIV through sexual transmission among at-risk individuals by more than 99%[4]. PrEP can be even more effective if it is combined with other HIV prevention methods such as condom and lubricant use, harm reduction and treatment.
In 2020, it was estimated that 30,300[5] people were living with HIV in Nepal with an estimated overall adult HIV prevalence of 0.13 %. Nepal continues to face a

1 Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

2 Fonner VA, Dalglish SL, Kennedy CE, Baggaley R, O'Reilly KR, Koechlin FM et al. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. AIDS. 2016; 30:1973–83.

3 Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

4 https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.

5 Factsheet 1, NCASC, 2021

concentrated HIV epidemic, and HIV transmission is largely driven by selected KPs, which includes female sex worker (FSWs), clients of FSWs, men who have sex with men (MSM), male sex worker (MSWs), transgender people, and people who inject drugs (PWID) (NCASC, 2019). The Integrated Biological and Behavioral Surveillance (IBBS) surveys indicate that HIV prevalence among key populations (KPs) has mostly either stabilized or decreased in some groups. As per the IBBS surveys, HIV prevalence among FSWs was 2.2% in Kathmandu Valley (2017) and 0.7% in Terai highway districts (2018). Similarly, HIV prevalence among MSM, MSWs, and transgender people in Kathmandu Valley and Pokhara was 6.2% and 2.2% (2017), respectively, and 8.2% in Terai highway districts (2018). The HIV prevalence among truckers (proxy for clients of FSWs) was 0.3%. The HIV epidemic in Nepal is largely driven by infections among KPs, and heterosexual transmission is dominant (around 80%)[6].

Condom is the major means of HIV prevention in Nepal. The coverage of condom use varies according to KPs. It ranges from 66% in PWID to 91% in transgender people[7]. As a method of biomedical prevention, antiretroviral therapy (ART) coverage is also not 100%. Of the total estimated, 19,410 (66%) were on treatment in 2020[8]. In the absence of 100% ART coverage and 100% condom use among KPs, it was necessary to have an additional method of HIV prevention in Nepal. As a result, PrEP was introduced in Nepal in November 2018 as a demonstration study. The study was conducted by USAID-and PEPRAR -supported Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES) Nepal managed FHI 360 in collaboration with National Centre for AIDS and STD Control (NCASC) and National Public Health Laboratory (NPHL). The study included 104 clients from MSM, MSWs and transgender people and each participant received 90-days of daily PrEP. The demonstration study showed that PrEP is feasible and acceptable among KPs in Nepal[9].

The National HIV Testing and Treatment Guidelines 2020 recommended use of PrEP among KPs and individual at substantial risk of HIV along with condoms

6 Factsheet 1, NCASC, 2020
7 http://aphub.unaids.org/
8 Factsheet 6, NCASC, 2020
9 FHI 360/LINKAGES Nepal. Exploring Feasibility and Acceptability of HIV Pre-Exposure Prophylaxis for Female Sex Workers, Men Who Have Sex with Men, Male Sex Workers, and Transgender Women in a Selected District of Nepal. Kathmandu, Nepal: FHI 360/LINKAGES Nepal; 2020.APRIL 2020

and lubricants, and harm reduction services (access to sterile or new injection materials and opioid substitution therapy (OST)[10]. The guidelines recommended to develop a standard operating procedure (SOP) for nationwide scale up.

Based on the experience of the demonstration study, the U.S. President's Emergency Plan for AIDS Relief (PEFPAR) Project in Nepal developed a project specific SOP and initiated HIV PrEP from November 2020. The project is providing PrEP to KP groups- FSWs, MSM (both sex workers and non-sex workers) transgender people (sex workers and non-sex workers) and index partners of newly diagnosed and virally not suppressed or unstable people living with HIV (PLHIV) on ART. As of August 17, 2021, total 2,789 clients were receiving PrEP from PEFPAR supported facilities in Nepal. Over 70% of these beneficiaries are from KP.[11]

The current SOP manual is developed based on the technical guidance recommended by *National HIV Testing and Treatment Guidelines, 2020*, *Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service delivery and monitoring: Recommendations for a Public Health Approach, WHO, 2021* and *Implementation Tool for Pre-exposure Prophylaxis of HIV Infection, WHO, 2021*.

Expected users of this SOP manual are PrEP service providers of government and non-government facilities, their supervisors, staff conducting monitoring, policy makers and others who are related to PrEP implementation.
The term "PrEP" or "pre-exposure prophylaxis" used in this document, means oral HIV PrEP only.

10 National HIV Testing and Treatment Guidelines, NCASC, 2020
11 DHIS 2 (MeroData) Dashboard, FHI 360 Nepal, accessed: August 17, 2021

# 2. Requirements for HIV PrEP service delivery

NCASC provides guidance for overall program implementation. HIV related reports should be provided to NCASC by reporting in One National HIV Information System (ONHIS) and to Health Management Information System (HMIS).

## A. Guiding principles of providing PrEP services

This SOP manual is a live document and will be revised based on national and international recommendations and the decision of NCASC.

1. For initiating HIV PrEP service from a service delivery site, a separate authorization from NCASC is needed.
2. Following basic service delivery, related principles should be followed while providing PrEP services from the service delivery sites:
   **Consent:** Clients must provide informed consent for receiving PrEP services. Clients should provide detailed information of the process and of their right to decline for the service. A consent form included in the annex should be signed by the client. All individuals should have a private opportunity to refuse the services. No coercion is allowed. Clients should not be denied of any services provided by the facility for their refusal to PrEP service.
   **Confidentiality:** All the information collected should be kept confidential and should not be shared with anyone without the consent of the client. Although confidentiality always needs to be respected, it should never reinforce secrecy, fear, shame or prejudice. All staff should sign oath of confidentiality before joining the job.
   **Counseling:** PrEP service must be accompanied by appropriate and good quality information and counseling. All people should have the opportunity to ask questions in a private setting if they request it.
   **Correct:** Quality assurance mechanisms with supportive supervision and mentoring system should ensure that people receive a correct quality service. All services should be provided as per SOP and National Guidelines.
   **Connection:** PrEP service should have linkage to prevention, care and treatment services. All clients on PrEP services should be offered and provided referral prevention services including OST, needle syringe exchange, behavior change counseling and condom and condom-compatible lubricants distribution.

## B. Recommended staff structure

Recommended staff structure for providing PrEP services is presented in table 1 below. These are the minimum staff with their training requirements and major roles. For government run facility, for example, the ART centers, the existing staff of the center can provide HIV PrEP services. Government facilities may not have staff supporting in the community, support in the community can be provided by nongovernmental stakeholders.

**Table 1: Recommended staff, training requirements and roles for PrEP**

| Staff | Training requirements | Role |
|---|---|---|
| **Staff at centers prescribing and continuing PrEP** | | |
| Medical doctor | • Training on Clinical Management of HIV<br>• Training for PrEP service providers | • Prescribing PrEP<br>• Follow up<br>• Managing side effects and adverse events,<br>• conduct sexually transmitted infections (STI) checkup and management,<br>• Order for laboratory investigation and providing referral to other services. |
| Health assistant/Staff nurse | • Training on Clinical management of HIV<br>• Training for PrEP service providers | • Conduct counseling for HIV diagnosis, treatment and care including PrEP<br>• Dispensing PrEP medicines based on recommendations of medical doctor<br>• Conduct syndromic management of STI<br>• Conduct monitoring of community workers if applicable |

| Staff | Training requirements | Role |
|---|---|---|
| Laboratory technician or assistant | Laboratory technician or assistant trained for HIV and STI diagnosis following approved training of NPHL | • Conduct HIV confirmation test before initiating PrEP<br>• Conduct other baseline tests (if testing service available) or collect samples for baseline test<br>• Coordinate with testing laboratories for testing and receiving results<br>• Conduct community visit for testing and sample collection when necessary |
| **Staff in the community (staff of the same agency or staff of community based organizations (CBOs) and NGOs other than PrEP providers)** | | |
| Community support staff (Community-based supporters plus (CBSs), peer navigators (PNs), community- and home based care (CHBC) worker and other community outreach/in-reach workers | • Basic CHBC Training, training of CBSs or PNs or any basic training of community outreach/ in-reach workers<br>• Orientation on HIV PrEP with focus on demand generation and adherence support in the community | • Demand generation of PrEP<br>• Referral for PrEP screening<br>• Adherence check and support for PrEP users in the community |

## C. Facilities needed for PrEP service

- Supply of medicines recommended by National HIV Testing and Treatment Guidelines-2020
- Provision of conducting baseline and follow up tests
- Lab equipment for above mentioned test if the existing laboratory in the facility does not have the setup
- Facilities with no laboratory can use the service from the government recognized laboratory
- Forms and formats and other supporting materials for recording and reporting

## D. Setup for providing PrEP service

- A confidential room for counseling and clinical services (existing clinic room with privacy can be used for the purpose)
- Instrument for syndromic STI examination
- Cabinet to store ARVs for PrEP, and any other medications required
- Requirements for safe health care waste management (HCWM) of the waste generated in the facility

## E. PrEP service delivery package

The following package of services is provided when PrEP is offered. This package presents services and laboratory investigations to be provided during PrEP use. Please refer table 2 below for the details.

**Table 2: PrEP service delivery package with laboratory investigations**

| Service packages including investigations | Baseline | Follow up | | | | |
|---|---|---|---|---|---|---|
| | | 1 month | 3 months | 6 months | 9 months | 12 months |
| Comprehensive HIV prevention, including risk reduction counseling | √ | √ | √ | √ | √ | √ |
| Condom/lubricant distribution | √ | √ | √ | √ | √ | √ |
| STI syndromic screening, syphilis screening, diagnosis, and treatment | √ | √ | √ | √ | √ | √ |
| HIV testing and counseling, including index testing and for couples testing | √ | √ | √ | √ | √ | √ |

| Service packages including investigations | | Baseline | Follow up | | | | |
|---|---|---|---|---|---|---|---|
| | | | One month | 3 months | 6 months | 9 months | 12 months |
| Creatinine clearance screening and monitoring | Clients younger than 30 years with no comorbidities | Not recommended | | | | | |
| | Clients 30-50 years with no comorbidities | √ | | | | | |
| | Clients over 50 years | √ | | | √ | | √ |
| | Clients with co-orbidities (Diabetes, hypertension or previous creatine clearance <90ml/min) | √ | | | √ | | √ |
| Hepatitis B screening | | √ | | | | | |
| Hepatitis C screening | | √ | | | | | √ |

# 3. Special conditions and PrEP

There are certain conditions when PrEP must be used with caution. For example, PrEP among clients with Hepatitis B. There are other conditions when PrEP is indicated but the beneficiaries may have concerns, like safety in pregnancy, interaction with gender transforming hormones and STI. Similarly, there are conditions with which PrEP is generally not indicated. Table 3 describes such conditions and provides recommendations for PrEP use in different associated conditions.

