Royal Government of Bhutan

Ministry of Health

Standard Operating Procedure for Pre-Exposure Prophylaxis for HIV in Bhutan

Save the Children

SKPA·2

October 2024

Contents

FOREWORD

It is with great anticipation and a deep sense of purpose that we introduce the Standard Operating Procedure (SOP) for Pre-exposure Prophylaxis (PrEP) for HIV in Bhutan. Set to be launched in a phased approach in October 2024, this initiative marks a significant milestone in our ongoing efforts to combat HIV and improve the health outcomes of populations at substantial risk of acquisition of HIV.

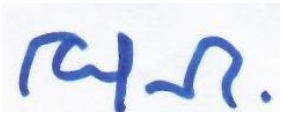
Developed through an evidence-informed framework, this SOP embodies a commitment to equitable access to healthcare leaving no one behind. We recognize that the fight against HIV requires the active participation of all sections of society, and therefore, this initiative is meticulously designed to ensure that every individual, regardless of their background or circumstances, can access the preventive measures when they are at high risk of acquisition of HIV.

Central to our approach is the affirmation of human rights. We firmly believe that health is a fundamental human right, and as such, every person should be empowered to make informed choices about their health. This SOP reflects a dedication to fostering an environment that respects individual dignity through a person-centered approach and offers support and resources without stigma or discrimination.

In addition to addressing HIV prevention, this SOP adopts a comprehensive public health approach that integrates the management of sexually transmitted infections (STIs), hepatitis, reinforces early referral of HIV cases for initiation of Antiretroviral Treatment (ART) and provide non-occupational Post-Exposure Prophylaxis (PEP) within 72 hours for those exposure to HIV risk. By incorporating these elements, we aim to promote overall sexual health and well-being, recognizing the interconnectedness of these conditions.

We extend our gratitude to the countless individuals, organizations, and stakeholders who have contributed their time, expertise, and passion to this project. Your unwavering commitment to advancing public health in Bhutan is invaluable. Together, we can build a healthier future for all, ensuring that everyone is informed, empowered, and cared for.

As we prepare to take the first steps in this essential initiative, we urge all healthcare providers, community organizations, and support networks to embrace this SOP and work collectively towards its successful implementation. Let us stand united in our resolve to end the HIV epidemic, foster inclusivity, and promote the health and rights of all individuals in Bhutan.



[Pemba Wangchuk]
[Secretary]

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ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reactions	**GC**	Gonococci
AHI	Acute HIV Infection	**HBsAG**	Hepatitis B surface Antigen
AIDS	Acquired Immune Deficiency Virus	**HCV**	Hepatitis C virus
ART	Antiretroviral Therapy	**HISC**	Health Information & Service Center
ARV	Antiretroviral	**HIV**	Human Immunodeficiency virus
CAB-LA	Long Acting Injectable Cabotegravir	**HIV-ST**	HIV Self testing
CBO.	Community Based Organization	**HPV**	Human Papillomavirus
CSO	Civil Society Organization	**HRW**	High risk Women
CSW	Commercial Sex Worker	**KPO**	Key population organization
CT	Chlamydia Trachomatis	**LTFU**	Lost to follow up
DSD	Differentiated Service Delivery	**MSM.**	Men having sex with men
DVR	Dapivirine Vaginal Ring	**NACP**	National AIDS control Program
EB-PrEP	Event-Based PrEP	**NG**	Neisseria gonorrhoeae
ED-PrEP	Event- Driven PrEP	**NSP**	Needle and Syringe Program
eGFR	Estimated Glomerular Filtration Rate	**ORW**	Outreach Worker
ELISA	Enzyme -Linked Immunoassay	**PEP**	Post-exposure prophylaxis
FTC	Emtricitabine	**POW**	Peer Outreach Worker
PrEP	Pre-exposure prophylaxis	**SW**	Sex Worker
PWID	People who inject drugs	**TAG**	Technical Advisory Group
PWUD	People who use drugs	**TDF**	Tenofovir disoproxil fumarate

RDT	Rapid Diagnostic Test	**3TC**	Lamivudine
RFT	Renal function test	**TGM**	Transgender Men
SAE	Severe Adverse Events	**TGP**	Transgender people
SDC	Serodiscordant couples	**TGW**	Transgender Women
STI	Sexually transmitted infection	**TPHA**	Treponema pallidum hemagglutination Assay
SUSARs	Suspected unexpected serious adverse reaction	**WHO**	World Health Organization

1. BACKGROUND

In 2015, WHO recommended offering oral PrEP containing tenofovir (TDF) as part of the combination prevention package for people at substantial risk of acquiring HIV, such as men having sex with men, sex workers and transgender people adding to the arsenal of a combination of preventive measures for key populations.

There is growing optimism that pre-exposure prophylaxis (PrEP) could have a major impact on preventing incident HIV infection. PrEP has the potential to contribute to effective and safe HIV prevention when it is used in individuals at substantial risk for HIV acquisition and offers greater benefits when delivered as part of a comprehensive package of prevention services that include risk reduction and PrEP medication adherence counseling, ready access to condoms, diagnosis and treatment of STIs, psychosocial support and monitoring of HIV status, side effects, adherence and risk behaviors.

Key populations such as sex workers, men who have sex with men, and transgender people and people who inject drugs could benefit from PrEP but WHO has been moving away from referring to only "people with substantial risk, for HIV" as to who can benefit from PrEP, so even young people, including adolescents could benefit from PrEP during the national roll out. In sum, PrEP should be an opportunity to better understand HIV and STIs including viral hepatitis prevalence within certain districts/catchment areas and for people who inject drugs/people who use drugs (PWID/PWUD) in Bhutan.

Despite Bhutan being a low-prevalence country for HIV, there is an opportunity to strengthen HIV prevention services by the introduction of PrEP, with a focus on key populations. There is growing concern that the HIV epidemic is concentrated among the key populations and their partners. More than 82% of the reported HIV infections are attributed to heterosexual HIV transmission with approximately half of these cases associated to sex work. In Bhutan the estimated 97% of high-risk women exchanged sex for money and also reported the highest level of unprotected sex in the last 30 days (76%) (3) Further, HIV prevalence among the subgroups of the key population was found to be higher than in the prevalence in the general population (3% in the female sex workers and 2% in the so-called "high risk women", 3% in among transgender people and 1.5% among MSM).

It is a clear indication for the need to prioritize our interventions on the key populations and improve the quality and coverage of services for them and to address the barriers faced by them to access health services. It has been well recognized that there is a clear gap in HIV testing coverage for key populations. Stigma and discrimination remain a critical barrier in people most affected by HIV to actually access services, and is reflected in the gap in HIV testing coverage. PrEP in Bhutan can be the gateway/opportunity for actually strengthening sexually transmitted infections (STI) management, including implementing asymptomatic STI testing for Gonorrhea / Chlamydia and appropriate treatment throughout the country. There are challenges (and implications) in the HIV response as far as late HIV diagnoses; for treatment initiation, depending on the provider and the setting, people can take many weeks to initiate antiretroviral treatment (ART) after a diagnosis (5)

For the phased implementation, Bhutan has taken the global and regional lessons and adapted the WHO Differentiated Service Delivery model for PrEP (Annexure 4). The implementation will be phased in gradually and is expected to generate critical information, learnings and recommendations before a full-scale nation-wide rollout in 2026. A focus on young people, including adolescents, should be a key component of the targeted approach to PrEP in Bhutan.

The approach adopted in Phase 1 is a pragmatic one with the outreach workers and Community Based Organization/ Key population Organization (CBO/KPO) like Pride Bhutan will be central to the services delivery of PrEP from identifying prospective clients to linkage to services and referral to PrEP delivery sites. The CBOs /KPOs and peer outreach workers (POW) are empowered to get clients for PrEP and stay on PrEP by assisting HIV self-testing, delivering PrEP medicine, client engagement, quality counseling to maximize effective use and retention when those using PrEP want to be maintained in services.

PrEP is also a gateway to strengthen STI management in Bhutan and will be included in the comprehensive service package for PrEP and later on will be adapted and implemented based on WHO's PrEP/STI integration guidance.

1.1 Purpose:

This SOP outlines the procedures, roles and responsibilities of the PrEP providers involved in the implementation of PrEP in Bhutan. The aim is to ensure a standardized approach to deliver PrEP services, facilitating access, adherence and ongoing support for the clients.

1.2 Scope:

This SOP is for the initiation of PrEP services for the target population (MSM, TG and Sex workers) in Thimphu and Paro in the Phase 1 of the implementation and covers standardized method of assessments of potential clients in the target group (MSM, TG and Sex workers), procedures for PrEP initiation and follow-up of clients, recording and reporting systems and client education and counseling on benefits of PrEP, usage of PrEP, adherence and side effects related to prevention of HIV acquisition.

1.3 General principles of the SOPs

This SOP acknowledges the importance of community-lead services and ensures that the community-lead services remain the program's primary focus in delivery of PrEP in Bhutan. In line with the global and regional principles for achieving the Sustainable Development Goal the PrEP implementation plan includes the following guiding principles:

A. **Evidence-informed** programming in providing quality care within the broader framework of quality health service provision.
B. **Equitable Access**: Identify individuals at highest risk of HIV acquisition and ensure access to combined HIV prevention packages.
C. **Human rights-based approach**: enable and empower individuals to make informed choices of HIV prevention options through a public health approach which includes confidentiality, access to non-discriminatory healthcare, privacy, choice and shared responsibility.

D. **Integration**: PrEP as a gateway to strengthen STI services and broader sexual and reproductive health services

1.4 Prerequisites for PrEP Services

A. ***PrEP Medications,*** Tenofovir Disoproxil fumarate (TDF) 300mg+Lamivudine (3TC) 300 mg is in the *National Essential Drug List 2021* and registered by Drug Regulatory Authority for use in Bhutan.
B. ***National guidelines for HIV Counseling and Testing*** with differential HCTs delivery approaches are already being implemented in Bhutan for HIV testing including Community-based testing services enabling HIVST test for triage-community-based HIV testing.
C. ***National ART Guideline of Bhutan 2024*** has updated PEP and incorporated non-occupational PEP which is an important component of PrEP.
D. ***The National HIV testing algorithm*** is aligned to WHO testing strategy.
E. ***The existing Human resources at the health facilities*** and existing facilities are adequate to provide the services in the comprehensive package for PrEP with only slight reinforcements.
F. ***The Community-Based Organization (Pride Bhutan)*** has committed community workers who are trained to deliver HIVST and are already experienced in providing community outreach services for HIV.

2. OVERSIGHT AND COMMUNICATION ARRANGEMENTS FOR PrEP

For the smooth implementation of PrEP and flow of communication/ reporting systems for PrEP the organogram below outlines the oversight and communication arrangements (Figure 2-1) to deliver PrEP.

The Technical Advisory Group (TAG) for HIV is the highest body that provides policy directive on all matters related to HIV/AIDS in Bhutan. For PrEP implementation the Technical Working Group (TWG), an expansion to the members of TAG includes professionals who provide services at the District and Primary Health Care levels, members from The Community- Based Organization. The TWG role is to support development of the operational plan for PrEP and ensure meaningful community engagement from the very beginning to strengthen participation and ownership of this PrEP program for a seamless nation-wide roll out in 2026. The TAG and TWG will advise NACP in all policy and technical matters related to PrEP.

The National Coordinator plays a pivotal role to support NACP in coordinating activities during planning and implementation phases of PrEP and is the key link between the NACP at the Ministry of Health and the PrEP sites. Each PrEP site has designated a PrEP Coordinator who will be the focal point for the respective PrEP site and is responsible to coordinate all activities related to PrEP within and outside.

Each PrEP site will have dedicated PrEP teams that will be led by the Medical Officer in the hospital-based setting or the Health Assistant at the Health Information and Service Centre (HISC) and at the Community based Organization (Pride Bhutan). The Medical Doctors,

Clinical Officers, Health Assistants are allowed to prescribe medications in Bhutan. They will provide the oversight required for the provision of PrEP. The VCT counselors are Health Assistants trained and certified to provide VCT services for HIV and are based in hospitals or HISCs.

