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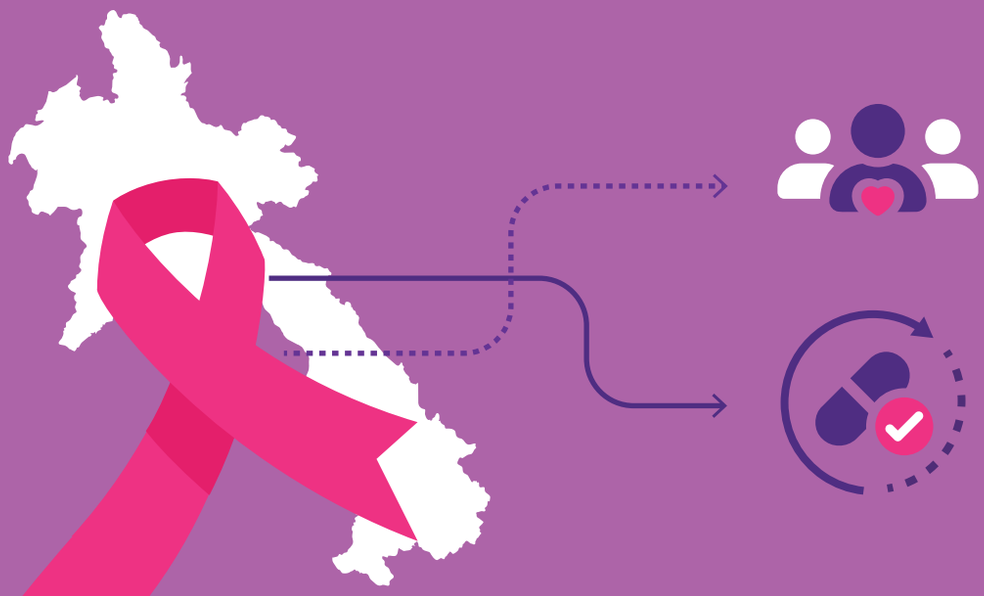


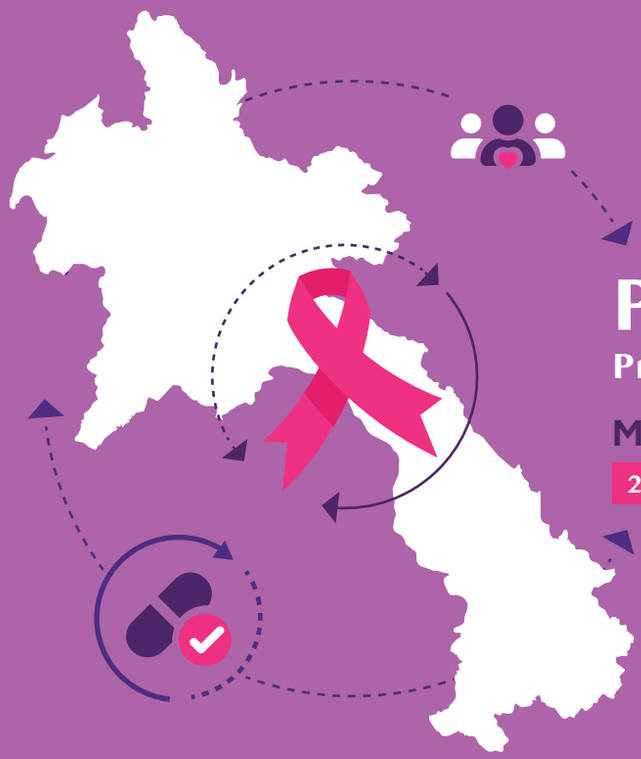
Pre-Exposure

Prophylaxis (PrEP) Guidelines

Ministry of Health, Lao PDR

First Version

20 January 2021



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Prophylaxis (PrEP) Guidelines

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20 January 2021

TABLE OF CONTENTS

FOREWORD

Lao PDR has responded to the HIV epidemic early and effectively in line with international strategies, policies, and lessons learned. Currently, the HIV prevalence among key populations is increasing, especially among men who have sex with men (MSM) (2.5%) and female sex workers (FSWs) (1%). Therefore, in order to reduce the HIV prevalence among key populations, the Centre for HIV/AIDS and STI (CHAS), Ministry of Health (MOH) has developed these Pre-Exposure Prophylaxis (PrEP) Guidelines. The purpose of these guidelines is to provide a reference for physicians and health care providers located in antiretroviral (ART) sites, health facilities, and communities to provide PrEP services for key populations, with the aim of reducing the rate of HIV infection in these populations. The guidelines also described the benefits of using PrEP as an additional prevention tool to effectively reach epidemic control.