**Table 3: Associated conditions and PrEP use**

| Associated conditions | Recommendations |
|---|---|
| Hepatitis B infection | Daily PrEP is not contraindicated in clients with hepatitis B infection; however, stopping PrEP may lead to exacerbation of Hepatitis B infection. Therefore, it is necessary to be cautious in starting PrEP in clients with Hepatis B infection. Therefore, Hepatis B antigen screening is recommended at the initiation of PrEP.<br><br>Anyone who is Hepatitis B positive and willing to use PrEP should be counseled for possible exacerbation while discontinuing PrEP. |
| STI | PrEP is not contraindicated for clients with STI. Treatment of STI should be provided to all clients presenting with STI as per National Guidelines on Case Mangement of STI. STI screening and treatment among PrEP users is recommended in every three months. Syphilis screening with Rapid Plasma Reagin (RPR) should be part of symptom screening, especially among KPs. All syphilis cases should be treated with benzathine penicillin. Reactive syphilis screening is not a contraindication for initiating PrEP. |
| Pregnancy | PrEP is not contraindicated in pregnancy and during breast feeding. |

| Associated conditions | Recommendations |
|---|---|
| Hormone use | Hormonal contraceptives or sex hormones do not interact with PrEP and concurrent use of hormones and PrEP does not diminish effectiveness of hormone or PrEP medicines. |
| Exposure to HIV in the past 72 hours | PrEP does not protect for the recent exposure, for which, post-exposure prophylaxis (PEP) is the option to prevent infection from recent exposure. Therefore, PEP is recommended for any exposure which occurred within the past 72 hours. A three-drug regimen of TDF +3TC (Lamivudine)+DTG (Dolutegravir) is recommended for PEP and should be provided for 28 days. Client on PEP can be transitioned to PrEP after completing 28 days of PEP. A negative HIV test result is needed for initiating PrEP immediately after PEP. |
| Acute HIV infection | Starting PrEP in the presence of acute HIV infection (AHI) involves a risk of drug resistance. There is no specific method available in Nepal for the identification of AHI and clinical features of AHI are also not specific. Therefore, if the symptoms of viremia (fever, sore throat, aches and pains, lymphadenopathy (swollen glands), mouth sores, headache or rash are present within 14 days of condomless sexual intercourse, acute HIV infection should be suspected. People with suspected acute HIV infection are to defer PrEP and repeat antibody testing after four weeks from the last date of possible exposure. |

| Associated conditions | Recommendations |
|---|---|
| Reduced kidney function | Reduced kidney function, indicated by a creatinine clearance of <60 ml/min, is a contraindication for using oral PrEP. Less than 1% of individuals who were screened before starting oral PrEP had abnormal creatinine clearance levels and less than 3% of oral PrEP users experienced a decline in creatinine clearance to <60 mL/min. Older individuals, especially those over 50 years, with baseline creatinine clearance of <90 mL/min and with kidney-related comorbidities such as diabetes or hypertension, had a higher probability of declining to abnormal levels of creatinine clearance. Creatine clearance calculation is recommended for all clients over 30 years. Waiting for creatinine screening results should not delay starting oral PrEP, since the results can be reviewed at a follow-up visit. Abnormal creatinine clearance of <60 mL/min should be repeated on a separate day before stopping TDF-containing oral PrEP. Creatinine clearance usually returns to normal levels after stopping PrEP, and PrEP can be restarted if creatinine clearance is confirmed to be to ≥60 mL/min one to three months after stopping PrEP.<br><br>The serum creatinine should be used to estimate creatinine clearance using the following Cockcroft-Gault formula:<br><br>***Est. Creatinine Clearance = [[140 - age(yr)] *weight(kg)]/[72*serum Cr(umol/L)]***<br><br>Note:<br><br>*1. Multiply by 0.85 for female at birth.*<br><br>*2. If creatinine clearance < 60 mL/min, refer client for further evaluation to nephrologist.* |

| Associated conditions | Recommendations |
|---|---|
| Summary of the contraindications | PrEP should NOT be provided to people with:<br>1. HIV-positive test result using the national HIV testing algorithm<br>2. Known exposure to HIV in the past 72 hours, offer PEP instead<br>3. Signs of AHI see Box 1 and potential risk within the past 14 days<br>4. Unwillingness to adhere to PrEP dosing regimen and attend scheduled PrEP visits<br>5. Drug allergy to any component of the drugs being used for PrEP<br>6. Creatinine clearance less than 60 ml/min<br>7. Concurrent nephrotoxic medication |

# 4. Recommended clinical flow of PrEP services

The chart below presents clinical flow of PrEP services from offering PrEP to HIV negative individuals to initiating PrEP in eligible clients.

| PrEP Services | Activities |
|---|---|
| **Offering PrEP eligibility screening to HIV Negative**  | 1. Conduct HIV testing following National HIV Testing Algorithm.<br>2. Provide accompanied referral to ART center for HIV treatment for those with confirmed HIV positive serostatus and offer screening for PrEP eligibility to confirmed HIV negative. |
| **Screening for substantial risk of HIV in last six months (One criterion requires)**  | 1. Engaged in condomless vaginal, neovaginal and/or anal sex within the past six months.<br>2. Self-reports one or more STI (urethral discharge syndrome, anorectal syndrome, genital ulcer disease syndrome or RPR reactive, vaginal discharge) within past six months.<br>3. Sexual partner with HIV who is not virally suppressed or has no evidence of viral suppression.<br>4. Exchanged (received or given) sex for money, valuables, drugs or favors in the last six months<br>5. Asking for frequent PEP over three times in past six months.<br>6. Asking for PrEP (plus one above mentioned criteria). |

| PrEP Services | Activities |
|---|---|
| **Screening for acute HIV infection (if meets both criteria -not eligible, if only one criterion-eligible) Duration: within two to six weeks.**  | 1. High-risk exposures: condomless sexual contact with a person who has an unknown HIV status or who is living with HIV but whose viral load (VL) is not known to be suppressed, sharing of injection among injecting drug users, or any exposure in which an individual's mucous membranes or breaks in the skin come in contact with bodily fluid potentially infected with HIV within past 14 days.<br>2. Presence of one or more of the following signs and symptoms: Fever, swollen lymph glands, skin rash, headache, sore throat/aches and pains and mouth sores. |
| **Collecting blood sample for laboratory test and decide based on test results.**  | 1. Collect the samples for serum creatinine (for those over 30 years or with comorbidities), Hepatitis B antibody, Hepatitis C antigen.<br>2. Check result of serum creatinine test (normal range: 0.4 2-1.4 mg/dL)- Raised not eligible.<br>3. Check result of Hepatitis B & C tests- Positive results are not contraindication for PrEP, however a consultation with physician or hepatologist are recommended.<br>4. Check the result of RPR- Treat for syphilis, eligible for PrEP.<br>5. Start PrEP on the same day as far as possible. |
| **Offering PrEP** | 1. Share the results with the client.<br>2. Inform the client whether he is eligible for PrEP or not.<br>3. If eligible, offer PrEP as an additional method of prevention with condoms and other methods of prevention, and if accepts, arrange for doctor's consultation for PrEP initiation. |

# 5. Initiating HIV PrEP

All clients completing the eligibility screening and providing consent to initiate the PrEP can start it. As per the national recommendations, PrEP is initiated after the evaluation is done by a medical doctor. Medical doctors are authorized to prescribe TDF+ FTC combination to initiate HIV PrEP.

## A. Checking requirements for initiating PrEP:

Please use the check list below for checking requirements to initiate PrEP. "Yes" to all questions in the check list is required to initiate PrEP.

**Table 4: Checklist for requirements to initiate PrEP**

| Details | Yes | No |
|---|---|---|
| 1. HIV test is nonreactive on PrEP initiation day or within 28 days | | |
| 2. Client is at substantial risk for HIV infection (or client has requested to use PrEP as an HIV prevention method) | | |
| 3. Client was not exposed to HIV in the prior 72 hours | | |
| 4. Client is not suspected to have AHI | | |
| 5. Client has normal findings in all baseline investigations | | |
| 6. Client is willing/able to come to for the next follow up as recommended | | |
| 7. Client has no contraindications to PrEP medicines (TDF+FTC) | | |
| 8. Client has provided formal consent to start PrEP | | |

## B. Counseling for PrEP

After confirming that all requirements are met, discuss the following message during counseling. Please reiterate the message even if it has already been discussed.