The HISCs are supported by the outreach workers who are members of the key population groups. They provide peer outreach services within the HISC and go out in the communities to provide community outreach. Pride Bhutan will play a critical role in PrEP implementation in community mobilization for PrEP and provide outreach services such as HIV ST and follow-up call-ins and reminders to those on PrEP to ensure adherence and continuation of PrEP. The Community outreach workers are trained and certified for providing HIVST in the communities. The Terms of References of the Committees and members of the PrEP team are clearly defined (ANNEX 1).

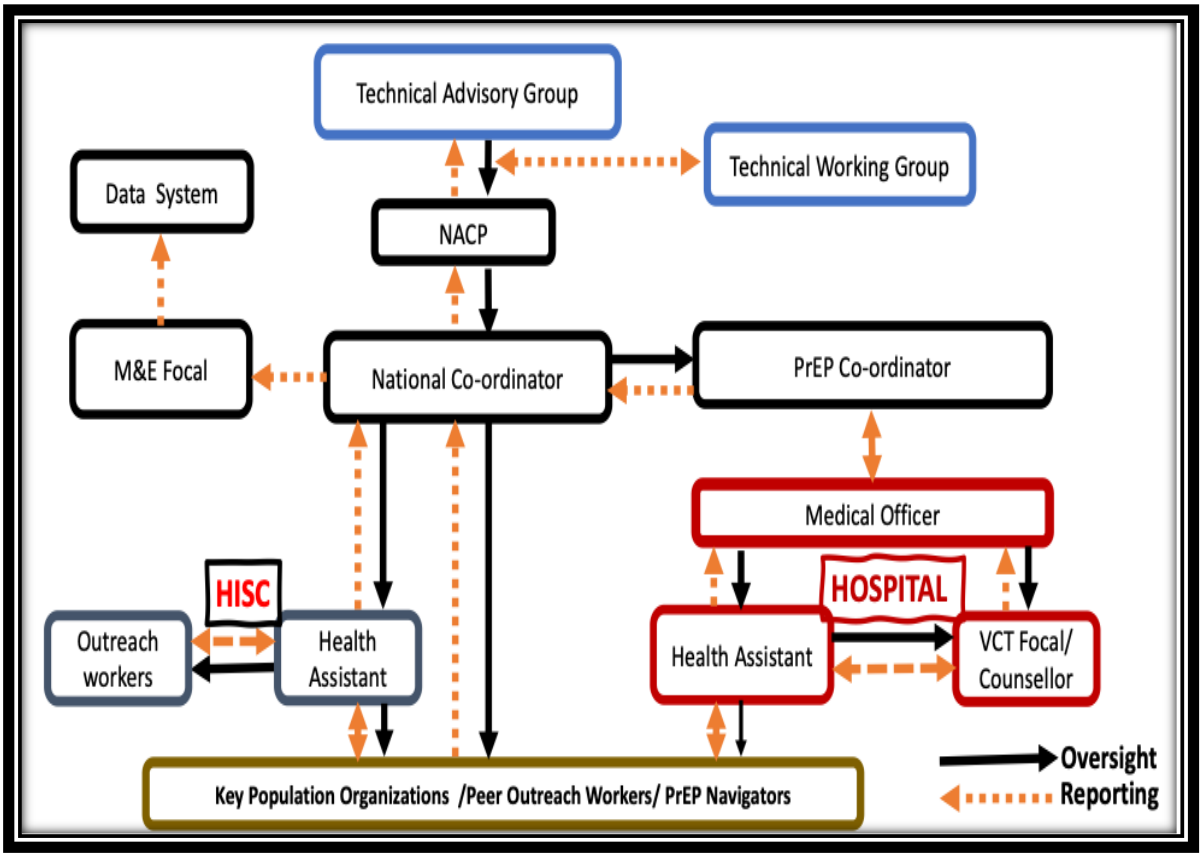

Figure 1. Oversight and Communication arrangements for PrEP Implementation

3. CLIENT FLOW AND REFERRAL ARRANGEMENTS FOR PrEP

PrEP delivery approaches adapted and planned are Facility-based approach through hospitals and HISCs and Community-based approach through Community Based Organization (Pride Bhutan) and their network of outreach workers in Thimphu and Paro.

For the seamless provision of patient-centered, quality PrEP services the client flow and referral mechanism have to be planned well. This section has been developed in consultation with the PrEP Coordinators from the eight PrEP Sites for Phase 1 and Phase 2. The hospital - based PrEP sites are very well equipped both in terms of range of services and infrastructure. The tertiary and district level hospitals have almost full capacity to provide the comprehensive service package for PrEP.

The HISCs have limited range of service and space to provide the comprehensive package for PrEP therefore, for the additional laboratory procedures the HISC will need to refer the clients to the hospital for the baseline procedures. For the Community-based approach the strength lies in their community network and their reach although the space and services that they can deliver are limited. The Community-based organization (Pride Bhutan) has a pivotal role in reaching the communities through the demand generation campaigns.

Community outreach workers under Pride Bhutan have been trained in HIV-ST and HIV counseling. With some support and empowerment on PrEP services, they can be instrumental in supporting the potential PrEP clients and support PrEP services delivery to the communities. The hospitals currently do not directly involve Community outreach workers for any service related to key populations. For PrEP implementation support will be needed to reach the communities. The hospitals would need the support of the community outreach workers for delivering PrEP services such as client motivation, follow up and facilitation of referrals to the health facilities. Support and oversight from HISC and hospitals will be needed to support Pride Bhutan in delivering person-centered PrEP services in the communities.

The PrEP coordinators have a key role and responsibility to ensure that PrEP service delivery is well planned and coordinated (Figure 3-1).

For any policy and technical matters related to PrEP that needs urgent attention and decision, the TAG / TWG will be the highest body to resolve issues, advice and provide directives therefore TAG/TWG is placed as an overarching umbrella for the PrEP implementation in Bhutan and will have significant responsibility to shoulder.

The plan is to have every person involved in delivering PrEP service listed and their responsibilities made very clear. A directory of PrEP service providers and PrEP teams in PrEP sites will be developed so that clients have access to the PrEP providers if they have any issues related to PrEP usage, side effects and medicine refills.

Demand generation campaigns led by the Community based Organization (Pride Bhutan) will be key to the PrEP implementation as Bhutan paves way for introduction of PrEP. Community outreach workers and Peers will play an important role in creating awareness and motivating the potential clients to show up for PrEP to the PrEP sites identified.

Their role is to identify potential clients and refer them to the PrEP sites. Depending on where they reside, they will access the PrEP site most convenient for them to go to for the scheduled visits. The PrEP sites will provide services that are available in their facility and if not facilitate and arrange appointments /referrals for services that are not available.

Bhutan does not have any private clinics, and all health services are provided free of cost by the government. The PrEP sites identified range from apex hospital in the country, a district hospital, a HISC and the Community Based Organization (Pride Bhutan). This 1st Phase of PrEP implementation is developed taking into consideration the challenges the key population face in terms of access to health services. With well-defined roles and responsibilities of all the PrEP providers, clear communication strategy and facilitated referral systems and processes of PrEP delivery. it is anticipated the access to health services for the key populations will be enhanced and get addressed.

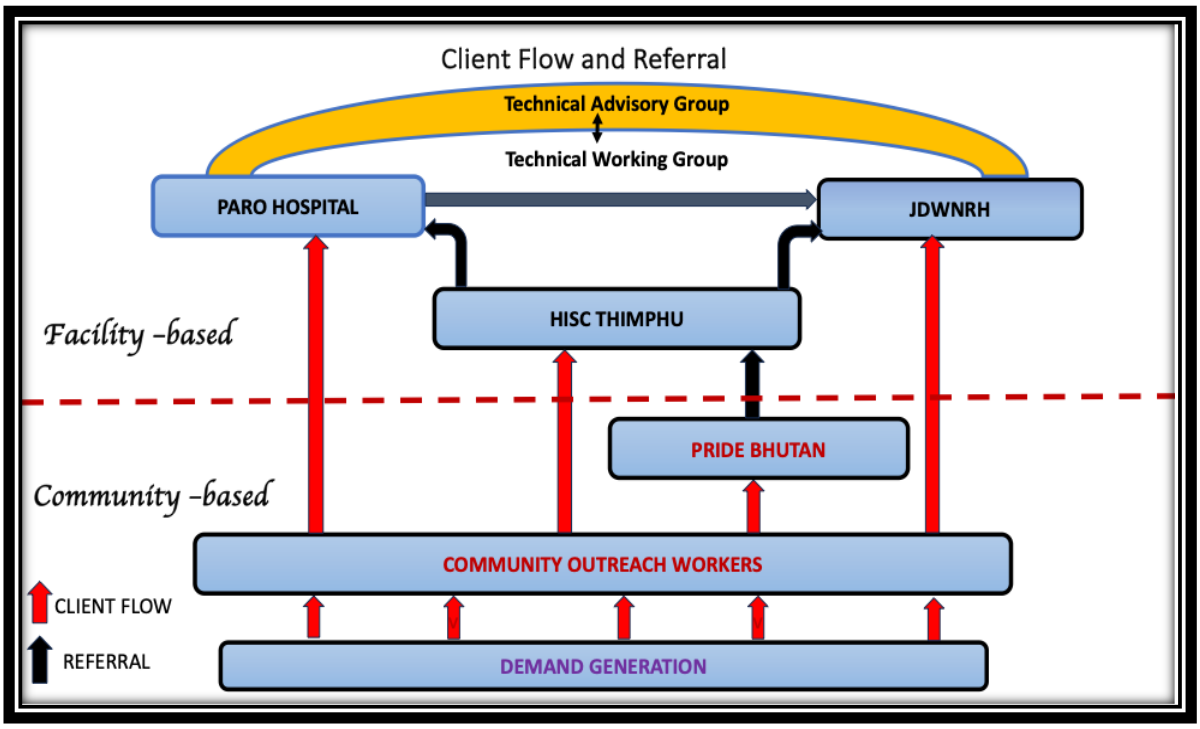

Figure 2. Client Flow and Referral

3.1 Community Health Department/JDWNRH CLIENT FLOW

The Community Health Department in JDWNRH will be the PrEP site for Thimphu. The hospital has facilities for all the laboratory procedures in the comprehensive package for PrEP including PAP smear, culture and sensitivity for bacterial STIs. The hospital has Adolescent Friendly Health Services and Pre-natal Unit, Antenatal, Postnatal and Family planning Unit, HIV care and treatment unit and potential clients for PrEP may be referred from Units within the hospital. Clients for PrEP may walk in or come through referrals from Pride Bhutan and from HISC.

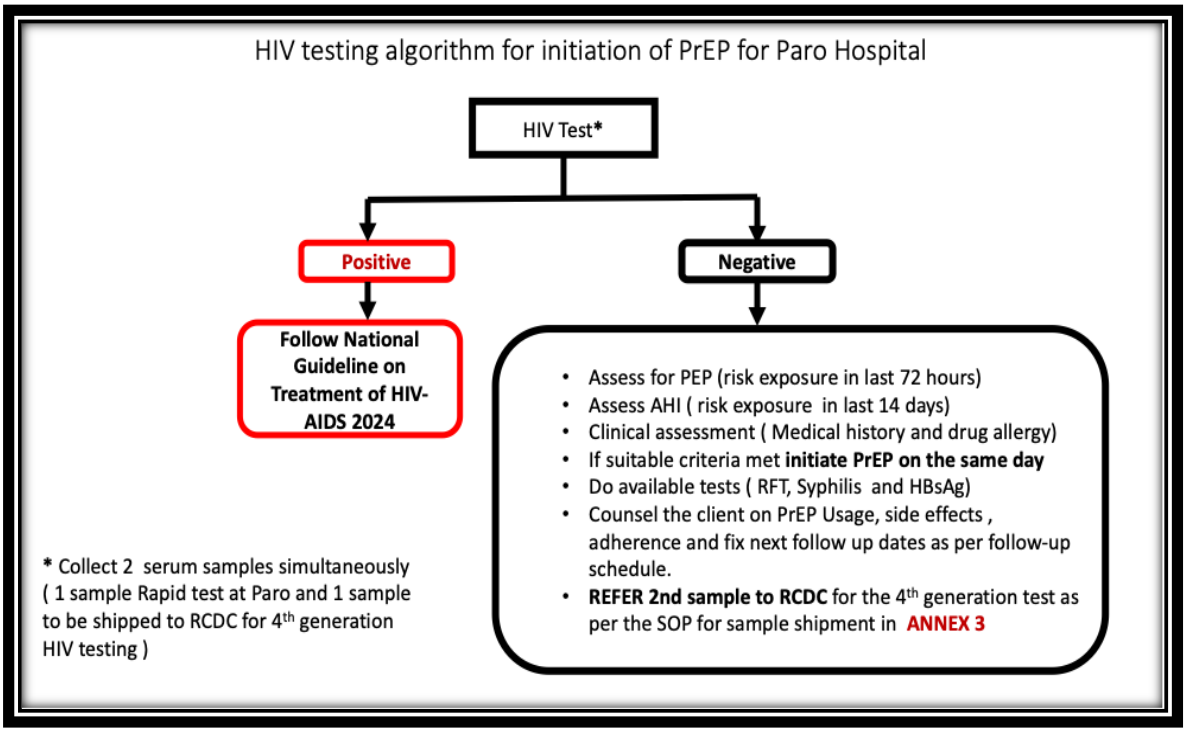

Figure 3. Client Flow and Referral Paro Hospital

3.2 Paro Hospital Client Flow

Paro District hospital has Adolescent Friendly Health Services, ANC, PNC and family Planning services. The hospital has a laboratory with capacity to provide the tests in the comprehensive package. The potential clients for PrEP are expected to flow in mostly from within the various units in the hospital, referred from the community outreach from Pride Bhutan and HISC Thimphu outreach in Paro area and some walk-in clients.