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Special thanks to:

Dr. Phouthone Southalack	Director, CHAS
Dr. Khanthanouvieng Xayabounthavong	Dep. Director, CHAS
Dr. Panina Phoumsavanh	Dep. Director, CHAS
Dr. Ketmala Banchongphanith	Head of the Management on AIDS and STI (MAS) unit, CHAS
Dr. Phengphet Phetvixay	Head of the Information Education Communication (IEC) unit, CHAS
Dr. Souphanthong Manichanh	Dep. Head of the Admin unit, CHAS
Dr. Chanvilay Thammachack	Dep. Head of the management on AIDS and STI (MAS) unit, CHAS
Dr. Khanti Thongkham	Dep. Head of the Monitoring and Evaluation (M&E) unit, CHAS
Dr. Phonexay Latthanavong	Technical staff, M&E unit, CHAS
Dr. Manichanh Thongsana	Head of the Infectious Disease unit, Mitthaphap Hospital
Dr. Saykham Phaxayaseng	Head of the Infectious Disease Unit, Setthathiraj Hospital
Dr. Anouphet Chanthamavong	Dep. Head of the Infectious Disease Unit, Mitthaphap Hospital
Dr. Thipphasone Vixaysouk	Project Management Specialist (Health & Disabilities), U.S. Agency for International Development
Mrs. Phayvieng Philakorn	Associate Country Director, FHI 360, Lao PDR
Mr. Khamtue Vonglorkham	M&E Officer,
Stephen Mills	FHI 360, Lao PDR Regional Director, EpiC Thailand, Burma, LaosEpiC , FHI 360, Asia Pacific Regional Office
Dr. Tanat Chinbunchorn	Technical Support Manager/Research Physician Institute of HIV Research and Innovation
Dr. Nittaya Phanuphak Pungpapong	Executive Director, Institute of HIV Research and Innovation
Mr. Amphone Phomphibanh	Project Coordinator, EpiC, Community Health and Inclusion Association (CHias)
Mr. Somphavanh Chanthasili	M&E Officer, EpiC, CHias
Mr. Anousone Phetmixay	Provincial Coordinator Voluntary Testing and Counselling, EpiC, CHias

ACRONYMS AND ABBREVIATIONS

AEM	Asian Epidemic Modelling
AHI	Acute HIV Infection
ARS	Signs/symptoms of acute HIV infection
ART	Anti-retroviral therapy
CLPP	Condom and lubricants promotion and provision
CSOs	Civil Society Organization
ED-PrEP	Event-driven PrEP
EpiC	Meeting Targets and Maintaining Epidemic Control Project
FTC	emtricitabine
GBV	Gender based violence
HCV	Hepatitis C virus
ICC	Inform Choice Counselling
iNSC	Integrated Next Step Counselling
IPV	Intimate partner violence
MSM	Men who have sex with men
LMIS	Logistics Management and Information System
NAAT	HIV nucleic acid amplification testing
NASP	National HIV/AIDS Strategic and Action Plan
NCCA	The National Committee for the Control of AIDS
NGOs	Non-governmental organization
PMTCT	Prevention mother to child transmission
PLHIV	People living with HIV
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
3TC	lamivudine
SDG	Sustainable Development Goals
SOC	Standard of Care
TAF	Tenofovir alafenamide fumarate
TDF	tenofovir
TG	Transgender
UNAIDS	Joint United Nations Programme on HIV/AIDS
USCDC	United State- Centers for Disease Control and Prevention
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization
3 Zero	Getting to Zero strategy _ Zero New Infection, Zero AIDS related Deaths and Zero Discrimination.