**Table 5: Key messages for discussion during counseling**

| Areas of discussion | Key messages for discussion during counseling |
|---|---|
| Taking PrEP regularly | 1. PrEP is highly effective if you take it as prescribed.<br>2. Taking PrEP each day is easiest if you make taking the tablets a daily habit, linked to something that you do every day without fail. For example, consider daily habits that could be linked with taking PrEP medicines, such as brushing your teeth, after the evening meal, watching television or checking Facebook or social media.<br>3. There are many other ways to facilitate adherence, you can disclose PrEP use to a partner or trusted person; you can use devices for reminding, such as mobile phone alarms etc.<br>4. If you forget to take a pill, take it as soon as you remember.<br>5. PrEP tablets can be taken any time of the day, with food or without food.<br>6. PrEP can be used discretely. Use some unbranded pill container or use bottles of vitamin or nutritional supplement to keep and carry PrEP pills. Ask if the client have any other idea to keep PrEP secret and discuss how it can be realized. |
| Effectiveness of PrEP | 1. If you are taking PrEP daily, it starts working after seven daily doses and does not provide protection in first seven days.<br>2. Additional HIV prevention measures should be taken for seven days after starting PrEP.<br>3. PrEP does not prevent STIs other than HIV, like syphilis, gonorrhea, chlamydia, trichomonas or chancroid. Consistent use of condom in every act of sexual intercourse provides protection against many of these infections as well as HIV.<br>4. PrEP does not prevent pregnancy. PrEP is safe to use during pregnancy and breastfeeding. |

| Areas of discussion | Key messages for discussion during counseling |
|---|---|
| Travel and use of PrEP | 1. During initial and follow up counseling for PrEP, ask the travel related plan and offer an extra supply of PrEP medicine.<br>2. Also provide guidance for using condoms and lube along with PrEP. This will prevent any accidental exposure leading to an HIV infection.<br>3. For everyone traveling out of the district and to another PEPFAR supported districts, provide referral to the PEPFAR supported site in that district so that the client can visit for HIV testing and taking supply.<br>4. For non PEEPFAR district, ask the client to visit nearest HIV testing lab for getting regular HIV testing. |
| Discontinuation of PrEP | 1. You can stop PrEP seven days after your last possible HIV exposure. You can consider stopping PrEP if you are no longer at substantial risk of acquiring HIV infection. For people in a serodiscordant relationship, HIV transmission risk is zero when the partner living with HIV has a durably suppressed viral load (VL) on ART. |

| Areas of discussion | Key messages for discussion during counseling |
|---|---|
| Using PrEP with alcohol, hormone and other drugs | 1. Although alcohol can be harmful to health and can make people forget to take the PrEP tablets, PrEP medicines are not contraindicated while taking alcohol.<br>2. PrEP is safe and effective even if you are taking hormonal contraceptives, sex hormones or nonprescription medications. There are no drug interactions between the PrEP medicines and hormonal contraception or sex hormones so they can be safely taken together. Oral, injectable or implant hormonal contraceptives do not significantly change the effectiveness of PrEP medicines also.<br>3. Taking recreational drugs does not reduce the effectiveness of PrEP.<br>4. Client can talk to their doctors if they feel they have issues with drugs or alcohol. |
| Side effects of the drugs used for PrEP | 1. PrEP is very safe, with minimal side-effects.<br>2. Few (around 10%) PrEP users experienced shortterm, mild side-effects like diarrhea, nausea, decreased appetite, abdominal cramping or flatulence, dizziness or headaches.<br>3. Side effects resolve without stopping PrEP within a month.<br>4. Long term side effects of TDF can be nephropathy and decreased bone mineral density, so monitoring needs to be done as recommended by the guideline and if PrEP is discontinued, the long-term side effects are reversible. |

| Areas of discussion | Key messages for discussion during counseling |
|---|---|
| Importance of testing for HIV | 1. Although rare, a person using PrEP may get HIV. Therefore, a regular HIV check is necessary for timely identification of HIV.<br>2. PrEP is not enough for the treatment of HIV infection.<br>3. Using PrEP in people who already have HIV infection can lead to resistance to PrEP medicines, therefore it is important to test for HIV in a regular interval, National HIV and Treatment Guideline recommends HIV testing one month after PrEP initiation, then in every three months. |
| If someone develops HIV? | 1. If someone develops HIV while on PrEP, PrEP should be discontinued and treatment with ART should be started following the National HIV Testing and Treatment Guidelines with the first-line regimen recommended. |
| Restarting after discontinuation | 1. PrEP can be restarted after discontinuation, if you suspect that you are in higher risk of getting HIV. An HIV test is needed for restarting PrEP. |

## C. Drugs used for oral PrEP and recommended regimen:

**Drugs used for daily oral PrEP[12]:**
ARV drugs include Tenofovir disoproxil fumarate, or Tenofovir or TDF and Emtricitabine or FTC. Emtricitabine can also be replaced by Lamivudine or 3TC for daily oral PrEP.

**Tenofovir disoproxil fumarate:** TDF is a nucleotide reverse transcriptase inhibitor (NRTI) which blocks the reverse transcription process during HIV replication. Usual dose is 300 mg per day. Common side effects of TDF include diarrhea, vomiting, nausea, dizziness, rash, feeling weak, decreased level of phosphate in the blood, headache, abdominal pain, feeling bloated, flatulence and liver problems.
Rare side effects are demineralization of bone and renal insufficiency. Consultation with the physician is necessary, for rare side effects and it may required stoping PrEP.

12 https://www.aidsmap.com/about-hiv/arv-factsheet

**Emtricitabine:** Emtricitabine is a nucleoside reverse transcriptase inhibitor (NRTIs). It also blocks the action of reverse transcriptase stopping the replication. Usual adult dose is 200 mg per day. Common side effects of emtricitabine include headache, diarrhea, nausea, vomiting, indigestion, muscle pain, dizziness, weakness, difficulty sleeping, abnormal dreams, pain, skin rash, itching, changes in skin color including darkening of the skin in patches. Rare side effects of emtricitabine include lactic acidosis and liver damage. Side effects are self-limiting and will resolve within a month. For rare side effects, consultation with the physician is necessary, it may require stopping PrEP.

**Lamivudine (3TC):** Lamivudine is also a nucleoside reverse transcriptase inhibitor which blocks the action of reverse transcriptase stopping the replication. Usual adult dose is 300 mg per day. The most common side effects of lamivudine include headache, feeling sick, diarrhea, stomach pains, tiredness, lack of energy, fever, general feeling of being unwell, muscle pain and discomfort, joint pain, difficulty in sleeping (insomnia), cough, irritated or runny nose, rash and hair loss (alopecia). Rare side effects of lamivudine include lactic acidosis and liver damage. Side effects are self-limiting and will resolve within a month. For the rare side effects, consultation with the physician is necessary and it may require stopping PrEP.

**PrEP Regimen:**

**Preferred regimen:** TDF/FTC: Each tablet containing 300 mg of TDF and 200 mg of FTC, one tablet daily.

**Alternative regimen:** TDF/3TC: Each tablet containing 300 mg of TDF and 300 mg of 3TC, one tablet daily.

## D. Supply:

Provide PrEP supply for one month at a time. Considering the adherence, multimonth supply of PrEP can be provided after ensuring the recommended tests are not missed.

# 6. Follow up for PrEP

**Providing counseling at each follow up visit**[13]

Counseling during each follow up visit should be prioritized and tailored according to the need of the clients. Try to access the clients' understanding, practice and assess risk behavior by asking questions. Be careful while discussing sexual practices, condom use, sharing injecting equipment and partners. Ask for permission before starting such discussion, if the client looks uncomfortable during the discussion, stop and ask the client if s/he wants to continue. Add or provide extra information only if it is needed. Area to discuss during follow up are mentioned below:

**Table 6: Discussion points for follow up counseling**

| Areas of discussion | Discussion points/possible questions for discussion |
|---|---|
| Pill-taking experience | 1. What is your experience of taking pills?<br>2. Did you feel any side effects? What were those?<br>3. Did you try any type of reminders to remember the time to take the pills?<br>4. Did you forget any doses? What were the reasons to forget? How did you overcome them?<br>5. What kept you motivated for taking pills?<br><br>*Based on the information provided earlier, discuss the possible ways out to resolve the problems faced by clients, suggest solutions.* |

13 WHO PrEP Implementation Guidelines, 2018

| Areas of discussion | Discussion points/possible questions for discussion |
|---|---|
| Willingness to continue PrEP | 1. Based on the pill taking experience, are you willing to continue PrEP?<br>2. If you are willing to continue, has PrEP made you feel safer about sex? Has PrEP made it easier for you to take charge of your health?<br>3. Let's again discuss about your possible risk of getting HIV and discuss the need of continuing PrEP.<br>4. If you are not willing to continue PrEP, lets discuss about other methods of HIV prevention- correct and consistent use of condoms with or without lubricants, ART for your partner (if partner is HIV positive), needle syringe exchange or OST (if the client belongs to PWID). |
| Discussing PrEP with others | 1. Have you discussed your PrEP use with others? Why or why not?<br>2. With whom have you discussed it?<br>3. What were the positive and negative experiences related to PrEP?<br><br>*These experiences might include improved relationship with a friend or a sexual partner, such as the ability to have a more open discussion with a partner about HIV status; or stigma and discrimination (S&D), eg. someone not wanting to use condoms after using PrEP.* |

| Areas of discussion | Discussion points/possible questions for discussion |
|---|---|
| Behavior and activity | 1. How has your sexual life been since your last visit?<br>2. How has PrEP changed your social and sexual goals?<br>3. Have you noticed changes in your usual sexual activities?<br>4. What are your thoughts about condoms?<br>5. What about sexual partners: Are you having different kinds of conversations with your sexual partners?<br>6. Have you increased or decreased the number of sexual acts and/or the number of partners?<br>7. Has taking PrEP changed what you do to protect yourself from getting HIV and STIs? |
| HIV testing and results | 1. How are you feeling about getting your HIV test result in a few minutes? What, if anything, would you like to discuss before I provide your results?<br>2. If HIV negative result is obtained:<br>a. What are your thoughts and feelings about your negative test result?<br>b. How, if at all, does this negative test result impact your plans and efforts to remain HIV negative?<br>c. Please tell me, how you are planning to be HIV/STI-negative?<br>3. If HIV positive result is obtained,<br>a. Provide full post-test counseling for HIV positive identified based on National HIV testing and Treatment Guidelines.<br>b. Arrange accompanied referral to ART center for immediate ART initiation. |

| Areas of discussion | Discussion points/possible questions for discussion |
|---|---|
| Clients wish to continue and no contraindication to continue | 1. Ask the clients to have necessary tests (HIV testing, Serum Creatinine, RPR etc. scheduled for the visit). Please refer to section D for frequency of laboratory test for monitoring of PrEP use.<br>2. Ask if the client has any questions to you or client wants any clarifications.<br>3. Discuss the travel plans before next appointment and find out the need of extra supply. |

# 7. Stopping and restarting PrEP

Unlike ART, PrEP is not required lifelong. The major aim of PrEP is to cover the risk period and simultaneously, efforts must be made to make behavioral changes and incorporate risk reduction methods in lifestyle. The duration of PrEP use may vary from individual to individual and time to time, depending on risk assessment at different periods in life and may get affected by factors like marriage or faithful relationship, breakups, travelling, emotional vulnerabilities, ability to adherence, etc. Discontinuation of PrEP may be categorized as completion of PrEP course (for that episode) or stopping (due to medical advice or client's will).