3.2.1 Referral from Paro hospital to JDWNRH

Paro hospital will need to refer clients on PrEP with medical comorbidities to JDWNRH for specialized care. As per the HIV testing for PrEP initiation, For Paro catchment area two simultaneous serum samples will be collected. Conduct rapid test for one sample and send the 2nd sample for 4th generation ELISA HIV test to Royal Centre for Disease Control (RCDC). If the rapid test is negative and if clinical criteria is met PrEP can be initiated based on the Rapid test result at Paro hospital without waiting for the 4th generation HIV test result. In case the 4th

generation HIV test comes positive PrEP can be immediately stopped and the client referred for ART to be started as soon as possible.

3.3 HISC Client Flow

Clients could walk in on their own will or are referred by outreach workers from Pride Bhutan or from communities in Thimphu and Paro **(Referred in figure 02).**

3.3.1 Referrals from HISC to JDWNRH

A. If a client is HIV positive refer to as per the ART guideline.
B. Those indicated for PEP should be referred to as the National Guideline on Treatment of HIV-AIDS 2024.
C. Those with underlying comorbidities and who test positive for HBsAg will need to be managed by the Specialist.
D. For all laboratory tests (STIs, RFT, 4th generation ELISA HIV test).

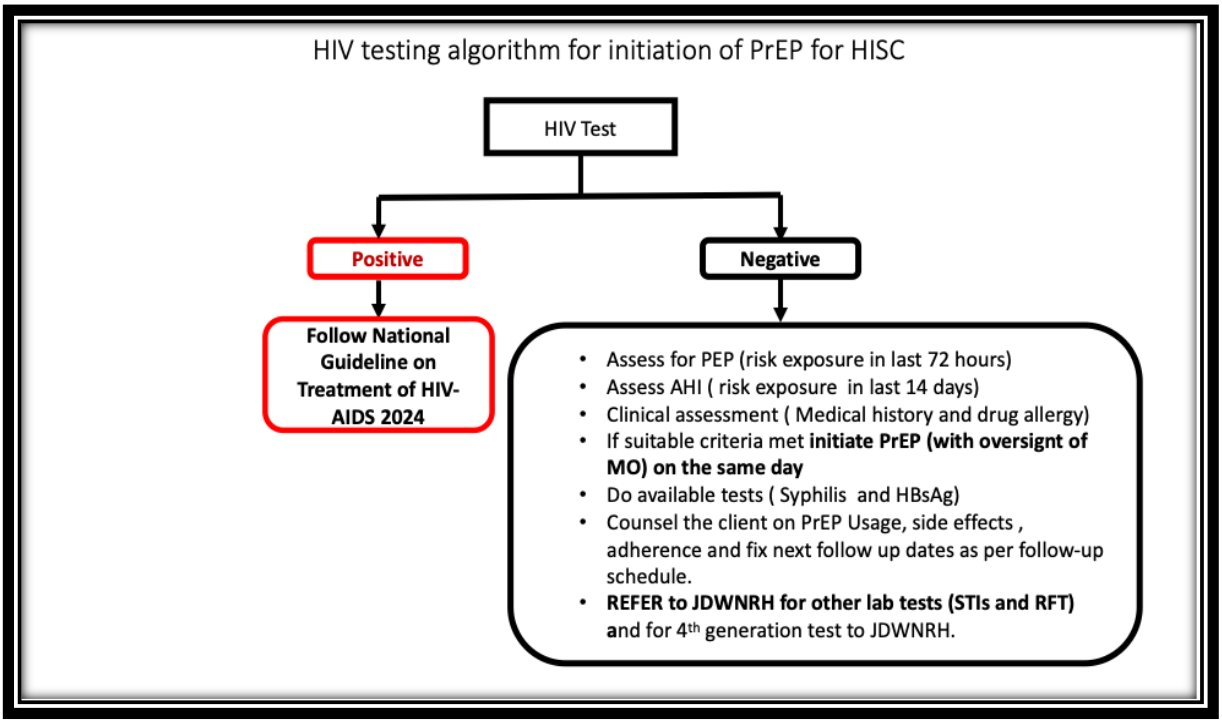

Figure 4. HIV testing algorithm for initiation of PrEP for HISC

3.4 Community-based approach through Peer Outreach workers (PRIDE BHUTAN)

3.4.1 HIV-ST

A. Clients may walk into Pride Bhutan Office, or they may be in the community/home and may request for PrEP.
B. If the client requests PrEP the outreach worker will conduct HIVST as per the protocol.
C. If HIVST is non-reactive
    - ORW will inform the client about the HIV test result and explain the next steps that the health workers need to clinically assess (such as rule out HIV risk exposure in the last 72 hours and AHI) to ensure that the client meets all suitability criteria, contraindications and other underlying medical conditions are ruled out before PrEP is initiated.
    - Explain about follow up scheduled visits at month 1 and every three months, benefits of PrEP, potential side effects, about adherence to PrEP. (The standard information must be read to each client).
D. Then Outreach workers will coordinate with the PrEP Coordinator of the respective HISC or Hospitals and arrange referral for completing the lab procedures and initiating PrEP.
E. The referrals will be documented in the ORW form and reported every month. Pride Bhutan will report on the number of potential clients reached and referred to various facility based PrEP sites.
F. They will be responsible for keeping an updated list of clients who are on PrEP and follow them up on a weekly basis to ensure that they are adhering to PrEP and using them appropriately.

4. PROCEDURES FOR STARTING PrEP AND DURING FOLLOW-UP

4.1 Behavioural Risk Assessment

- If a person comes and requests PrEP, proceed with clinical suitability assessment. He has a self-perceived risk of HIV infection and might want to enroll for PrEP.
- If the person has low or no risk but asks for PrEP, find out if he is likely to have risk of exposure to HIV in the days ahead and in such case, PrEP may be considered after clinical assessment. Those with low risk should be counseled to use **combination prevention measures** (such as limiting the number of sexual partners, testing HIV and STIs status at least once a year, using condoms and lubricants, seeking PEP treatment if exposed to HIV risk in the last 72 hours).
- If the person is unsure whether to start PrEP or not it is important to assess the risk for HIV before proceeding for clinical suitability assessment. **To identify potential candidates for PrEP**, it is important to understand the factors that put people at increased or substantial risk for HIV.

4.1.1 Risk Factors:

Some of the high HIV risk factors to consider are:

- Having an HIV positive sexual partner with whom condoms use is **inconsistent** and who are either **not on ART**, if on ART **not yet virally suppressed** or **not adherent to ART**.
- Engaging in anal or vaginal sex (receptive or penetrative) with **multiple partners without condoms/inconsistent condom** use in the last 6 months.
- Engaging in transactional sex.
- **Inconsistent condom** uses with a partner of **unknown HIV** status.
- **History of STI in the last 6 months** by laboratory report or self-reported syndromically.
- History of **repeated use of non-occupational post exposure prophylaxis** (PEP).
- Having a **self-perceived risk of HIV** infection and requesting PrEP.
- History of sex whilst **under the influence of alcohol or recreational drugs** as a habit.

4.2 HIV Testing

4.2.1 HIV self-test (HIVST)

It is used for the population at risk at the district hospitals, HISCs and at the community level. Outreach workers under Pride Bhutan and HISC are trained and certified to use HIVST and pre and post-test counseling. As per the existing protocol for the use of HIVST, the reactive cases are referred to the HISC and the non-reactive cases are linked to preventive services for HIV. Any HIVST done outside of a health facility will not be used for PrEP initiation and scheduled PrEP follow-ups. HIVST can be done in between scheduled PrEP visits to give assurance and confidence if the client wishes.

Rapid Test (Antibody Testing)

It is conducted at all district hospitals and the 4th Generation ELISA Test is conducted only at RCDC (Regional Center for Disease Control) and JDWNRH.

4.2.2 Baseline HIV Testing for PrEP Initiation

- For PrEP initiation in Bhutan two tests will be performed at baseline (a rapid antibody test and a 4th generation ELISA simultaneously). The hospitals will collect two samples of blood and conduct the rapid test and ship the other sample to Thimphu (JDWNRH /RCDC) as per the SOP for handling and shipment of samples (ANNEX 3) where the 4th generation test is available. **A 4th generation test done simultaneously will be mandatory for initiation of PrEP.**

- **If Rapid Test is Positive:** The National Algorithm for HIV testing and management will be followed.
- **If Rapid Test is Negative:** Assess for potential HIV risk exposure in the last 72 hours or 14 days before onset of the AHI as per the algorithm for PrEP initiation and follow-up (Figure 2). If high risk exposures are excluded and rapid HIV is non-reactive, **initiate PrEP without waiting for the 4th generation ELISA test results.**

4.2.3 HIV testing for PREP continuation

- Follow up with HIV Rapid test (Antibody testing) for follow up at **1 month, 3 month and 6 months.**
- Thereafter, follow up with alternative self-testing and rapid testing every 3 months (i.e: self-testing at 9th month, rapid testing at 12th month) till the time the individual continues to take PrEP.

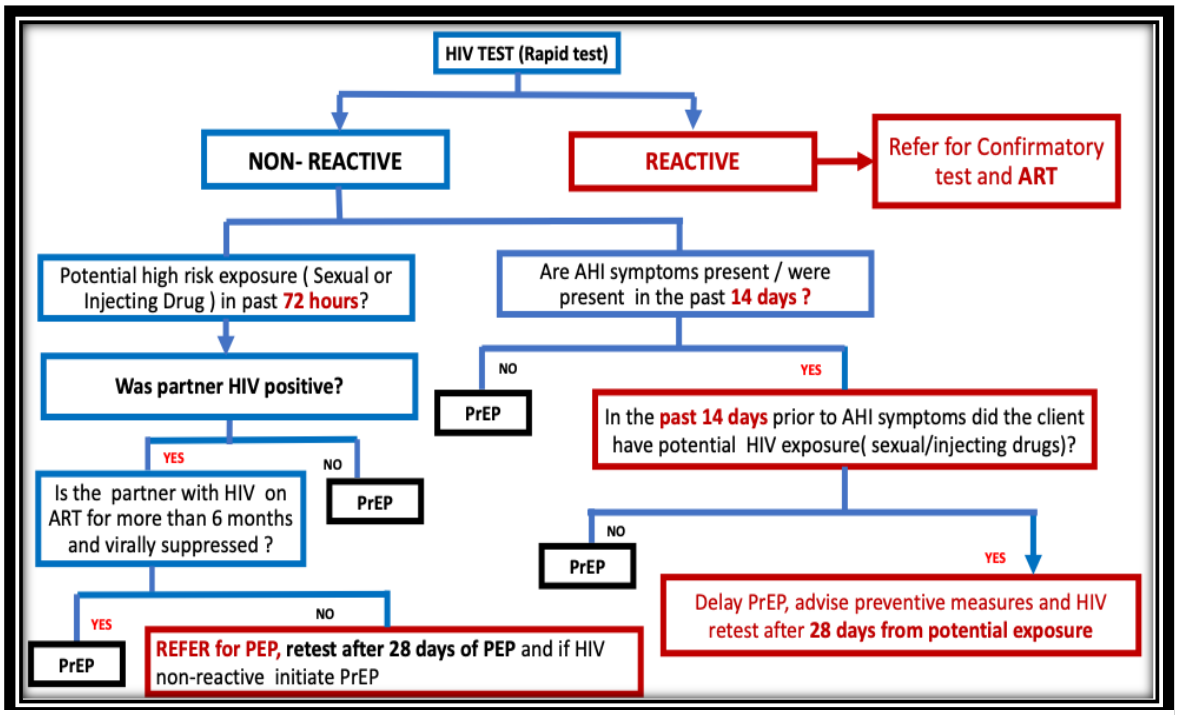

Figure 5. Algorithm for HIV non-reactive Rapid Test to Assess PEP and AHI

4.3 Assess For PEP

- All PEP clients who have HIV non-reactive results should be assessed for the likelihood of exposure to HIV in the past 72 hours.
- If the client has high risk exposure in the past 72 hours PEP is indicated. The client should be immediately assessed for PEP.
- If the sexual partner is confirmed to be HIV negative or if the HIV positive sexual partner is on ART for more than 6 months with good adherence and has a confirmed undetectable viral load there is low risk of HIV transmission so in that case PEP may not be required.