## A. Stopping PrEP

PrEP can be stopped when the risk status of client changes from substantial risk to low/no risk. Decision for stopping PrEP shall be done only after a detailed and frank conversation between the provider and the client discussing all the aspects of risk and ways to preventing those risks.

1. The low or no risk conditions for HIV include:
    a. In serodiscordant couple, the HIV positive partner is virally suppressed and is adherent to treatment for last three months
    b. The risk status changes from substantial risk to low or no risk
    c. Client enters in mutual monogamous relationship
    d. Consistent and correct use of condoms for last three months and willingness to continue the same
    e. No signs and symptoms of STI in last three months
2. Clients completing PrEP shall be advised to continue it for seven days since last potential exposure[14].
3. An HIV test is needed when clients stop PrEP voluntarily or PrEP is stopped due to medical reasons.

14 Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

**Medical reasons to stop PrEP:**
If PrEP is stopped based on the medical reasons mentioned below, then PrEP should be stopped immediately, and restarting is not recommended:

a. Diagnosis of HIV infection
b. Renal toxicity (creatinine clearance below 60 ml/min)

**Client related factors impacting efficacy of PrEP:**
PrEP may be stopped if client related factors impact the efficacy of PrEP. In these situations, clinician shall put all the efforts for improving compliance and adherence by understanding the barriers, involving peers or professional counselors. However, in case no improvement is noticed PrEP can be discontinued. Client related factors include:

a. Continued non-adherence to PrEP, despite efforts of improving it
b. Not willing / unable to follow up
c. Client not willing to continue

For discontinuation other than medical reasons as mentioned above, advise client to continue PrEP for at least 28 days after the last potential exposure to HIV. Offer HIV risk reduction counseling including use of condoms with or without condom compatible lubricants and follow upto the client. Advise to report back if s/he wishes to restart PrEP, or notices symptoms of STI and for regular HIV testing (in every three months or when client wishes to get the test).

## B. Interruption in PrEP

Sometimes client may interrupt PrEP without informing the service provider. Interruption in PrEP is considered when client does not pick up PrEP within seven days of next appointment. Upon such discontinuation, document the duration of PrEP taken and reasons for interruption (if known).

## C. Restarting PrEP

Anyone can be reintegrated to PrEP if required. PrEP after interruption shall be considered as a fresh episode and the client should be

- Assessed for eligibility again
- Undergo HIV testing (if interruption is less than one month from the last HIV negative result, HIV testing is usually not recommended)
- Conduct serum creatine (if interruption is more than six months from last test and the client is above 50 years and has underlying conditions for renal insufficiency)
- Conduct counseling for PrEP initiation.

# 8. Demand generation for PrEP

Demand generation is conducted by community workers, such as CHBC workers, CBS plus, PNs or assigned outreach/in-reach workers, in the community and online platforms. Demand generation can also be conducted at clinic or HIV testing and counseling (HTC) site where HIV negative diagnosis has been made. Social and behavior change communication (SBCC) strategies tailored to the needs of specific KPs can be adopted to create demand for PrEP initiation, support in adherence and continuation. Gain framing message on PrEP will be used in local languages.

## A. General demand generation

This will include SBCC approaches and materials to raise awareness, demand creation, and counseling to KPs tailored to their needs, which will help to address known barriers and motivating factors for subpopulations. General information education and communications (IEC) materials developed in consultation with the targeted communities and using locally appropriate messages and images are useful for general demand generation. Gain framing messages related to PrEP should be included in such materials. These materials range from goodies with very little information to posters and brochures with relatively comprehensive messages.

**Brochures/flyers:** Using brochures and posters for general demand generation are traditionally used for message dissemination and at the same time for demand creation. Brochures introduce PrEP, highlight its importance, benefits, steps for starting and stopping PrEP, using other methods of HIV prevention follow up, frequently asked questions, myths and facts, addressing stigma etc. Brochures can be provided to the targeted groups of population as well as distributed to general public for providing information. Brochures developed in a local language can be distributed to targeted people in the community and, in the clinics.

**Job aids:** Job aids, printed and digital materials, focusing on informed-choice counseling and preventing stigma among KPs can be developed. These job aids can be used in orientation and training sessions on PrEP.

**Posters**: A short catching positive message on PrEP with the information on availability, designated health facilities with contact numbers can be included in a poster. Posters build familiarity with PrEP and can prompt question. These posters can be displayed in the places where people from targeted groups often visit. KP clinics, general health facilities, ART centers, offices of CBOs are ideal places to display posters.

**Web-based messages and online platforms**: Using web-based message through a KPs dedicated website, social media, and/or dating apps can also be used to reach the potential PrEP users. Social media can play a key role in disseminating important scientific information. Information on the high effectiveness of PrEP and stories from early adopters of PrEP may encourage people who could benefit from PrEP to seek PrEP services.

**Short videos:** Depending on the target audience and local context, short videos or animated videos can be used for demand generation and community awareness.

**Mobilizing PrEP Champions:** PrEP champions are the PrEP users, who are willing to speak publicly and provide message about PrEP. They speak on the reasons why they chose to use PrEP to protect themselves and their partners. They can share the experience of side-effects which they encountered, how these effects were coped and how long these effects lasted.

## B. Demand generation in the community

An outreach visit at the hotspot or cruising site is one of the approaches for creating demand for PrEP among KPs. KPs can be contacted either one-on-one or in groups. Privacy and confidentiality should be maintained during outreach session as far as possible. The trained community workers can also conduct HIV screening in the community. Outreach workers are recommended to do the following:

1. Deliver information on PrEP in addition to the HIV prevention service package, as part of their standard SBCC activities during outreach.
2. Conduct HIV screening using determine or HIVST test kits if the community worker is trained and equipped to do screening.
3. Discuss PrEP as an additional prevention option with HIV non-reactive KPs and provide information on the availability of PrEP in the area.
4. Offer screening for PrEP using community screening forms and refer the eligible for further eligibility screening in clinics.

## C. Demand generation at PrEP service delivery point

Demand generation can also be done at HIV testing clinics. HIV counselor during HIV post-test counseling conducts demand generation targeting HIV negatives clients at highest risk of HIV. Staff during demand generation are recommended to do the following:

1. Deliver messages on PrEP during the counseling and education session in the clinics.
2. Discuss the benefits, its doses, possible side effects and adverse events, follow up including laboratory testing, regimen and duration to use.
3. Provide information about the availability of PrEP at the clinic.
4. If the client is interested in initiating PrEP, offer eligibility screening.

# 9. Monitoring of adverse events

In the context of PrEP, an adverse event is an incident that results in harm to the client as a result of taking PrEP. Severe adverse event (SAE) in PrEP is any unfavorable or unintended condition that is related to the use of PrEP drugs or due to program related activities. All SAEs should be reported to higher authorities. Any SAEs and social harms arising from PrEP intake will be addressed through clinical services or through counseling as required on a case-by-case basis.

**Severe adverse event of drug used in PrEP**

Renal toxicity with lower creatinine clearance is considered reportable SAE of the TDF used in PrEP regimen. The renal toxicity of TDF is characterized by proximal tubular cell dysfunction, which may be associated with acute kidney injury or chronic kidney disease. However, the incidence of clinically significant renal toxicity with TDF is very low. The clinician should consider discontinuing PrEP if a creatinine elevation is confirmed on a separate specimen and if the estimated creatinine clearance decreases to less than 60 ml/min.

**Managing elevated serum creatinine**

Repeat serum creatinine test, just to make sure it is not a lab error. If the result is same, stop PrEP immediately after getting elevated serum creatinine. Clients stopping TDF-containing PrEP should be advised to use condoms with or without condom compatible lubricants during every sexual intercourse. Stopping PrEP is enough to restore baseline renal function. Refer for consultation with nephrologist, especially, if any of the following are present:

- Creatinine elevations are more than 1.5-fold the upper limit of normal
- Renal function or creatinine elevations do not return to normal levels within three months of stopping PrEP
- Creatinine elevations progress at one month or more after stopping PrEP

**Reporting severe adverse events**

Reporting of SAE is as recommended by National HIV Testing and Treatment Guidelines for ARV drugs. If any adverse reactions are noted, an adverse event recording and reporting form should be completed by the health-care provider

(Annex 6) Report on suspected serious drug reaction). All the Adverse Drugs Reaction (Annex 6) should be sent to the NCASC every month. All severe adverse events should be immediately reported to hospital authority through PrEP clinician. Adverse event monitoring should be done at two levels:

- site level monitoring (by PrEP focal person)
- client level monitoring (using exit interview)

**Actions regarding adverse clinical events of PrEP**

The health assistant (HA)/counselor must do the followings:

1. Report any adverse event to the respective clinic or hospital in charge immediately.
2. Record all adverse events related to PrEP such as drug treatment, type of event, time of onset, dosage, assessment of severity and relationship to medication, time of resolution of the event, seriousness, as well as any required treatment or evaluations, and outcome, including abnormal lab values adverse events (AE) record form (Annex 6).
3. Report all AEs resulting from concurrent illnesses, reactions to concurrent illnesses, reactions to concurrent medications, or progression of disease states.
4. Document any serious AEs using a specific form and report to NCASC every month.
5. Maintain a tracking log for all AEs using AEs tracking form.
6. Consult ART physician as a medical monitor for monitoring of and providing support for side effects and adverse event management.

**Monitoring of drug toxicity**

The drug toxicities will be graded per the AIDS Clinical Trial Group grading by trained ART physician. Clients who develop a Grade 1 or Grade 2 AE or toxicity may continue to take medication at the discretion of the technical advisor. Clients who develop Grade 3 or Grade 4 laboratory abnormalities should have the results confirmed (See Annex 10 for grades definitions). The interruption or discontinuation of PrEP medication should be considered if the abnormality is related to the medication or not consistent with International Council of Harmonization, Good Clinical Practice (ICH GCP) guidelines. Resumption of therapy may be considered after consultation with the ART physician.