- PEP is most effective if taken **within 24 hours after exposure**, and so ensure to start PEP as soon as possible. If there is high risk exposure in the past 72 hours.
- For PEP three drug ARV combination, TDF+3TC with dolutegravir (DTG) should be provided to adults and adolescents for 28 days and ensuring good adherence is important.
- In persons with ongoing risk, they can be directly started on PrEP without a gap after 28 days PEP is completed.
- All procedures for initiation of PrEP should be completed in persons transitioning from PEP to PrEP.

4.4 Assess For AHI

PrEP Providers should clinically examine the potential PrEP clients for signs and symptoms of AHI and take a detailed exposure history. Acute HIV infection should be suspected in individuals at high risk of HIV who may have had recent exposure to HIV within the last 14 days (e.g., condomless / condom broken during sex with an HIV-positive partner not on treatment, or casual partner of MSM; recent injecting drug use with shared injection equipment with MSM, or person known to be HIV positive).

The signs and symptoms of Acute HIV Infection (AHI) are seen in the earliest stage of HIV infection, when a person gets infected with the HIV virus. It is sometimes also called primary HIV infection and may last till 21 days of exposure. All with high-risk exposure may not have AHI symptoms. The PrEP provider must make clinical judgment in ruling out all other causes of similar symptoms as these symptoms are nonspecific for AHI and may mimic many other common illnesses. 4th generation positive indicates that an HIV positive individual has entered the late course of HIV infection when immune response wanes, production of antibody decreases and titers of HIV p24 antigen increase usually positive after 2nd week of HIV infection.

4.4.1 Signs and symptoms of AHI

The signs and symptoms of AHI area are as follows:

- Fever
- Feeling tiredness
- Swollen lymph nodes
- Swollen tonsils
- Sore throat
- Joint and muscle aches
- Diarrhea
- Rash

4.4.2 Suitability criteria

- Age ≥ 15 years (weight >35 Kg)
- HIV-Negative status
- No suspicion of acute HIV infection
- No contraindications to PrEP medicines (e.g., TDF/3TC)
- Willingness to use PrEP as prescribed, including periodic HIV testing-
- Have at **least one high-risk behavior** criteria which include:
    - Unprotected sexual intercourse (Vaginal/Anal sex) with a man or woman or TG within the last 6 months.
    - STI (self-reported or recorded) in the last 6 months.
    - Taken Post-exposure Prophylaxis (PEP) in the last 6 months.
    - Know the HIV status of your sexual /injecting partner/Partners.
    - Anticipate having sex without a condom in the next 3 months.
    - Recurrently have sex under the influence of alcohol /recreational drugs

4.5 Contraindication

- HIV positive
- Those indicated for PEP with potential exposure in the last 72 hours.
- Suspected of Acute HIV Infection (AHI) with a probable recent HIV exposure in the previous 14 days.
- History of allergy to components (TDF+3TC) in oral PrEP (self-reported or documented)

4.6 Other Tests

- Syndromic assessment for STI and Viral hepatitis followed by laboratory test for STIs and Viral hepatitis as per the *National STI management guideline*.
- If HBsAg positive refer to the appropriate Specialist and treat as per the *National Hepatitis guideline.*
- Renal function tests

Table 1. Procedures for Prep Initiation and Follow-up

	Procedures	Month					
		0	**1**	**3**	**6**	**9**	**12**
1	HIV test (baseline and 3 monthly)	×	×	×	×	×	×
2	Assess for PEP (baseline and every visit)	×	×	×	×	×	×
3	Assess for AHI (baseline and every visit)	×	×	×	×	×	×
4	Assess for contraindications	×					
5	Provide oral PrEP (month 1 then 3 monthly refill)	×	×	×	×	×	×
6	Renal function test (baseline, at Month 3 and then 6 monthly)	×		×		×	
7	STI Testing (Baseline and 6 monthly)	×			×		×
8	Hepatitis B surface antigen testing (Baseline and then annually)	×					
9	Hepatitis C antibody testing (Baseline and then annually)	×					
10	Counseling (effective use, side effects, successes and challenges) every visit	×	×	×	×	×	×
11	Preventive measures (condoms/lubes/NSP) every visit.	×	×	×	×	×	×
12	Pregnancy testing and contraception (if needed)						
13	HBV vaccination for those born after 1997 who have not been vaccinated and those born before 1997						
14	PrEP medication issuance	×	×	×	×	×	×
15	Behavioral sexual risk reduction counseling	×	×	×	×	×	×

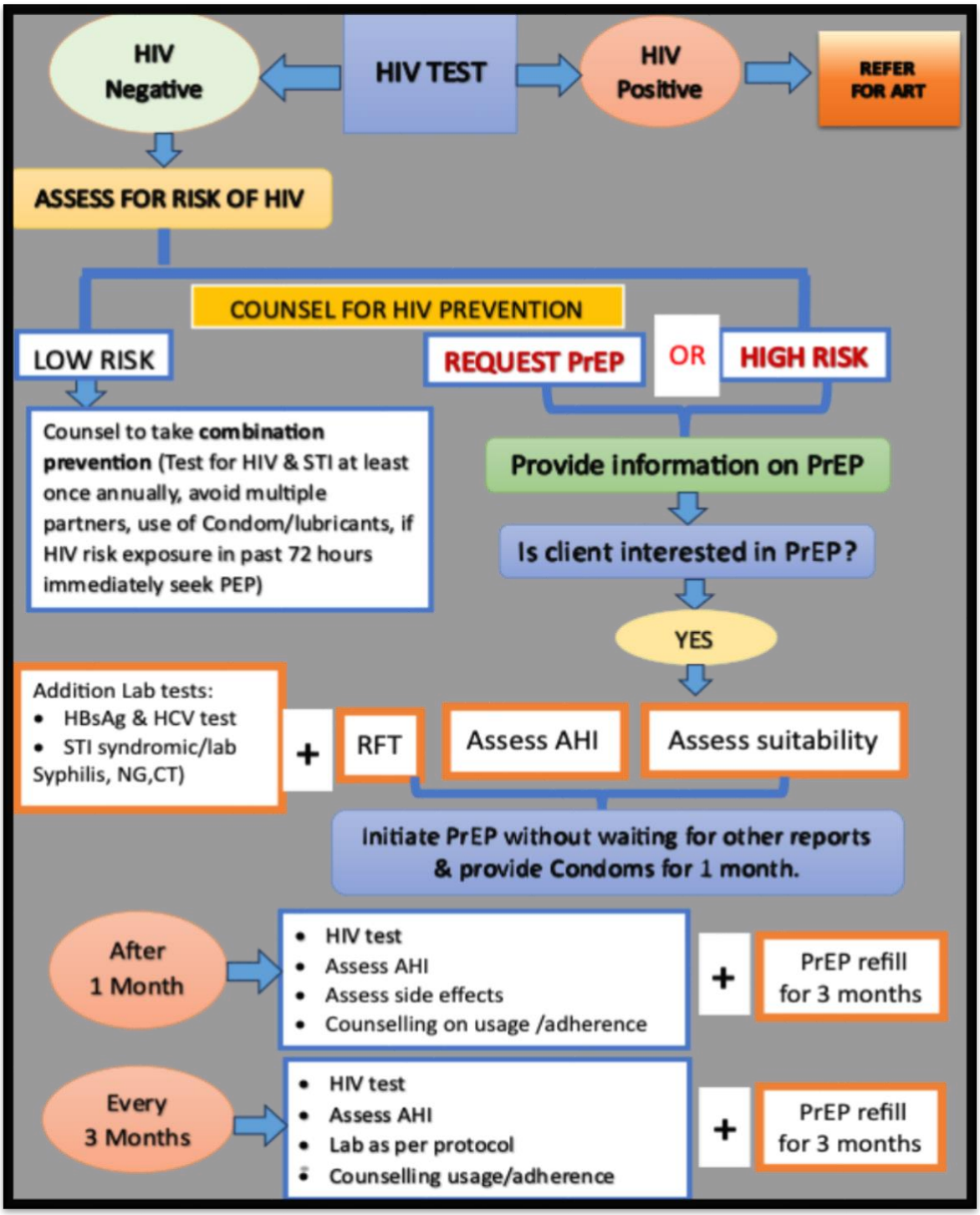

Figure 6. Algorithm for PrEP initiation and follow-up

5. PROCEDURES AT BASELINE

5.1 Baseline Visit (M0)

- The potential client may come to the PrEP site directly or will be referred from the community when the HIV ST result is non-reactive.
- When the client visits the PrEP site, the HA/Counsellor/ VCT meets him/ her and provides information on PrEP.

5.1.1 Information to be provided to client

While waiting for the HIV test result, the PrEP Provider can provide information on the following topics:

- Suitability criteria for initiating PrEP,
- Benefits of PrEP
- Follow up schedule and the importance and benefits of HIV tests during each visit.
- Other services offered with PrEP (STIs, HBV and HCV tests and referral for management)
- PrEP usage and the importance of adherence.
- Emphasis that the PrEP uptake is voluntary, and the client can decide to start using or stop PrEP at any time if they feel they are no more at risk of HIV infection.
- Only if the client is willing to take PrEP and willing to come back for the scheduled follow-up visits and HIV tests will the client be suitable for PrEP initiation.
- In case the client needs time to think about it or discuss it with the partner or family members they should be allowed to make their own decision.

Only the HIV test result is needed for starting PrEP and waiting for other results should not delay starting PrEP.

Table 2. Baseline Laboratory Procedures

Procedures	Priority actions
HIV testing	Based on the findings from behavioural risk assessment and a non-reactive result for the first test in the national algorithm, start PrEP without waiting for the 4th generation ELISA test result.

Renal function test (Serum creatinine clearance) *	**RFT reports need not be available prior to starting PrEP** If eGFR < 60ml/min DO NOT initiate PrEP, repeat in 2 weeks and if eGFR > 60 ml/min start PrEP. If the Renal function test is abnormal, the client should be contacted immediately and told to stop PrEP immediately.
Hepatitis B surface antigen (HBsAg)	**Results of the HBsAg test need not be available prior to starting PrEP.** If HBsAg -ve: start PrEP and vaccination for those born before 1997 and those who have missed if born after 1997. If HBsAg Positive: start PrEP and refer to the doctor /specialist for management of Hepatitis B.
Hepatitis C Antibody tests (anti-HCV)	**Result of HCV test need not be available prior to starting PrEP.** If HCV -ve: start PrEP If HCV +ve: start PrEP and refer to the doctor /specialist for management of HCV infection.
STI (Syndromic or Laboratory for syphilis, Swab for GC, CT)	Syndromic management For syphilis TPHA as first line testing till HISC. Swab for GC will be done at hospital settings only. Asymptomatic testing for CT and GC if made available later on. If STI diagnosed, provide treatment for STI based on the National STI Guidelines 2024.
Pregnancy testing and contraceptive services	Assess reproductive intentions and offer pregnancy testing, if appropriate and reliable contraception.

**Note: Known kidney impairment (indicated by an estimated glomerular filtration rate (eGFR) of under 60mL/min per 1.73m2 or a creatinine clearance of less than 60mL/min) is a for TDF-based oral PrEP.*

5.1.2 Informed Decision Making

- Each client must be provided with information on PrEP so that the client can make informed decisions whether to use or not to use PrEP.
- The PrEP Provider will inform about suitability criteria.

- Explain about follow up visits, potential risks, benefits, side effects, check-up schedules, how to take medicines, use of other medications if required.
- The standard information must be read to the client.
- The client must be informed that it is voluntary and can decide to stop taking PrEP anytime.
- Inform that precaution will be taken to protect confidentiality in data handling at all steps.
- Encourage the client to ask questions and if any clarification is sought help them with information.
- After the questions are answered if the client is willing to participate the health worker puts the date and signs on it.
- If the client is not sure and wishes to discuss it with family, they should be allowed.
- The form should be filled, and it should be checked by the PrEP Coordinator of the PrEP site for completeness**.**
- If the client is determined to take PrEP then the Suitability Form 1 is to be filled up.
- In case Gonococci is positive, start immediate treatment as per National STI treatment guidelines while other results can wait till next visit.
- If renal function is deranged the client should be informed and referred to the Medical Officer to decide on PrEP discontinuation. Additional counseling should be provided while PrEP is discontinued.
- Information on starting, using, stopping and restarting PrEP is given based on the client's preference and suitability and also informs about the follow-up visit schedules.
- Side effects should be discussed and information that side effects, if any, will resolve within a month and he/she should ensure PrEP can be continued. The client should be informed to contact the Medical Officer if side effects do not resolve or bother the patient. Symptomatic treatment can be given if symptoms persist.

5.2 Special situations to be considered

- **Clients who Seroconvert during follow-up**: Clients who test positive for HIV at baseline or any follow-up visit are not suitable for PrEP.
- **PrEP and serum creatinine:** If Serum creatinine <60 ml/min PrEP will be interrupted and **if clearance stays <50 ml/min after repeat testing ideally after 1-3 months PrEP can be permanently discontinued.**
- **STI and PrEP:** STIs are not a contraindication to initiate PrEP but they need to be treated immediately as per National STI guidelines.
- **HBsAg and PrEP:** If HBsAg is reactive, PrEP can be continued. However, the client should be referred to a specialist for further assessment for HBV treatment and management. Those non-reactive can be provided with HBV vaccines if they have not been previously vaccinated. Such cases on PrEP should be carefully managed in consultation between the physician and the PrEP provider ensuring there is no overlap or gap in the treatment. PrEP discontinuation may lead to flare up of Hepatitis B infection.

- **PrEP to PEP due to missed doses**: if Cisgender men on daily PrEP (with sexual exposure) **miss 3 doses in the last 7 days**, PEP should be considered. For all other groups on daily PrEP (with all sorts of HIV risk exposures) if **5 doses in the last 7 days** is missed, PEP should be considered (10).

6. COUNSELING

6.1 Counseling Prior to PrEP initiation:

- Counseling prior to PrEP initiation should focus on increasing awareness around PrEP as a prevention choice and helping the clients to decide whether PrEP is right for them.
- Once the client chooses PrEP as an option, the focus should be on preparing the client and supporting self-efficacy, explaining its use (including starting, stopping and restarting), limitations of PrEP, side effects and making a specific plan for effective use
- Always encourage open conversation where clients will feel free to share accurate information on risk and concerns about PrEP.

6.2 Counseling during the initiation visit:

- PrEP is highly effective and a responsible prevention option.
- About limitation of PrEP that it does not offer protection against other STIs (such as Herpes, Chlamydia, gonorrhea or syphilis) or pregnancy, but the PrEP package offered has many benefits such as STI screening, Hepatitis screening and prevention packages such as Condoms and lubricants.
- Correct use of condoms is less effective than PrEP in preventing HIV infection as condoms can break accidentally but when PrEP is taken as prescribed it reaches the blood circulation and tissues and prevents HIV infection.
- Regular HIV/STI screening while on PrEP offers additional benefits and reinforces the need for regular HIV/STI testing.
- Regular clinic visits are an important part of the PrEP package. These regular visits will include testing for HIV and other STIs, monitoring of side effects, an opportunity to discuss client's sexual health and HIV prevention goals, any challenges or successes clients had with taking PrEP and any other questions they may have.
- Drugs used in PrEP are safe. World-wide millions of people are now taking PrEP. Only 1 in 10 people may develop side effects. These are usually mild and resolved within a few days or weeks. If the symptoms persist or if it worries clients or they have questioned the contact number of PrEP providers will be provided.
- It is safe to take contraceptives and gender affirming hormones while taking PrEP.
- Alcohol and recreational drugs do not make PrEP less effective.
- For PrEP to work optimally, it's important to take PrEP as prescribed. This will allow the drug levels in the body to be high enough to prevent HIV infection.
- While very unlikely, there is a very small chance that someone taking PrEP as prescribed could still get HIV, and this chance is high if PrEP is not taken as prescribed. Thus, the need for regular HIV testing is still very important. **On every visit HIV testing should be conducted before refilling PrEP.**

- PrEP is not required lifelong, one can safely start, stop and restart oral PrEP based on the circumstances (high or low risk) you are in. The starting, stopping and restarting of PrEP should be very clear and followed diligently for effective use of PrEP.

6.3 Counseling during Follow-up visit

- Discuss the client's sexual health and HIV prevention goals and develop a plan of action for achieving the client's sexual health and HIV prevention goals:
- Explore sexual history since the last visit and discuss successes with HIV prevention and any opportunities to increase protection against HIV.
- Discuss their experience with taking PrEP, including satisfaction with it as a prevention method and intention (or otherwise to continue), sexual history and patterns of PrEP use, any challenges and successes with taking PrEP as prescribed.
- If needed, explore potential strategies for taking PrEP as prescribed/ effective use.
- Discuss use of other HIV, STI and pregnancy (if appropriate) prevention strategies, and any support needed to improve their use (in accordance with client's goals).
- Reminders, if needed, that PrEP prevents HIV but **NOT** other STIs or pregnancy therefore reinforce the use of condoms while on PrEP.
- Confirm an effective and acceptable contraception plan where indicated.
- Reinforce information on efficiency, guidance for starting, stopping and restarting PrEP and importance of regular visits, side effects and how to manage them.

7. STARTING, USING, STOPPING OF ORAL PREP

Provide information on PrEP (0,1,3,6,9,12 months) - Regimen, Dosing & Possible side effects

7.1 Dosing regimens for oral PrEP

There are currently two dosing regimens for TDF-based oral PrEP. The dosing regimen to use depends on the person's characteristics, circumstances and the route of exposure. The dosing regimens are:

  - **Daily PrEP**
  - **Event-Driven or Event-based PrEP (ED PrEP or EB PrEP)**
- Irrespective of the dosing regimen, everyone should be empowered to safely start, continue, stop and restart oral PrEP in accordance with their preferences and likely exposures, to effectively prevent HIV acquisition.
- There is no time limit on how long a client can take oral PrEP, nor on the number of times a client can restart oral PrEP**.**
- **If an individual misses a dose, they should take it as soon as they remember; but should not take more than two doses in one day.**
- **If an individual stops taking PrEP (specifically, has more than two days without taking a dose), the next time they anticipate having sex or want to restart oral PrEP, they should start their regimen again.**

7.1.1 Daily PrEP

Dosing regimen for most groups of people with sexual and injecting exposure.

- Daily PrEP is suitable for all people who are at risk of HIV.
- Daily PrEP is the only PrEP regimen recommended for Cis-gender and transgender women, for the transgender men who have vaginal sex, for men who have anal sex with women, PWID and for people with Chronic hepatitis.
- **Daily PrEP is preferential for those MSM who cannot predict when sex will occur, who cannot delay sex for more than 2 hours and for those whose potential exposure to HIV occurs more than twice a week.**
- Daily PrEP is the only regimen for cis-**gender MSM with chronic hepatitis B infection** to maintain virological suppression, prevent drug resistance and hepatitis flares.
- Only Cis-gender MSM has a choice between daily and on-demand PrEP.

Whether the person intends to use oral PrEP for a short or extended time the process should be as follows:

- Start PrEP with one dose of TDF-based oral **PrEP per day for seven consecutive days prior to potential exposure.** Alternative HIV prevention methods should be used during this time.
- Continue to take one dose per day for as long as there is sexual exposure and for **at least seven days after the last potential exposure.**
- This regimen is appropriate to reduce the risk of HIV acquisition through both sexual and parenteral exposure.

Table 3. Starting, Using and Stopping Oral PrEP

Population	Type of dosage regime	Starting	Using	Stopping
For all other groups	Daily Oral PrEP	Take one dose per day for day *for seven days prior to exposure;*	Take one dose per day during exposure; and	Continue with one dose per day *for seven days after the last exposure.* (Refer figure 6-1)
For all individuals assigned male at birth with sexual exposure and NOT	Event Driven or Event based PrEP	Take two doses *2-24 hours prior to exposure;*	Take one dose per day during exposure; and	Continue with one dose per day for *two days after the last exposure.* (Refer figure 6-2)

taking gender affirming hormones[1]				

[1]*Cisgender men and transgender women* ***not*** *taking gender-affirming hormones can adapt PrEP use to their HIV prevention needs and preferences. Some people may use PrEP for a single event (for example, sex on only one day), or for infrequent "single" events that are weeks or months apart. This is sometimes called event-driven PrEP (ED-PrEP) or 2+1+1.*

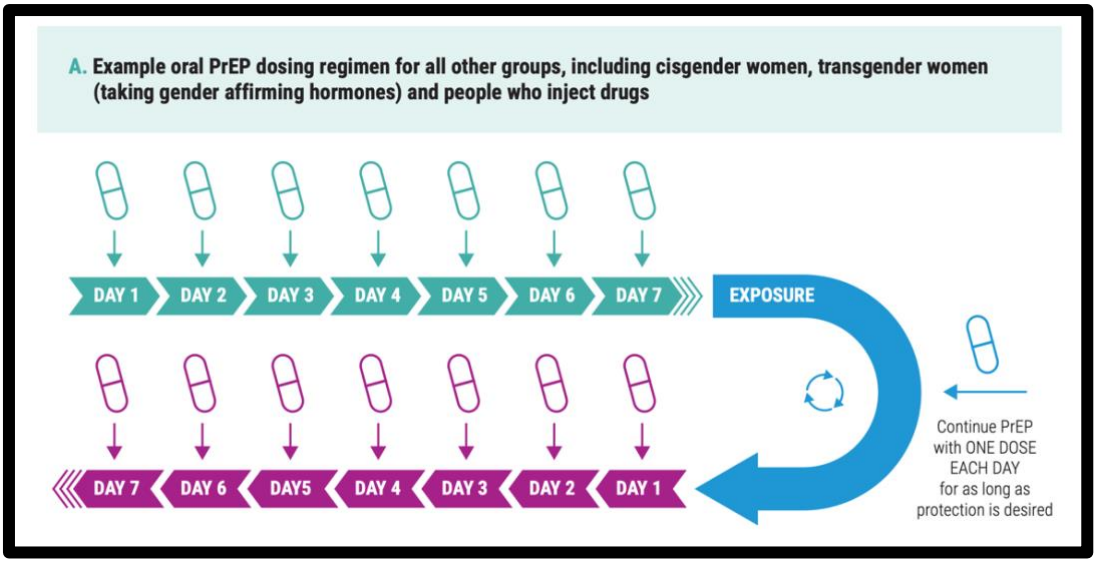

Figure 7. Daily Oral PrEP Dosing Regimen

7.2 Event-driven or Event-based PrEP

Recommended for people assigned male at birth with sexual exposure and ***not*** *taking estradiol- based hormones*

- Cisgender men (including men who have sex with men (MSM) and men who have sex with women (MSW) with sexual exposure to HIV
- On-demand PrEP would be suitable for those MSM whose preference is for the on-demand regimen, who have **sex less than twice a week**, who can **plan ahead for sex at least 2 hours** in advance.
- Trans and gender diverse people assigned male at birth (including transgender women) who are **not** taking exogenous estradiol-based (gender-affirming) hormones and with sexual exposure to HIV.

Whether the person intends to use oral PrEP for a one-off sexual exposure, or for a short or extended time the process should be as follows:

- Start by giving two doses **2–24 hours before sex**. Ideally, this loading dose should be taken closer to 24 hours before sex to allow more time to absorb the PrEP.