**Overdose management**

An overdose is defined as any dose taken (accidently or intentionally) that exceeds the assigned dose of any of the active medications (PrEP and treatment). Occasional intake of double dose of PrEP medicines is not considered as overdose. Staff should refer to the specific package insert of the medicine for advice on management of overdose. Along with full documentation of the overdose, all subsequent adverse clinical sequelae must be reported as an AE as applicable. Overdose will be tracked in the site AE tracking log by following national guidelines.

# 10. Referral for other services

- Keep a referral directory at the site providing PrEP with the details of contact address, contact person of the site, related departments etc.
- Referral and linkage could be provided
    - within HIV services, that include HIV testing, HIV treatment, condom distribution, risk reduction and harm reduction services,
    - between HIV services and other health services that include STI services, antenatal care (ANC), family planning services, youth-friendly services, human rights and gender related services, viral hepatitis services, mental health services, and others as appropriate.

# 11. Recording and reporting

Below are the indicators recommended by WHO, which can be used for regular reporting,

**Table 7 : Indicators recommended for reporting**

| Indicators | Definition | Numerator | Denominator | Disaggregation |
|---|---|---|---|---|
| PrEP Uptake | Percentage of eligible people who initiated oral antiretroviral PrEP in the last 12 months. | The number of people who initiated oral PrEP in the last 12 months. | Number of people who were newly offered PrEP in the last 12 months. | • People who received PrEP for the first time in their lives<br>• Age (15–19, 20–24, 25–49 and 50+ years)<br>• Gender (male, female or transgender)<br>• KP (MSM, sex workers, PWID, people in prisons and other closed settings, and transgender people)<br>• Geographic and other administrative areas of importance. |

| Indicators | Definition | Numerator | Denominator | Disaggregation |
|---|---|---|---|---|
| Continuation on PrEP | Percentage of PrEP users who continued oral PrEP for three consecutive months after having initiated PrEP in the last 12 months. | Number of people who continued PrEP for three consecutive months after having initiated PrEP in the last 12 months. | Number of people who initiated oral PrEP in the last 12 months. | Age (15–19, 20–24, 25–49 and 50+ years)<br>• Gender (male, female or transgender)<br>• KP (MSM, sex workers, PWID, people in prisons and other closed settings, and transgender people)<br>• Geographic and other administrative areas of importance. |
| PrEP associated toxicity prevalence | Percentage of people who received oral PrEP who have discontinued or interrupted PrEP due to a serious ARV-associated toxicity in the last 12 months. | Number of people who received oral PrEP and have discontinued or interrupted PrEP due to a serious ARV related toxicity in the last 12 months. | Number of people who received oral PrEP at least once in the last 12 months. | |
| HIV positivity among people who have been prescribed PrEP | Percentage of people who test HIV-positive among people who received PrEP at least once in the last 12 months and had at least one follow-up HIV test. | Number of people who had a positive HIV follow-up test among people who received oral PrEP at least once in the last 12 months. | Number of people who received oral PrEP at least once in the last 12 months, and who had at least one follow-up HIV test. | |

# 12. Logistic management of Oral PrEP medicines

Logistics management is the fulfilling of the six-rights—getting the right product, in the right quantity, in the right condition, delivered to the right place, at the right time and at the right cost. The fulfillment of six-rights ensures that the medicines are always accessible. The medicine used for PrEP is FTC 200 mg and TDF 300mg as the fixed dose combination tablet. These tablets are available in a jar containing 30 Tablets. The required storage condition is ≤30°C and should be stored in the original container. Drugs are supplied by NCASC to the designated sites upon submission of logistics consumption report.
For details regarding the logistics procedure of handling supply from NCASC, please refer **Annex 10**

# Annex 1: HIV PrEP—Eligibility Checklist

**National Centre for AIDS and STD Control (NCASC)**
**HIV PrEP—Eligibility Checklist**

**CLIENT INFORMATION**

UIC:
District:
Service delivery site:
Person conducting screening:
Date of Appointment:

**INCLUSION CRITERIA**

**Circle if the client has/did the following:**

1. **General**
   a. HIV negative from the most recent HIV test done in the HIV testing centers
   b. No known allergy to TDF-FTC or pill ingredients

   *If yes to all, then eligible from section 1*
   *If eligible from section 1, go to section 2; if not eligible, stop screening, explain client that he/she is not eligible for PrEP, suggest ART initiation and/or any support*
2. **Sexual Risk (at least one required)**
   a. Engaged in condomless vaginal, neovaginal and/or anal sex within the past six months
   b. Self-reports one or more STI (urethral discharge syndrome, anorectal syndrome, genital ulcer disease syndrome or RPR reactive, vaginal discharge) within past six months
   c. Sexual partner with HIV who is not virally suppressed or has no evidence of viral suppression
   d. Exchanged (received or given) sex for money, valuables, drugs or favors in the last six months
   e. Asking for frequent PEP over three times in the past six months
   f. Asking for PrEP (delete or check the above-mentioned points)

   Note: If exposure is within 72 hours, stop screening offer PEP, start PrEP after completing PEP (on 29$^{th}$ day)

*If eligible from section 2, go to section 3; if not eligible, stop screening, explain the client that he/she is not eligible for PrEP, suggest other method of HIV prevention.*

**3. Screening for acute HIV infection (Both present not eligible, if only one criterion present, eligible)**

Acute HIV-1 infection should be suspected in individuals with signs or symptoms described below and recent (within 2 to 6 weeks) high risk of exposure to HIV-1.

a. High-risk exposures: sexual contact with a person who has HIV-1 infection or a person at risk of HIV-1 infection, sharing of injection among injecting drug users, or any exposure in which an individual's mucous membranes or breaks in the skin come in contact with bodily fluid potentially infected with HIV.

b. Presence of signs, symptoms, of acute HIV-1 infection: one or more of the following: fever, lymphadenopathy, skin rash, myalgia, arthralgia, headache, diarrhea sore throat and oral ulcers.

**(***Adopted from AIDS info, US Department of Health and human Service, https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/20/acute-and-recent--early--hiv-infection)*

*If eligible from section 4, ask client to go to laboratory for blood; and urine collection (for female only); if not eligible, stop screening, explain client that he /she is not eligible for PrEP, and thank the client for interest and time.*
*If the client him/herself does not wish to continue at this level, ask the reason and record:*

**4. Sample collection for baseline in investigations**

Collect the samples for serum creatinine, Hepatitis B antibody, Hepatitis C antigen following all aseptic measures, ask the client to visit the clinic after one working day.

All sample collected: Mark 'X' if completed (  )

**5. Laboratory findings**

Check the laboratory result as per the report received from laboratory and mark below, keep result in client's folder

- Serum creatinine level
  (Normal range: 0.4 2-1.4 mg/dL) Normal (_____) Raised (____)
  Not indicated (____)
- Hepatitis B Antigen test: Positive (____) Negative (___)
- Hepatitis C Antibody: Positive (_____) Negative (____)
- RPR: Reactive **(_____)** Nonreactive (_____)

*If eligible from section 5, consider eligibility as below, if not eligible, explain client that he /she is not eligible, and thank the client for interest and time. Proceed for consent and registration for enrollment in PrEP*

6. Consent: Written consent: Provided (____), Not accepted: (____)
7. If not accepted, ask the reason and record:
8. Registered in PrEP: Yes (___). No (____)
9. PrEP client ID:

Name and Signature of person conducting screening
Name:
Signature:
Date:

# Annex 2: Recommended visit schedule

| Visit type | | Purpose of visits | | | | | |
|---|---|---|---|---|---|---|---|
| | Eligibility Screening | Enroll in PrEP | Month-1 visit | Follow up visits | | | |
| Visit number | 1 | 2 | 3 | Every month after the first month | Every 3 months | Every 6 months | Every year |
| **Eligibility assessment** | √ | | | | | | |
| **Laboratory testing** | √ | | | | | √ | |
| Serum creatinine (for those over 30 years or anyone with comorbid conditions) | √ | | | | | √ | |
| Hepatitis B antibody test | √ | | | | | | |
| Hepatitis C antigen test | √ | | | | | | √ |
| HIV antibody test | √ | | √ | | √ | | |
| Syphilis screening | √ | | | | | | |
| Visit for receiving result and decision about eligibility and participation in study | | √ | | | | | |
| Calculating creatinine clearance and making decisions | | √ | | | | √ | |

| Visit type | | Purpose of visits | | | | | |
|---|---|---|---|---|---|---|---|
| | Eligibility Screening | Enroll in PrEP | Month-1 visit | Follow up visits | | | |
| Visit number | 1 | 2 | 3 | Every month after the first month | Every 3 months | Every 6 months | Every year |
| Initial history taking with sexual and behavior history, clinical examination, STI syndromic screening & treatment, dispensing PrEP | | √ | | | | | |
| Follow up visit history taking with sexual and behavior history, clinical examination, STI syndromic screening & treatment, dispensing PrEP | | | | √ | | | |
| Treating for syphilis if newly reactive on syphilis screening | | | | | √ | | |

# Annex 4: HIV PrEP initial record form

**National Centre for AIDS and STD Control (NCASC)**
**HIV PrEP initial record form**

Registration
**Client ID:** Date:
Service delivery site: KP:
Name of service provider: Designation:

**Medical history**

1. Pregnancy:
2. LMP:
3. Allergy to any medicine: Yes/No
   Details_____
4. History of taking ARV for prevention in past: PEP, times
   Details_____
5. Any illicit drug use: yes/No
   Details_____
6. Hormone use (Transgender people): Yes/No
   Details_____

**Sexual history and behavior (in last six months)**

7. Do you have sexual contact with: men, women, or both?
8. When was the last sexual contact? _____
9. Did you use condom last time when you had sex? Yes/No
   If not, please specify reason_____
10. How many sexual partners you had in last 6 months?
11. Which sexual contact do you prefer to have? anal, vaginal, or both

**Clinical examination:**

12. Vital signs:
    a. Pulse:
    b. Blood pressure:
    c. Temperature:
    d. Height:
    e. Weight:

13. STI screening as per National STI Guideline done: Yes/No
14. Diagnosed syndrome or individual STI:
15. Results of baseline tests:
    a. Syphilis screening result:
    b. HIV antibody rapid diagnostic test result:
    c. Hepatitis B antibody test:
    d. Serum creatinine level:
16. Date of enrollment in PrEP:
17. Education for adherence and retention in PrEP