- Continue taking one dose per day for as long as oral PrEP protection is desired AND for **at least two days after the last** potential sexual exposure.

This regimen is **only** appropriate to prevent the sexual acquisition of HIV.

If exposure to HIV continues for more than one day or if an individual prefers to continue to take oral PrEP daily rather than stopping and restarting, they should take one dose of oral PrEP every day (sometimes called daily oral PrEP) for as long as desired **AND until at least two days after the last potential exposure.** This means that ED-PrEP can become daily oral PrEP simply by extending the time a client takes PrEP; **there is no difference in how to start or stop oral PrEP.**

Some of the reasons why some individuals may prefer to take oral PrEP every day over a period of time rather than starting and stopping repeatedly:

- when sexual exposures are unpredictable,
- taking daily routine is found more convenient /easier,
- taking oral PrEP every day will provide continuing protection, even if a dose is missed.

Note: Cisgender men and transgender women **not** taking gender-affirming hormones can adapt PrEP use to their HIV prevention needs and preferences. Some people may use PrEP for a single event (for example, sex on only one day), or for infrequent "single" events that are weeks or months apart. This is sometimes called event-driven PrEP (ED-PrEP) or 2+1+1.

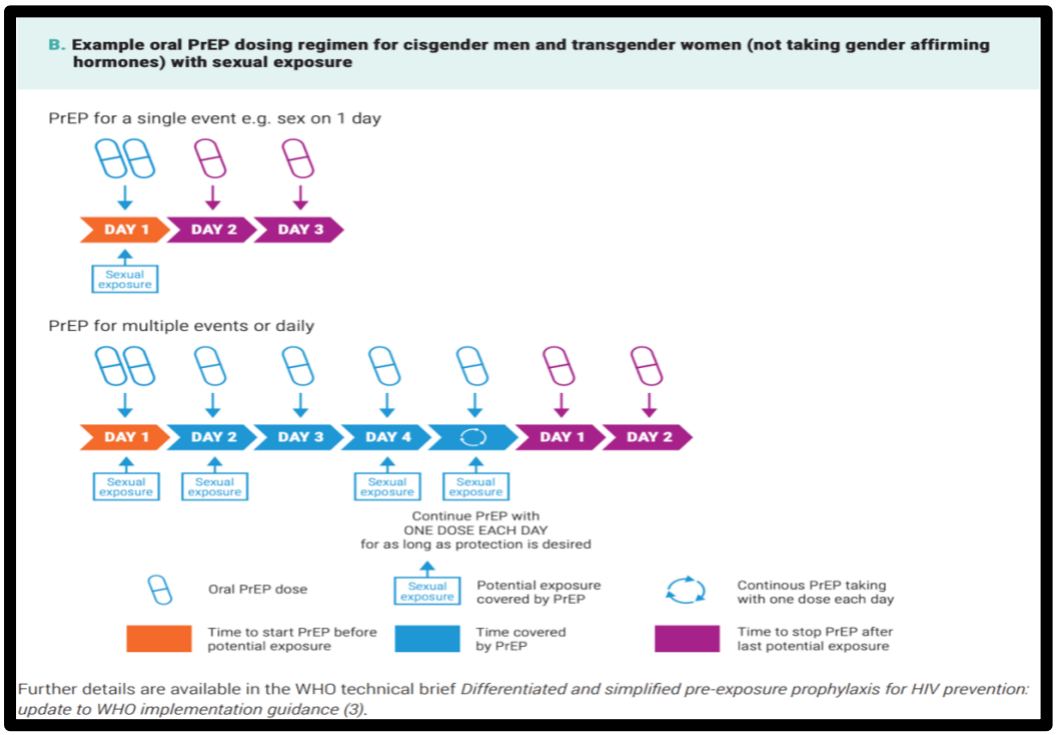

Figure 8. Event-driven Oral PrEP Regimen

8. STOPPING OF PrEP:

- Reasons for stopping PrEP may be:
    - Tests HIV-positive
    - Has persistently low eGFR or high serum creatinine levels.
    - Is non-adherent to PrEP
    - If there are other safety concerns where the risks of PrEP use outweigh potential benefits.
    - Client wishes to stop.
    - No longer likely to be exposed to HIV.
    - Decision to switch to another HIV prevention strategy.

- Duration of PrEP use may vary, and individuals may start, stop and restart PrEP depending on their circumstance including changes in HIV exposure and HIV prevention preferences.

- Ideally clients will inform the Doctor /HA/ Counsellor when they want to discontinue PrEP. However, as this may not happen in some cases, **clients should be counseled by the health care provider on how to safely discontinue, at each visit including initiation visit**.

- During counseling providers should discuss with clients **how to safely stop using PrEP** emphasizing the need to continue PrEP for the recommended time after their last potential HIV exposure.

- Clients need not return to the PrEP provider to stop PrEP **if they know how to stop safely**.

- The PrEP Provider should complete the exit form in case the client decides to withdraw using PrEP or fill up the unscheduled visit form if the client comes in unscheduled for any reason like wishing to temporarily discontinue with an intention to start after a gap or reporting serious adverse effects, reporting the loss of PrEP medicines, requiring additional bottles of PrEP, temporary discontinuation, etc.

9. RESTARTING PREP

Clients may start, stop and restart PrEP depending on their circumstance including changes in HIV exposure and HIV prevention preferences. If the client has stopped for some time and wants to restart the same PrEP regimen, the PrEP provider should use the similar approach as was used when they first initiated PrEP.

10. ADVERSE DRUG REACTION (ADR)

Side effects are usually mild and include gastrointestinal symptoms such as nausea, abdominal cramps, nausea, decreased appetite, diarrhea, flatulence, headaches and dizziness.

10.1 Adverse drug reactions may be considered when:

A. It results in death or is life-threatening.
B. The condition requires in-patient hospitalization.
C. It results in some sort of disability.

10.2 Documentation of Adverse Drug Reactions

- If minor side effects are reported symptomatic management can be given and separate reporting is not needed.
- PrEP (TDF /3TC) has a good safety profile. However, if Adverse Drug Reactions are seen it will be reported in detail to ensure safety of clients.
- All documentation on ADR will be filed in the office.
- A copy of laboratory results, behavioral questionnaire, all forms and client notes will be filed in the client's file and kept safely.
- All ADRs must be clinically evaluated to determine if it is drug related.
- Any event before a client is enrolled must be documented as medical history.
- The medical officer will assess the problem based on the vital signs and laboratory reports.
- Such cases should be followed up until the problem is resolved.

10.3 Reporting Adverse Drug Reactions

- All information needs to be documented in the clinical form.
- SAE should be reported to TAG **within 24 hours**
- Fatal/life-threatening suspected unexpected serious adverse reactions (SUSARs) also need to be reported to TAG **within 7 days.**
- Non-fatal life-threatening SUSARs must be reported **within 15 days.**

- All SAE must be reviewed by an independent senior medical specialist who will review each case and advise if the PrEP needs to be halted or if the safety data needs further review).
- The Prescribing Medical officer should be responsible for monitoring safety and serious adverse outcomes

11. FOLLOW-UP VISITS

- Counseling a client on PrEP should focus on understanding sexual health and HIV prevention goals and whether PrEP is supporting those.
- Support clients to use PrEP effectively (correct usage during times of potential HIV exposure).
- Address the concerns and challenges raised by clients and support and encourage continuing engagement with services, whether the client wishes to continue PrEP or not.
- Avoid being judgmental about the preferences of the client and contribute to open conversations which will make clients feel free to share accurate information on risks and concerns.
- Prescribers will conduct clinical evaluation of the client based on recent history and current signs and symptoms, assess for side effects at all visits and must differentiate between drug related issues and other medical issues that may present simultaneously and can provide symptomatic treatment where necessary.
- Counseling to continue PrEP is very important and clients must be informed that PrEP should not be discontinued unless the client is not able to take the medication.
- Serious side effects must be ruled out if suspected. If a client develops serious adverse effects, he/she may **be required to come to the health facility immediately as an "unscheduled visit".**
- STI should be screened at 6 and 12 months (syndromic and speculum examination, Swab collection for Gonococci), test for syphilis and serum creatinine if indicated.
- Recording of all procedures is important and must not be forgotten.
- If Laboratory reports are not available PrEP should be continued if clients are eligible based on **non-reactive HIV tests** and the **behavioral and clinical assessment.**
- PrEP drugs should be prescribed on a monthly basis for those who are eligible and wish to continue PrEP.
- The bottles should not be tampered with or transferred to another bottle before supplying to the patient.
- This counseling and referral will be facilitated by the counselor.

12. HIV SEROCONVERSION

- All PrEP users will receive HIV Testing and Counseling (HTC) at each visit.
- Individuals who test positive at any visits will be counseled and will undergo HIV confirmatory test as per the National Testing Algorithm.
- **Till the confirmatory test results are obtained, PrEP will be temporarily discontinued.**

- For those who test positive, counselors will provide counseling based on the guidelines that will encompass issues related to PrEP in addition to standard HTC post-test counseling guidelines.
- Additionally, the PrEP users will be discontinued PrEP and will complete the following procedures:
    - The HIV positive client will be linked to HIV Care and Treatment services.
    - The Counsellor and the KP counselor will support and facilitate the counseling and referral process.
    - If any client tests positive outside the health facility, he/she will be asked to come to the health facility for an HIV confirmation test.
    - If the test is positive then they will follow the process for the HIV positive clients.

All HIV seroconversions must be immediately notified to the TAG no later than 24 hours.

13. DRUG REFILL VISITS

- At initiation of PrEP, a bottle of pills (contains 30 tablets) to be given for the first month, then three monthly (3, 6, 9 and 12) for Daily PrEP.
- For the ED-PrEP, a bottle of 30 tablets will be dispensed for the first month and the refill will be based on the consumption pattern and requirement of the client, may need less refills than Daily PrEP users.
- For persons who may switch from ED-PrEP to Daily dose regimen due to various reasons, they **should discuss with the PrEP provider before making the decision** to change regimen.
- ED PrEP users should also come for the follow-up visit as per the schedule every three months.
- They should be counseled on how to start, use and stop the medicines for the new regimen correctly to be effective.
- The refill should be discussed and planned properly during each visit and if need be refills can be sent through outreach workers and documented in the individual drug distribution form.
- The counselor will discuss any issues arising since the last visit including challenges with taking PrEP as prescribed. **Such information should be recorded in the client's notes.**
- If a client requests more than a month's supply, the client should be asked to visit the health facility to discuss with the provider who will then decide how it can be done.
- This decision should be noted in the individual drug distribution form.
- In the event of any side effects that are not resolved, the client will be referred to the medical Officer who should conduct a clinical evaluation.
- The PrEP coordinator should maintain a schedule of the timing of all drug refills, and liaise with the medical officer for dispensing.
- The Medical Officer/HA in charge of the PrEP site should be responsible for ensuring that any dispensing and changes in dispensing pattern are properly recorded in the Individual Drug distribution form.

14. MISSED VISITS

- **Anticipated visits that are missed or out of protocol specified timeframe (± 15 days) must be documented as missed visits.**
- Clients have authority to withdraw from PrEP use at any time without having to provide a reason.
- However, all attempts and action taken should be recorded in the client record.
- **If clients do not turn up for scheduled visits, the PrEP team including Counsellor and Outreach worker should make attempts to contact the client and encourage them to come for an unscheduled visit even if they wish to discontinue PrEP.**
- The benefit of returning for a discontinuation visit should be outlined to the client.
- If the client can be contacted but declines a follow-up or discontinuation visit, he/she should be counseled to stop PrEP safely and alternate prevention methods that need to be adopted should be discussed.
- The PrEP Provide should complete the **exit form for the client wishing to withdraw and discontinue. (EXIT FORM)**
- An unscheduled visit form will be used for others who come in unscheduled for any other reasons.
- **Client is declared Lost to follow up (LTFU) if the client missed two consecutive visits** and all attempts to recall them are unsuccessful until or unless they return.
- It is important that no clients are declared LTFU until all efforts to locate and bring them back has been exhausted.

15. UNSCHEDULED VISIT

- In addition to the scheduled visits, clients will have option to visit health center /HISC for unscheduled visit if they have any questions about PrEP or any aspect of their care, experiencing side effects, PrEP is lost/stolen, test positive for HIV or facing any episode of violence, stigma and discrimination.
- All unscheduled visits should be documented on the unscheduled visit form.
- The staff should make every effort to trace the users if they become HIV positive or in the event of an abnormal test result.

16. MANAGING PrEP DRUGS

- Managing the stock of medicine is critical so that the clients' demands can be met.
- The In-charge of the health facility /HISC will be responsible for receipt of the medicines.
- The medicine quantity has to be physically verified and the invoice has to be signed and sent back to NACP.
- The stock register should be updated as soon as the drugs are received on the receipt column with date of receipt, batch number and number of bottles received and signature.
- Daily the In-charge /Medical Officer should update the number of bottles dispensed and the balance stock available.

- If medicine is sent to the ORW for distribution or sent to outreach clinics, maintain a separate register with details of the individual who has taken the medication, the date, the numbers issued, signature of the person who has taken it and the person who issued it.
- The main stock must be physically verified, cross checked with the register and updated month.

17. MONITORING AND EVALUATION

The monitoring and evaluation framework has been aligned to the Global and national vison, goals and targets and will enable monitoring of the PrEP Program from the time PrEP is initiated. To facilitate standardized and systemic monitoring all the PrEP sites will use the forms listed below. A copy of all the forms will be found in ANNEX 5. For each client the complete set of forms will be filled up ensuring completeness and will be filed in the PrEP site. All routine data collected at each step of the PrEP service delivery will be transferred to the database and used for continuous improvement of the PrEP Program.

The data generated from the Phase 1 will enable learning for the further improvement of the PrEP Program for the 2nd phase of the implementation. The indicators generated at each step of PrEP service will be monitored weekly, monthly, quarterly so that gaps can be identified early and corrected as soon as possible. Therefore, routine monitoring to track the PrEP Programme will be accorded high priority.

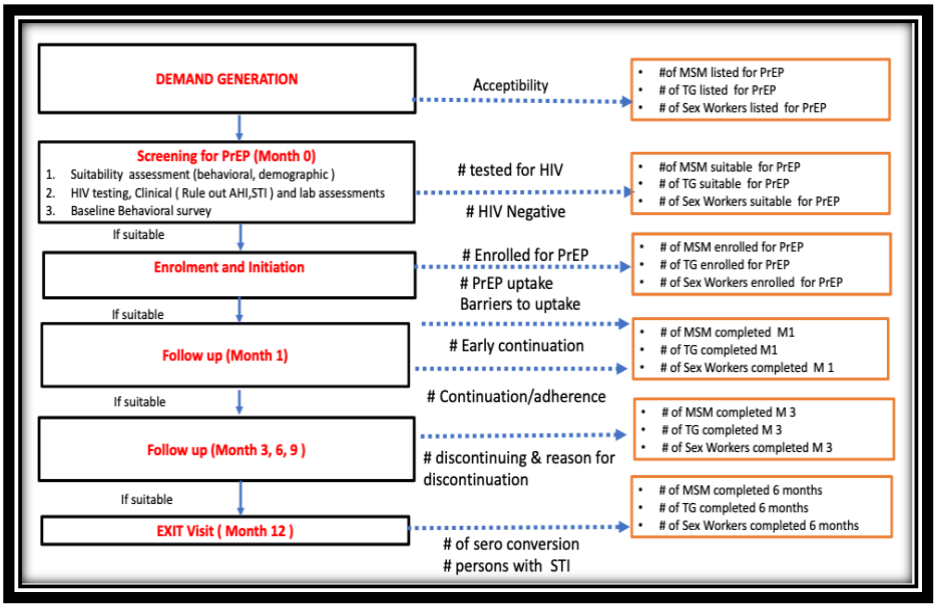

Figure 9. Flow of PrEP service and point of data generation

Table 4. Steps in the PrEP cascade and the definitions

	Steps	Definitions	Responsible
1	Interested in PrEP	Number of persons listed for PrEP	Pride Bhutan
2	Referral to PrEP sites	Number of persons that were referred by ORW to each PrEP.	Pride Bhutan
3	Tested for HIV	Number of persons tested for HIV	PrEP sites
4	HIV test negative	Number of persons tested for HIV who tested negative for HIV	PrEP sites
5	Suitable for PrEP	Number of persons who tested negative found suitable for PrEP	PrEP sites
6	Initiated PrEP	Number of persons who full fil suitability criteria who are initiated on PrEP	PrEP sites
7	PrEP use continuity at M1	Number of persons who initiated PrEP used continuously for one month	PrEP sites
8	PrEP use continuity at M3,6,9,12	Number of persons who initiated PrEP used continuously for three months	PrEP sites
9	Referral for ART	Number of persons screened for PrEP referred for ART	PrEP sites
10	Referral for PEP	Numbers of persons screened for PrEP referred for PEP	PrEP sites
11	Discontinuation of PrEP due to seroconversions	Number of seroconversions reported and investigated	PrEP sites and TAG
12	Discontinuation due to Adverse drug Reactions	Number of Adverse drug Reactions reported and investigated	PrEP sites and TAG
13	Number of PrEP clients Lost to Follow Up (LTFU)	Number of PrEP Clients who missed two consecutive visits in spite of all efforts to recall them	PrEP sites and Pride Bhutan

Monitoring and Evaluation Indicators (ANNEX 5):

1. Pre-Uptake:

1.1. PrEP service availability aims to track access to PrEP services by showing to whom PrEP is available in a certain geographical area.

1.2. PrEP awareness among potential users and willingness to use PrEP provides insight into the pre-uptake stages of PrEP from a user perspective. It shows how well the concept of PrEP for HIV prevention permeates certain communities or population groups. Their measurement over time may be useful to track the impact of **demand creation** activities conducted within a PrEP programme.

2. Uptake and coverage: These are core indicators to be reported by any PrEP programme. To understand **whether PrEP is reaching those** who could benefit most from it, is essential to the monitor

2.1. Current PrEP users

2.2. New PrEP users.

3. Continued and effective use the ultimate impact of PrEP on the HIV epidemic is highly dependent on the continuous and effective use of PrEP as long as people are at risk of HIV. It has become increasingly clear that, on an individual level, people adapt the use of PrEP according to actual or perceived HIV risk. Stopping PrEP for the time being, and re-starting at a later point, can therefore be a part of appropriate PrEP use. PrEP continuation/discontinuation may be influenced by the clients' good or bad experiences with the services provided to them and also on their individual ability to use PrEP effectively. Side effects, adverse reactions and seroconversions may affect continuation of PrEP and to document them for learning and further improvement of the PrEP program is crucial.

Tools and forms used during the PrEP implementation (ANNEX 6):

- Clinical Data Form (Initial visit and all scheduled visits)
- Baseline Behavior tool (at Baseline)
- Suitability Assessment during initiation for PrEP.
- Follow up tool (M1, M3, M6, M9)
- Unscheduled visit form (for clients who visit any time for any reason out of scheduled visits)
- Exit form (anytime client decides to exit irrespective of duration on PrEP)
- Clinical record and follow-up schedules monitoring form (to be updated at every scheduled visit)
- Oral PrEP sero-conversion reporting form as soon as HIV report comes out positive.
- Individual drug distribution form (to be updated as soon as drug dispensed)
- ORW client mobilization form (to be filled by Outreach workers)

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ANNEXURE

Annexure 1. Roles and responsibilities of various working groups and individuals

ToR of TAG

1. Provide policy directives to NACP on PrEP.
2. Provide technical support to revise the PrEP treatment guidelines and to incorporate revised PrEP treatment and management whenever the ART guidelines, STI Guidelines and the National M&E guidelines are revised.
3. Treat/ manage/advice the complicated cases referred from the PrEP centres.
4. Provide guidance to the national, regional, district hospitals and other relevant stakeholders in clinical and programmatic aspects of PrEP.
5. Monitor PrEP acceptability, efficacy, adherence and outcomes every quarter.
6. Conduct and analyze reviews for the PrEP clients.
7. Engage in formulation of policies and programmatic interventions.
8. Technically support NACP in conducting training programs on PrEP as resource persons.
9. Revise and review PrEP guidelines as and when there are global/ regional updates.
10. Initiate clinical monitoring of PrEP clients to rule out extreme Adverse Drug Reactions (ADR), Drug-Drug Interaction and drug resistance cases with support of the Clinical Laboratory and Public Health Laboratory.
11. Support NACP in conducting monitoring and supervision and programmatic reviews on PrEP.
12. Identify research priorities and advise the program in conducting operational research.
13. Technical guidance and support to the program to achieve the 2030 target of ending the AIDS epidemic through the Comprehensive Prevention Package for the prevention of HIV by 2030.

ToR of TWG

14. To provide support (Technical and scientific) in the preparatory phase of PrEP being introduced in Bhutan, including finalizing protocol(s), tools, M&E plan, site assessments, etc.
15. To ensure that the introduction and roll-out of PrEP is implemented as per the latest PrEP WHO, in-country guidelines, and best practices from other countries with ongoing successful PrEP programs.
16. To ensure meaningful community engagement, participation and ownership in this program.

17. To provide overall supportive supervision to the PrEP coordinator and the implementation team.
18. To be responsible for resolving any conflicts arising in the field (if not resolved otherwise).
19. To ensure approval is sought from TAC if any amendments to the clinical/implementation protocol are required as PrEP is rolled-out.
20. To review reported adverse events, and respond to any concerns raised by people receiving PrEP and implementing service delivery points
21. To be the reference point for training on PrEP for HIV for Medical Officers and Health workers.

ToR of National PrEP Coordinator

1. Support the development of national PrEP guidelines, protocols, and standards in collaboration with relevant stakeholders.
2. Coordinate the planning and implementation of PrEP services and guidelines across identified health facilities and community settings.
3. Coordinate capacity building programs including information sessions for health workers and communities in close liaison with the National Consultant and PrEP program.
4. Monitor and evaluate the performance of the national PrEP Program
5. Facilitate coordination and collaboration among government agencies, NGOs, community organizations, civil society groups, and other stakeholders engaged in HIV prevention efforts. Facilitate the integration of PrEP services into national guidelines/policies.
6. Support the development and implementation of behavior change communication strategies and community mobilization activities.
7. Support and oversee community events and forums, outreach activities aimed to promote PrEP.
8. Support the development, printing, and dissemination of PrEP IEC materials/resources.
9. Represent the national PrEP program in relevant meetings, conferences, and technical working groups with guidance of the NACP.
10. Coordinate meetings, training, and workshops for the successful initiation of the PrEP program.
11. Support with implementation of a PrEP Formative Assessment and Health Facility Assessment.

12. Ensure documentation of lessons and meeting notes and prepare reports as needed.

13. Any other tasks related to the PrEP program as assigned by the National Program Manager.

ToR of PrEP Coordinator

1. A PrEP coordinator will be identified from among the staff at each PrEP site to coordinate all the activities at the respective PrEP site.
2. He/She will support /assist the Medical Officer for all the PrEP drugs, logistics and stock management of all commodities of the Centre.
3. Review and manage drug logs.
4. Manage transportation of samples to the laboratory.
5. Manage schedule for PrEP drug dispensing for the clients.
6. Responsible for reporting
    a. Ensure correct filling of all forms.
    b. Check the forms.
    c. Countersigns the forms.
7. Conduct monitoring visits ensuring quality of the services provided.
8. Prepare monthly reports on the progress of the indicators.
9. Report on a monthly basis to the National Coordinator.

ToR of Medical Officer

1. Is the overall in-charge of all the clinical aspects of the PrEP program in the health facility.
2. The Medical Officer will provide remote oversight to the HA /Counselors.
3. Ensure the clients' notes on all the procedures, examinations, results and relevant information are recorded and maintained properly.
4. Clinical history taking, examination and suitability screening to initiate/not to continue/ discontinue PrEP
5. Prescribe PrEP to the clients in person or through e- prescription after reviewing all the reports referred by the HA/Nurse.
6. Manage side effects, if any.
7. Conduct physical examination for STIs and order tests for HIV and STIs.
8. Review test results including STI diagnosis and ensure syndromic management and ensure appropriate referral if needed.