Provide following education to client before dispensing medicine, circle the item after providing information:

a. Brief information about HIV, its mode of transmission, prevention, role of PrEP in prevention, why HIV testing is needed, why baseline investigations were done
b. Effectiveness of PrEP, when it starts to work
c. Possible side effects, their severity and duration
d. When and how PrEP can be started, stopped and restarted safely
e. How to take pills and what to do if pills are missed
f. Discuss interaction of PrEP medicine with hormone, alcohol and drugs
g. Importance and need of HIV testing during PrEP use and other investigations
h. Care support and treatment provided to HIV positive
i. Importance of HIV prevention methods other than PrEP (e.g. Condoms with lubes, Opioid Substitution therapy, use of safe needles and syringes
j. Needs and importance of monthly STI check ups

18. Dispensing:

    **Medicine for STI**:

    Preferably directly observed for single dose treatment, write medicine, dose and duration below:

    **Medicine for PrEP:**

    Name of the medicines, total doses:
19. Next appointment date:
20. Name and Signature of authorized doctor prescribing PrEP:
21. Name and Signature of authorized dispensing PrEP:

# Annex 5: Follow up record form

**National Centre for AIDS and STD Control (NSASC)**

**Follow up record form**

**Registration**

Client ID Date:

Service delivery site: KP:

Name of service provider: Designation:

**Medical history**

1. Any clinical complaints:
2. Any current (within one month) illicit drug uses: yes/No
3. Details_____
4. Current hormone use (Transgender people): Yes/No
5. Details_____

**Sexual history and behavior (within one month)**

1. Do you have sexual contact with: men, women, or both?
2. When was the last sexual contact? _____
3. Did you use condom last time when you had sex? Yes/No
   If not, please provide reason_____
4. How many sexual partners you had in the last one month_____
5. Which sexual contact you had? anal, vaginal, or both_____

**Clinical examination:**

Vital signs:

1. Pulse
2. Blood pressure
3. Temperature
4. Height
5. Weight
6. STI screening as per National STI Guideline done: Yes/No
   a. STI symptoms experienced:
   b. Signs of STI seen during examination:
   c. Test performed (RPR) and result (enter below under lab investigation)

d. Diagnosed syndrome or individual STI:

7. Any unwanted symptom (side effects) client experienced in last one month:
   Mentioned side effects experience: _____
   _____
   Did client continue the medicine after experiencing side effects?
   _____
   _____
   If discontinued, how many days? _____
   _____
8. Serious adverse event: clinical and social: Please also fill adverse event reporting form:
   - Adverse event experienced:
   - Action taken:
   - Did the event resolve?
   - PrEP drug use: If discontinued, mention date of discontinuation and date restart below
   - Date of discontinuation:
   - Restarting date:

**Results of follow up tests:**

9. Syphilis screening result (every three months):
10. HIV antibody rapid diagnostic test result (every three months):
11. Serum creatinine level (at the end of six month):
12. Adherence check by pill count: Discuss the regularity of taking pills, if the client is taking pills regularly no need to do the pill count as it disempowers clients and fosters distrust. Please check only if absolutely necessary.
    a. Total prescribed at last visit:
    b. Total pill remaining as presented by client:
    c. Total pill taken by the patient in last 30 days:
    d. Adherence percentage:
    e. Reasons for not taking pill:
13. Education for adherence and retention in PrEP

Discuss the following with the clients before dispensing medicine. Circle the item after providing information:

- **Discuss pill-taking experiences** (side effects, challenges for

adherence, reasons for forgetting pills, approaches which helped to remember pill taking times, thoughts that motivated to take pills), do pill count

- **Disclosure of PrEP use with others** (if done, why, if not what were the reasons, what other people may feel, reaction of partner if disclosed
- **Behavior and activity**: (Sexual behavior since PrEP use, any change in sexual behavior after taking PrEP, increasing or decreasing sexual acts or partners), encourage for minimizing partners and minimizing condom-less sexual exposure
- **HIV testing and results:** expectation of HIV test results

14. **Dispensing:**
    **Medicine for STI**:
    Preferably directly observed, describe the dose and provide, write medicine, dose and duration below:
    **Medicine for PrEP:**
    Name of the tablet, total doses:
15. **Next appointment date:**

Signature of authorized person prescribing and dispensing:

# Annex 6: Report on suspected serious drug reaction

Government of Nepal
Ministry of Health and Population
Department of Drug Administration

**Adverse Event Reporting Form for ARV Medicines**

| PATIENT DETAILS | | |
|---|---|---|
| Patient ID No: | Patient Name: | Sex: F/ M /O |
| Age: _____ years_____ months | Weight(kg): _____ | |
| Patient residential/contact information: | | |

Type of Treatment: ☐ ART ☐ PMTCT ☐ PEP ☐ PrEP

| Drug Details (dosage and frequency) | Brand, generic name, manufacturer, batch No. | Date started | Date stopped | Remarks/reason for discontinuation |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

DETAILS OF ADVERSE EVENT

Date event started: __ /__ /__ Date event stopped: __ /__ /___

Adverse reaction observed (please tick all that apply)

☐ Vomiting ☐ Nausea ☐ Itching ☐ Skin rashes ☐ Diarrhoea ☐ Dizziness

☐ Headache ☐ Mouth sores ☐ Abdominal pain ☐ Insomnia ☐ Dark coloured urine

☐ Clinical jaundice ☐ Weight gain ☐ Others (pls specify)

| |
|---|
| Description of event (continue on back page if necessary): |
| Treatment or action taken (continue on back page if necessary): |
| Seriousness (please tick all that apply)<br>☐Not Serious ☐ Life threatening ☐ Caused hospital admission<br>☐ Death ☐ Other outcome (please specify): |
| Outcome (please tick all that apply)<br>☐ Recovered ☐ Recovering ☐ Ongoing ☐ Change of therapy ☐ Died<br>☐ Unknown ☐ Other outcome (please specify): |
| REPORTER DETAILS |
| Name: Position:<br>Signature: Hospital:<br>Date: Contact No: |

**Please return this form to the focal person at the NCASC via email/fax, Email: data@ncasc.gov.np Fax: +977- 1- 4261406**

# Annex 7: PrEP eligibility and referral slip from community

**सामुदयिक कार्यकर्ताका लागिः** तपाईले सीएलटी वा सेल्फ टेष्टिङ गर्दा एचआइभी नभएको रिपोर्ट आएमा तलका प्रश्नहरू सोधी प्रेप दिन मिल्छ कि मिल्दैन हेर्नुहोस् । यदि तपाई यदि एचआइभी जाँच सेवा दिनु हुन्न भने पनि यो प्रश्नावली प्रयोग गर्न सक्नुहुन्छ । यदि प्रश्न नं १, २, ३, ४, ५ मध्ये कुनै एकमा "छ" र प्रश्न नं ६ मा "छैन" भन्ने उत्तर आएमा प्रेप दिन मिल्छ, नजिकैको क्लिनिकमा प्रेपको लागि पठाउनु होस् । यदि प्रश्न नं ५ मा "छैन" भन्ने उत्तर आएमा किन भनेर सोधी कारण डायरी मा लेखी रेकर्ड गर्नुहोस् ।

हाम्रा क्लिनिकहरूबाट एचआइभीलाई सर्नबाट रोक्ने औषधी निशुल्क वितरण भै रहेको छ। यदि तपाई त्यो औषधी प्रयोग गरेर आफूलाई एचआइभीबाट सुरक्षित बनाउन चाहनुहुन्छ भने हामी तपाईलाई सहयोग गर्न तयार छौँ । यसको लागि हामी केही प्रश्नहरू सोध्दछौँ, कृपया जवाफ दिनुहोला ।

1. के तपाईले पछिल्लो छ महिना भित्र कण्डम प्रयोग नगरी यौन सम्पर्क राख्नु भएको छ ? (छ । छैन)
2. के तपाईले पछिल्लो छ महिना भित्र मुत्र नलीबाट पिप बग्ने, यौनाङ्गमा घाउ भएको या डाक्टरले यौन रोग लागेको रहेछ भनेर भनेको छ ? (छ । छैन)
3. के तपाईको यौनसाथी एचआइभी संक्रमित हुनुहुन्छ ? (छ । छैन)
4. के तपाइका यौनसाथीहरूको संख्या एक भन्दा बढि छ ? (छ । छैन)
5. के तपाई दैनिक रुपमा खाइरहनु पर्ने औषधी खान तयार हुनुहुन्छ ? (छ । छैन)
6. के तपाई मृगौला सम्बन्धी समस्या छ भनेर डाक्टरले भनेका छन् ? (छ । छैन)

धन्यवाद उत्तरहरुका लागि, तपाईलाई प्रेप शुरू गर्नको लागि आवश्यक जाँच गर्न पठाउन मिल्छ/मिल्दैन ।

मिल्ने भएः रेफरल स्लिप लेखेर दिई कसरी क्लिनिक सम्म पुग्ने बताउनु होस् र गएर एच ए लाई सम्पर्क गर्न भन्नुहोस् ।

नमिल्ने भएः (कुनै ब्राकेट भित्र चिन्ह लगाउने र सेवाग्रहीलाई किन प्रेप खान नमिल्ने बताउने)

1. तपाई एचआइभीको उच्च जोखीममा हुनु हुन्न ! (___)
2. तपाईलाई मृगौलाको समस्या भएकाले प्रेप शुरू गर्न मिल्दैन ! (___)
3. तपाईलाई नियमित औषधी खान समस्या रहेछ ! (___)

सेवाग्राहीले चाहेमा अन्य सरसल्लाहका लागि क्लिनिकमा पठाउनुहोस् ।

## Annex 8: PrEP consent form

म मेरो राजी खुशीले एचआइभी रोकथामको लागि टेनोफोभिर र एमट्रिसिटाबिन मिसिएको औषधी नियमित लिइ  प्रेप कार्यक्रममा भाग लिन तयार छु। मलाई यो औषधी प्रयोग गर्दा हुने फाइदा र नोक्सानी बारे पूर्ण जानकारी लिएर मात्र मैले यो मन्जुरी दिएको / दिएकी हुँ । यो कार्यक्रम भाग लिन मलाई कुनै पनि दवाव दिइएको वा जवर्जस्ति गरिएको छैन।  म जानकारी दिए बामोजिम नियमित समयमा आएर औषधी लिने छु, साथै स्वास्थकर्मीले दिएको निर्देशन बमोजिम प्रयोगशालामा गएर जाँच गर्न तयार छु ।

मन्जुरी दिने ब्यक्तिको  हस्ताक्षर वा सहीः

नाम दिन चाहेमा नामः

मितिः

मेरो उपस्थितिमा यो मन्जुरीनामा दिइएको हो भनी प्रमाणित गर्ने कर्मचारीकोः

हस्ताक्षरः

पदः

पुरा नामः

मितिः

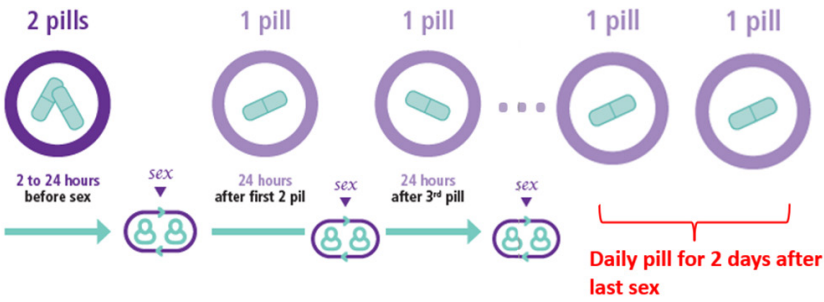
# Annex 9: Future perspectives of PrEP

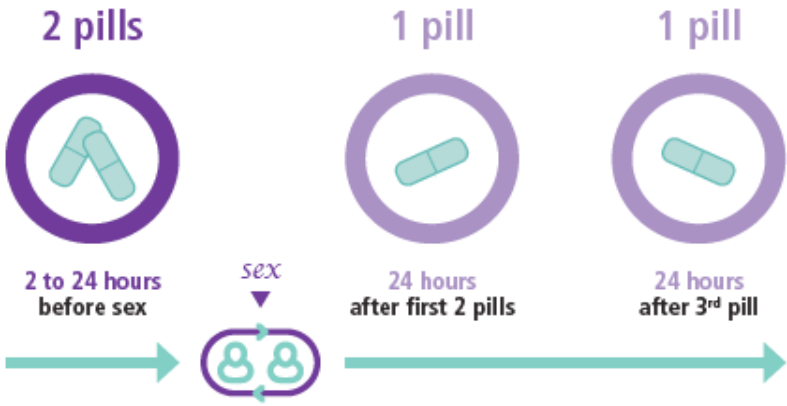
**Event driven (ED) Regimen**: Event-driven PrEP (ED-PrEP) for men who have sex with men consists of the use of a double dose (two pills, which serves as the loading dose) of TDF/FTC (or TDF/3TC) between two and 24 hours in advance of sex; then, a third pill 24 hours after the first two pills, and a fourth pill 48 hours after the first two pills (Fig. 1). ED-PrEP has been described as "2+1+1" dosing, a term that can be helpful to communicate this approach as an alternative to daily dosing for men who have sex with men.

This 2+1+1 dosing is the only ED-PrEP regimen that has been demonstrated to be effective. This process should be repeated for each period of potential exposure to HIV. This is sufficient to achieve high levels of protection against HIV. Event-driven PrEP is not an appropriate option for other PrEP users such as, cisgender women, transgender women or transgender men having vaginal sex.

Oral PrEP may be offered to MSM as a daily regimen or an event-driven regimen (ED-PrEP). MSM should be provided the opportunity to decide which regimen works best for them. ED-PrEP should not be the only option for MSM. ED-PrEP may be appropriate for MSM who find the dosing schedule more effective and convenient, have infrequent sex (for example, less than two times per week, on average), and are able to plan for sex at least two hours in advance or can delay sex for at least two hours after taking the loading dose of two pills. Start ED-PrEP with a loading dose of two pills taken two to 24 hours before having sex to ensure that drug levels are maximally effective. Continue taking one pill daily at the same time as the loading dose until two days after the last potential exposure.

Figures below provide examples of ED-PrEP dosing that correspond to different exposure scenarios. This process should be repeated for each period of potential exposure to HIV. However, ED-PrEP is only recommended for the prevention of HIV acquisition during anal sex. MSM with other potential exposures to HIV should consider daily oral PrEP or use other prevention methods for other types of exposures.




Because of the pharmacokinetics of TDF-containing oral PrEP, event-driven PrEP is not recommended for cisgender women and transgender men or non-binary people who have frontal or vaginal sex. Event-driven PrEP may be an appropriate option for all cisgender men (not just those who have sex with men), but little is known on oral PrEP dosing preferences among heterosexual cisgender men. Moreover, event-driven PrEP may be appropriate for transgender men and non-binary people assigned female at birth who exclusively have anal sex. However, there has been very limited research involving members from these diverse populations on preferences for different PrEP dosing regimens and the pharmacokinetics of TDF-containing oral PrEP, including in the context of gender-affirming care.[17]

17 Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

The world is working towards long-acting PrEP regimens. The first regimen for future use is cabotegravir injections and use of dapivirine vaginal ring. In 2021, WHO recommended that the dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches (conditional recommendation, moderate-certainty evidence)[18]. However, these regimens are not yet recommended for use in Nepal. In Nepal, daily PrEP is the currently recommended PrEP choice.

18 Ibid.

# Annex 10: Toxicity grades of adverse events

The significance of an adverse event is used to describe the patient/event outcome or action criteria associated with events that pose a threat to a patient's life or functioning (i.e., moderate, severe or life threatening). Based on the National Cancer Institute Guidelines for the Cancer Therapy Evaluation Program[19], severity can be defined by the following grades of events:

**Grades 1**: are mild adverse events. (e.g., minor event requiring no specific medical intervention; asymptomatic laboratory findings only; marginal clinical relevance)

**Grades 2**: are moderate adverse events (e.g., minimal intervention; local intervention; non-invasive intervention; transfusion; elective interventional radiological procedure; therapeutic endoscopy or operation).

**Grades 3:** are severe and undesirable adverse events (e.g., significant symptoms requiring hospitalization or invasive intervention; transfusion; elective interventional radiological procedure; therapeutic endoscopy or operation).

**Grades 4:** are life threatening or disabling adverse events (e.g., complicated by acute, life threatening metabolic or cardiovascular complications such as circulatory failure, hemorrhage, sepsis; life–threatening physiologic consequences; need for intensive care or emergent invasive procedure; emergent interventional radiological procedure, therapeutic endoscopy or operation).

**Grades 5:** are fatal adverse event resulting in death.

19 Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0, November 27, 2017
U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute

# Annex 11: Detail instructions for logistics management of PrEP medicines

**Receiving of PrEP medicines:** Once the medicines arrive at the service delivery point, inspect the packaging of the medicines, tally the quantity, batch number of medicines as in the handover note and write any discrepancy noted on the handover note. Sign the handover note and send a copy of the handover note to National Center for AIDS and STD Control (NCASC).

**Preparing Good receipt note:**

- Write the name of your office/facility in Hospital/ clinic Name. E.g. SACTS, Kathmandu.
- Write the good receipt note number "दाखिला प्रतिवेदन नं". It is a serial number which starts from 1 in each fiscal year. E.g : GRN-NNSWA-2076/77-01
- Write the date the good received note is prepared against "दाखिला मिति".
- Write issue number which can be handover note number (हस्तान्तरण फारम नं.) or purchase order number (if the item is purchased from by the service delivery point.
- Write the stock book page number "जिन्सी खाता पाना नं." in which the commodity is entered in stock book.
- List the name of commodities in "सामानको नाम "as Emtricetabine 200 mg + Tenofovir 300 mg. This should match with the hastantaran farum as well as stock book.
- Write the specification of the commodities in the corresponding row of name of the commodities in the column "स्पेशिफिकेसन" as 200 mg/300 mg and unit in "इकाइ" as Tablet also write quantity received in "परिमाण" column.
- Sign the good receipt note "दाखिला प्रतिवेदन" by logistics focal person, Section Chief's signature and Office Head's signature with date.
- Send a copy to the issuing organization along with handover note and keep a copy for the office record.

**Entry in the Stock Book**: Enter the HIV commodities to stock book at its respective page following a recommendation described below:

*Starting a new stock book:*

- Write the name of your office/facility in Hospital/ clinic Name. E.g. SACTS, Kathmandu

- Write page number besides "जिन्सी खाता पाना न". Please note that the page number should be in a continuous manner.
- Write the name of the commodity besides "जिन्सी सामानको नाम :" as Emtricitabine 200 mg/Tenofovir 300 mg
- Write the unit of the commodity besides "इकाई" as tablet
- Write the specification of the commodity such as strength and description besides "स्पेसिफिकेसन:". E.g. 200 mg/300 mg.
- Write fiscal year besides "आर्थिक वर्ष". E.g. 2076/77.
- Write date in a "मिति" column and received quantity

*Recording the transaction:*

- Write in the date of the transaction in date "मिति" column. If you are carrying over the commodities from the previous fiscal year, write the page number of last year's Stock Book, and the first date of the fiscal year in the beginning line of the Stock Book. Write the total remaining quantity from last fiscal year's stock book in the balance column.
- If you are recording a receipt, write good receipt note number "दाखिला नं" in the "दाखिला नं / निकासा नं." column and write the quantity of HIV commodity received in "निकासा ( खर्च )" column. Write the balance quantity by adding up the remaining quantity in the stock book with the quantity you entered just now in "बाँकी" column.

Recording a transaction:

- Write in the date of the transaction in date "मिति" column. If you are carrying over the commodities from the previous fiscal year, write the page number of last year's Stock Book, and the first date of the fiscal year in the beginning line of the Stock Book. Write the total remaining quantity from last fiscal year's stock book in the balance column.