9. Order tests
10. Counseling.
11. Work closely with the PrEP Coordinator.

ToR HEALTH Assistant /VCT focal/ COUNSELLOR

1. After meeting /greeting the clients, provide basic information on PrEP.
2. If clients decide to take PrEP, a pre-briefing on PrEP and pre-test counseling for HIV testing.
3. Complete the behavioral form and Clinical assessment form and then fill up the suitability assessment form and get the Medical Officer's signature client meets suitability criteria.
4. Sample collection (STI) and phlebotomy, record the laboratory reports on the clinical forms.
5. Conduct HIV and syphilis tests on clients who need them (if they are due for their tests or on clients who are HIV non-reactive and want to start PrEP).
6. Schedule the clinic appointments for PrEP clients from month 3 visit onwards.
7. Set up the drug refill dates along with clients and share with respective ORW.
8. Send reminders to the outreach workers for drug refills.
9. Conduct feedback surveys at the end of clinic visits for PrEP.
10. Follow-up calls to clients to monitor social harm.
11. Maintain notes for all procedures, examinations and relevant information.
12. Prescribe PrEP if suitability criteria are met.

ToR of Outreach workers (ORW)

1. Provide information on PrEP and HIV-ST in the outreach.
2. Mobilize the community to take PrEP and HIV-ST.
3. Registration of the clients
4. Refer clients to the PrEP centre
5. Regular "check in" calls with the clients on PrEP.
6. Remind the clients for "follow-up" visits; contact clients who have missed appointments.
7. Provide condoms and lubes.
8. Timely requisition and dispensation of PrEP drugs.

9. Maintain mobilization form (ORW form)
10. Provide a report on mobilization, referral, follow-up (from the out-reach register)

Annexure 2. HIV testing facilities

Table 5. HIV Testing Facilities

Health Facility Level	HIV Testing Services	Human Resource	Remarks
Royal Centre for Disease Control (RCDC)	• Rapid diagnostic test • Enzyme-linked Immunoassay (ELISA) (4th Gen. Ag-Ab/ latest Assays) • PCR-DNA for viral Load estimation (NAAT) • CD4 Count • PCR-RNA test for early Infant Diagnosis (EID)	Laboratory Specialists, Laboratory Technologists, Laboratory Technicians	HIV confirmation is decentralized to three Regional Referral Hospitals and Phuentsholing Hospital
National/Regional Referral Hospital	• Rapid diagnostic test • Enzyme-linked Immunoassay (ELISA) • HIV Viral Load Testing by Gene Xpert • NAAT for Early Infant diagnosis (EID) and Viral Load • CD4 count	Laboratory Technologists,	GeneXpert facility available in JDWNRH, ERRH, CRRH, Phuntsholing, Samtse, SamdrupJongkhar, Nganglam, Trashigang and Wangduephodrang Hospitals
District/General Hospital	• Rapid diagnostic test NAAT for Early Infant diagnosis (EID) and Viral Load	Laboratory Technologists, Laboratory Technicians	NAAT, ELISA and CD4 count testing available hospitals located in strategic areas.
Ten Bedded Hospitals	Rapid diagnostic test	Laboratory Technicians	
Primary Health Care	Rapid diagnostic test	Trained Health Assistants counsellor/Basic Health Worker	

Health Information and Service Center (HISC)	Rapid diagnostic test (Oral and Blood based)	Trained counsellor	Includes mobile, home-based, onsite and at the community centers.
Community testing centres	HIVST (oral based)	Community based Trained counsellors CBTC) /laymen	
Private Diagnostic Lab	Rapid diagnostic test (oral based)	Laboratory Technicians	

(*Source: National Guidelines for HIV Counseling and Testing 2021*)

Annexure 3. Guidelines for specimen collection, handling and shipment for HIV PrEP Testing

1. Purpose of the document

This document is intended to guide the health workers in Paro District Hospital involved in specimen collection, testing and shipment of the same to the Royal Center for Disease Control (RCDC) for the purpose of initiation and providing HIV Pre-exposure prophylaxis (PREP).

2. Objective of the document

This document aims to provide guidance and assist healthcare workers in:

- Proper handling, labelling and packaging of specimens
- Safe specimen referral to a Royal Centre for Disease Control (RCDC) for HIV testing and confirmation
- Strengthening of communication and maximizing safety of all involved in handling specimens

3. Documentary Requirements

Healthcare centers requesting HIV 4th generation ELISA testing for PrEP must ensure that a line listing form (see annexure 1) is duly completed and is shipped together with the specimen.

4. Biosafety Considerations

All specimens must be considered potentially infectious and should be handled with caution.

- All personnel handling specimens must wear appropriate personal protective equipment (PPE) such as gloves and gown.
- Proper hand hygiene must be followed and an alcohol spray (70%) should be available within reach for frequent sanitization.
- A proper shipment box for biological substances, category B, must be used.
- Ensure that leak-proof vials are used.

5. Specimen requirements and handling

- Serum is the specimen of choice. Plasma can also be used in absence of serum.
- Serum obtained from a patient's blood specimen can be divided into two parts. First one can be used for on-site rapid testing and the second one can be sent to RCDC for HIV 4th generation ELISA testing.
- Ensure the specimen vial is labelled clearly and kept in an upright position while packaging.
- Specimen can be rejected by the receiving laboratory if:
    - Specimens are mislabeled
    - Specimens are hemolyzed
    - Tubes are broken/ specimen has leaked
    - Specimens are highly turbid or icteric

6. Specimen packaging, storage and Shipment

- Patient identifiers and specimen labels must be written on the sample vial (patient code, age/sex, and date of specimen collection)
- Specimens should be immediately shipped in a cold chain box. If delay in shipment is expected, it can be refrigerated at 2-8°C for a maximum of 5 days. In case of prolonged delays, specimen can be frozen at -20°C.
- Triple packaging system must be ensured (Figure 1).

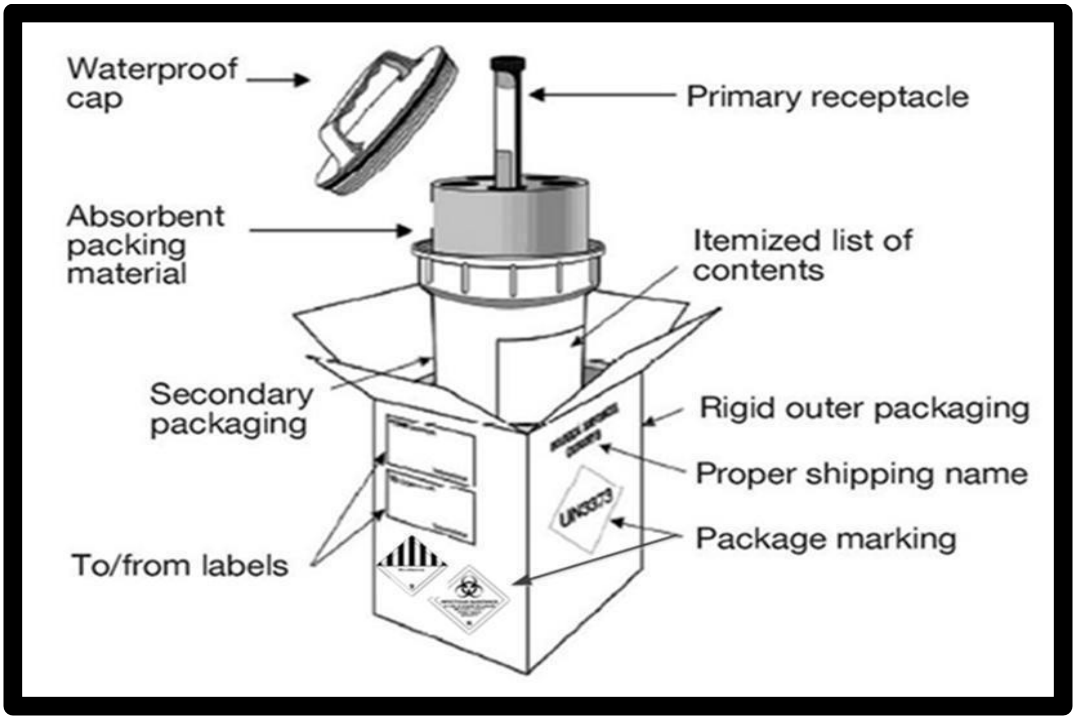

Figure 10. Triple packaging of infectious materials, category B.

Note: Proper shipping name and UN number are not required for in-country shipment

Shipment schedule:

- Shipment of samples from Paro Hospital to RCDC is scheduled for Thursday evening.
- Laboratory personnel responsible for the task should ensure the shipment box is dropped to the local post office by Thursday evening.
- Laboratory personnel must contact the local post office personnel to make appropriate arrangements.
- In case of emergency, the hospital may arrange vehicles on their own with prior information to RCDC.
- Call RCDC (17336964/17411950-whatsapp available) for shipment enquiries and information prior to shipment.

HIV PrEP Line-listing form for specimen referral to RCDC

Name of health Centre:				
Date and time of shipment:				
Sl. No	Specimen ID	Type of specimen	Date of collection	Remarks
Shipment prepared by:			Contact number:	

Annexure 4. Framework for implementing differentiated service delivery for PrEP in Bhutan

Building block	**PrEP initiation, initial follow-up (0-3 months) and reinitiating**			**PrEP Continuation**	
	Initiation	**Initial follow-up**	**Re-initiation**	**PrEP refill**	**Follow-up**
WHERE	Facility-based (Hospital & HISC)	Facility-based (Hospital & HISC)	Facility-based (Hospital & HISC)	Facility-based (Hospital & HISC) Pride Bhutan through Outreach workers (ORWs)	• Hospital • HISC • Community Outreach by ORWs.
WHO	Prescribers (Medical Officer (MO)/ Heath Assistants/ (HA)/Clinical officer (CO) Counsellors)	MO/HA/CO/ Counsellors	MO/HA/CO Counsellors	ORWs	MO/HA/ Counsellors & ORWs
WHEN	Screening and initiation on same day but not later than 2-3 days	Month 1 and then 3 monthly	Any time after completing the required assessment by an authorized prescriber	3 Monthly refill	Every 3 months
WHAT	Comprehensive service package (HIV test, suitability criteria screening, PrEP medication, preventive measures Condoms/Lube, counselling)	HIV test and other procedures/ services as per the protocol	Same procedures to be repeated as done at initiation	PrEP refill, condom/ lubes and counselling on adherence	HIV test and follow-up as per protocol

Annexure 5. The Monitoring and Evaluation for PrEP care continuum in Bhutan

Domain	Indicator	Definition	Numerator	Denominator	Reporting period
Pre-Uptake	PrEP service availability	This indicator aims to describe the availability of PrEP services in the country	The number of facilities that offer PrEP		Annual
	PrEP awareness among potential users	This indicator aims to track the awareness of PrEP as an HIV-prevention option among a specific population group	The number of people who report being aware of the existence of PrEP as an HIV-prevention option (Regardless of whether PrEP is available to them), among the denominators	The number of people from a sample population who are questioned about PrEP awareness	Depends on the feasibility of collection
	Willingness to use PrEP	This indicator aims to measure whether individuals among a specific population group are willing to use PrEP if it was available to them	The number of people who report willingness to use PrEP if available to them	The number of people who express willingness to use PrEP	Depends on the feasibility of collection
Uptake and coverage	Current PrEP users	This indicator aims to keep track of how many people used PrEP	The number of individuals who received PrEP for HIV prevention at		12 months

		during the reporting period	least once during the reporting period.		
	New PrEP users	This indicator aims to keep track of how many people used PrEP for the first time in their lives during the reporting period	The number of people who were prescribed PrEP for the first time in their lives during the previous reporting period		12 months
	PrEP coverage	This indicator aims to describe how many people currently use PrEP relative to the population in need of PrEP	The number of people who used PrEP at least once during the reporting period	The estimated number of people that are eligible for PrEP, according to PrEP-eligibility criteria	12 monthly
Continued and effective use	Recent PrEP use among people newly diagnosed with HIV .	This indicator aims to measure how many people experienced an HIV seroconversion, recently accessed PrEP	The number of people who received PrEP at least once in the 12 months prior to being diagnosed with HIV, and who had at least one follow-up HIV test, among the denominators	The number of people newly diagnosed with HIV during the reporting period	12 monthly
	PrEP continuation	This indicator aims to describe how many people who started PrEP continue to use it in the 12 months after PrEP initiation	The number of people who had at least one PrEP refill in the 12 months after PrEP initiation, among the denominators	The number of people who were prescribed PrEP for the first time in their lives during the previous reporting period	12 monthly

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