*If you are recording a receipt:*

- Write good receipt note number "दाखिला नं" in the "स्टोर दाखिला ( आम्दानी )." column.
- Write the quantity of HIV commodity received in "निकासा ( खर्च )" column.
- Write the balance quantity by adding up the remaining quantity in the stock book with the quantity you entered in the "बाँकी" column.
- Unit price and rate are not applicable for implementing partners of different projects of FHI 360.

*If you are recording an issue:*

- Write issued number in the "दाखिला नं / निकासा नं." column.
- Write the name of issuing facility in the remark's column.

- Write the quantity of the commodities that you are issuing in the "निकासा ( खर्च )" column.
- Write the balance quantity by subtracting the remaining quantity in the stock book with the quantity you entered just now in "बाँकी" column.
- Unit price and rate are not applicable for implementing partners of different projects of FHI 360.

*If you are recording consumption data:*

- Write the period of consumption data in date column.
- Write the quantity that are issued during the period (reference of the data is the daily consumption register) in the "निकासा ( खर्च )" column.
- Write the balance quantity by subtracting the remaining quantity in the stock book with the quantity you entered just now in "बाँकी" column.
- Unit price and rate are not applicable for implementing partners of different projects of FHI 360.

*If you are entering loss and adjustment during physical verification, then follow the following:*

- Write the date physical verification is done in the "मिति" column.
- If there is loss and adjustment column in the format, write down quantity in the column with "+" sign for adjustment and "-" sign for losses and describe the reason for loss or adjustment in remarks column.
- But if you do not have loss and adjustment column then, write losses in the "निकासा ( खर्च )" column and describe the reason for loss in the "मालको भौतिक अवस्था" and add physical verification besides that.
- Write adjustments in the "स्टोर दाखिला ( आम्दानी )." column and describe the reason for adjustment in the "मालको भौतिक अवस्था" and also write physical verification besides that.
- Write the balance quantity by subtracting or adding the remaining quantity in the stock book with the quantity you entered just now in "बाँकी" column.
- Unit price and rate are not applicable for implementing partners of different projects of FHI 360.
- Sign each page of the stock book Storekeeper's signature, Section Chief's signature and Office Head's signature with date. The signatures are done at the end of the fiscal year or end of the page. Once signatures are done, data entered in the page cannot be changed.

*The transactions recorded in the stock book are reported in a bimonthly report in*

*Combined Report – Requisition and Issue form for ARV Medicines*

**Maintaining Daily Consumption Register:**

Daily consumption records and filled whenever supplies are dispensed to clients or used by service providers during service provision. For recording PrEP medicines, daily consumption record of ARVs is used.

- Write the name of your facility, month & year.
- Write total number of clients in this month. This is a cumulative number for a month and start with one for each month.
- Write the consecutive number of this entry in "क्र.स." column. Always start from one.
- Write the date in "मिती" column. Use new page for a new date.
- Write client no. in "बिरामी नं" column.
- Write the number of tablets in the corresponding medicines and take a signature of the client as a proof of receipt of medicines by the client.
- Write the total number of medicines in each of column "जम्मा वितरण गरेको परिमाण". This is the total of this page.
- Write the total number of medicines from the first day of the month till this day in the "हालसम्म वितरण गरिएको जम्मा".
- If the medicine is not used in the day, then write "0" in the both rows "जम्मा वितरण गरेको परिमाण" and "हालसम्म वितरण गरिएको जम्मा".
- The daily consumption record is reported in Stock book for recording consumption & Combined bimonthly report of ARV medicines

**Preparing combined bimonthly report of ARV medicines**

- Write the name of your facility. E.g. SACTS, Kathmandu.
- Write the two months that you are reporting besides "Two months reporting interval". Eg. Shrawan-Bhadra and write the current fiscal year besides year. E.g. 2076/77
- Write the order prepared date, that is, date the report is being prepared.
- Copy the ending balance of the last reporting period and paste in the beginning balance column (column A) of the current reporting period.
- Add the quantities of each commodity that you received in the current reporting period. This should match with stock book. If the source of commodity is different than NCASC, mention in the remark column. Write the quantity in the quantity received column (Column B).
- Calculate the total consumption quantity from the daily consumption

record "हालसम्मको जम्मा" and put the number in the corresponding commodities under the column quantity consumed (Column C).

- Write the lost and adjusted quantities from the stock book in the loss and adjustment column (Column D). Number of medicines, test-kits or other commodities that are expired, broken or that are returned from other facilities are recorded as loss and adjustment. Commodities that cannot be used is to be deducted (-) and commodities returned from other facilities are added (+) to the stock. Do not forget to write "-" sign in the lost commodities.
- Calculate the ending balance using the formula: Ending balance (E)= {Beginning balance (A) + Received Quantity (B)} – (Consumed Quantity (C) + Adjustment) - Losses (D)
- Calculate the maximum stock by multiplying Consumed quantity by "2": Maximum stock (F) = 2 x consumed quantity (C)
- Calculate the Quantity to order (G) by subtracting Ending Balance (E) from maximum stock (F)
- Quantity to order (G) = Maximum stock (F) – Ending Balance (E)
- Sign the report by concerned official and stamp with office stamp.
- Scan the report and send the scanned report along with excel sheet.

*Note: The report format is in excel with auto calculation of Ending balance, Maximum stock and quantity to order.*

**Store Management**

- Store all drugs/supplies in the locked room to prevent theft. Only authorized person should be allowed inside storeroom. Take necessary precautions during transportation.
- Keep the storeroom clean and unpolluted. There should be proper cleaning schedule with use of disinfectants which prevents entering of harmful insects.
- Prevent PrEP medicines from direct sunlight and keep these commodities in well lit, dry, and ventilated storeroom as indicated in the label.
- Store in a dry, well ventilated place temperature not exceeding 30° C.
- Separate batch of PrEP medicines need to be piled up separately.
- Expiry tracking chart need to be updated and First Expiry First Out (FEFO) need to be followed by dispensing first expiring medicines first. Practice to update on expiry tracking chart as you receive the supplies and regularly review the chart.

- Perform physical verification to find out any discrepancies in the stock book. Count the total number of tablets available, their physical status and record any discrepancies.
- Separate all damaged and expired medicines, test kits and HIV commodities from useable commodities and destroy them as per the procedure/guidelines/rules at local level. Record the deduction in stock book. The damaged and expired drugs occupy the space and affect the first in, first out (FEFO) system.

*Proper maintenance of stock book, temperature monitoring chart and following of expiry tracking charts assure that the commodities stored are managed properly.*

**Review of Stock**

- *Calculate Average Monthly Consumption (AMC):* Collect consumption data of at least two reporting period. Divide the consumption by number of months of consumption.
  For example, if the consumption of PrEP medicines of reporting period Chitra–Baishakh is 500 kits and for Jestha–Asar is 700 kits, we calculate AMC using the formula:
  AMC = Total number of consumption of kits in "n" number of months.
  Or, AMC = (500 + 700) kits/4 months = 300 kits
- *Calculate the Months of Stock on Hand (MoSoH):* Calculate the stock on hand (SoH) from stock book. This should be physically verified to determine actual stock that are useable. SoH can be calculated using the following formula:
  SoH = Beginning balance + Received quantity-consumption ± loss and adjustment
  Now divide the SoH by AMC. Months of Stock tells us how many months the current stock will last if future consumption remains the same as current consumption.
  MoSoH is calculated using the formula:
  MoSoH = SoH/AMC

Use following table for actions to take after reviewing the stock:

| Situation No. | Situation | Interpretation | Decisions |
|---|---|---|---|
| 1 | Months of stock is between four months and two months. | Stock status is adequate. | No action required. |
| 2 | Months of stock is greater than four months. | The service delivery point is overstocked with this product. | Contact NCASC and discuss the stock status of the product. If some or all of the stock will expire in the near future, you can transfer some stock to another facility that may be able to use it more quickly. |
| 3 | Months of stock is less than two months, but greater than one month. | The service delivery point is understocked with this product, but stock levels have not yet reached the emergency order point of 1 month. | Verify that your order has been placed. Continue to monitor stock levels until the next delivery arrives, or until they reach the emergency order point. |
| 4 | The number of months is equal to or less than one month. | The service delivery point is understocked of this product. The stock level is at or below the emergency order point of one month. | Contact NCASC and discuss the stock status of the product. An emergency order may be needed. |

Results of review of stock are reflected in bimonthly report and handover note (हस्तान्तरण फारम)

# Annex 12: Participants of the workshop for finalization, August 12, 2021

1. Dr. Sudha Devkota, Director, National Centre for AIDS and STD Control, Kathmandu
2. Dr. Anup Banstola, Director, Shukraraj Tropical and Infectious Disease Hospital, Kathmandu
3. Dr. Pawan Shah, Senior Medical Superintendent, National Centre for AIDS and STD Control, Kathmandu
4. Prof Dr. Sushil Shakya, ART expert and clinician, Kathmandu
5. Dr. Suresh Prasad Nepal, Senior Consultant, National Academy of Medical Sciences, Bir Hospital, Kathmandu
6. Mr. Deepak Dahal, Statistics Officer, National Centre For AIDS and STD Control, Kathmandu
7. Mr. Lokraj Pandey, Senior Health Education Officer, National Centre for AIDS and STD Control, Kathmandu
8. Ms. Laxmi Pandey, Senior Community Nursing Officer, National Centre for AIDS and STD Control, Kathmandu
9. Dr. Rajya Shree Kunwar, Senior Program Manager, Save the Children, Kathmandu
10. Dr. Prakash Shakya, Technical Advisor, Save the Children
11. Mr. Komal Badal, UNAIDS, Kathmandu
12. Dr. Sabin Thapaliya, Consultant Physician, Tribhuvan University Teaching Hospital, Maharajgunj
13. Dr. Parmeshwari Shrestha, Medical Officer, Shukraraj Tropical and Infectious Disease Hospital, Kathmandu
14. Dr. Unnat Shrestha, Medical Advisor, AIDS Health care Foundation Nepal, Kathmandu
15. Mr. Bhagawan Shrestha, Country Director, FHI 360 Nepal, Kathmandu
16. Dr. Durga Prasad Bhandari, Senior Technical Advisor, EpiC/FHI 360 Nepal, Kathmandu
17. Dr. Kriti Adhikari, Technical Specialist, EpiC/FHI 360 Nepal, Kathmandu