1 INTRODUCTION

Lao PDR is categorized as a low HIV prevalence country, with an epidemic concentrated predominantly in key affected populations. National prevalence is estimated at 0.3% of the adult population (ages 15 to 49).1 Prevalence is significantly higher among key populations (KPs): 2.8% among men who have sex with men (MSM) and 1% among female sex workers (FSWs), though these levels are much higher in larger cities[1]. There is limited information on people who inject drugs (PWID), prisoners, and mobile populations; a 2010 survey reported 17.4% HIV prevalence among PWID.[1] To note, there has been no recent surveillance among transgender (TG) people, and this group is included among MSM in prevention and testing efforts. In 2014, HIV prevalence for MSM was 1.6% [2].

The latest available Asian Epidemic Modelling (AEM)[3] projects an increasing trend of new HIV infections among MSM, clients of sex workers, and former sex workers. New HIV infections are likely to occur in KPs who have higher prevalence and exposure to HIV transmission, as well as people involved in cross-border labor migration where sex work may concentrate[4].

1 UNAIDS AIDS Info 2018, UNAIDS 2018
2 IBBS draft report, 2014
3 AEM 2018
4 NSAP 2021-2030

1.1 ACHIEVEMENTS TO DATE

Lao PDR has responded effectively to the threat of HIV through strategic choices in line with international best practices in prevention, treatment, care, and support services, and effective programme management. The current strategic focus remains largely relevant to meet the challenges predicted for the next five years, namely the potential emergence of concentrated epidemics among most-at-risk populations. Adjustments needed to sharpen the current focus areas include scaling up coverage, increasing the quality of interventions, ensuring financial and organisational sustainability of HIV services, and increasing the capacity of implementing partners.

There were two milestones passed that support an enabling environment: National Strategic and Action Plan for HIV/AIDS and STI Prevention and Control 2021-2030 (National HIV and AIDS Strategic and Action Plan) and the AIDS law. These two milestones confirm the commitment of the Government of Laos to reach Millennial Development Goal 6 and the Three Zeros strategy. The law is progressive in terms of addressing stigma and discrimination and promoting equity. The National Committee for the Control of AIDS (NCCA) and Centre for HIV/AIDS and STI (CHAS) are at the forefront of spearheading support for the HIV response and are actively collaborating with different sectors to ensure the response's efficiency and effectiveness. Significant progress was achieved in the past planning period,

but with an increased number of people living with HIV (PLHIV) accessing antiretroviral (ARV) treatment, and with reduced donor support in recent years, prevention interventions have not reached sufficient coverage among key affected populations to make a significant impact[5].

1.2 STRATEGIC PRIORITY INTERVENTIONS

The goal of the National HIV and AIDS Strategy and Action Plan 2021-2030 of Lao PDR is to end the transmission of HIV and alleviate the impact of AIDS, with specific objectives to

1) strengthen an enabling environment for an effective HIV/AIDS and STI response;

2) improve access to quality prevention and testing services; and

3) increase access to quality testing, treatment, and care services.

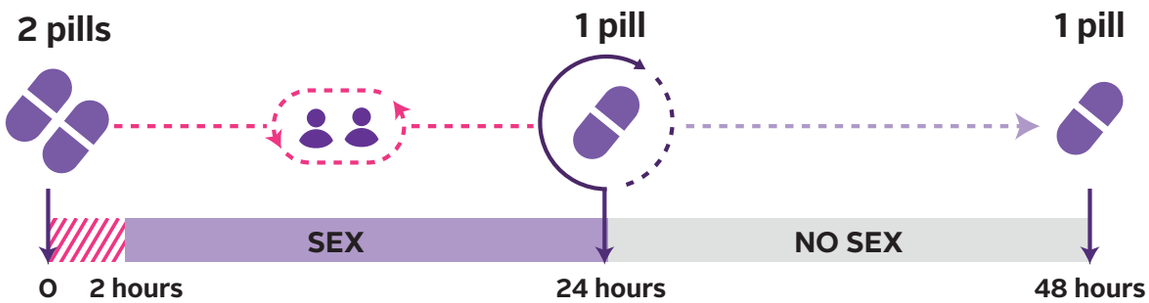
Under strategic objective 2, to improve access to quality prevention and testing services, the National HIV and AIDS Strategy and Action Plan 2021–2030 recommends that pre-exposure prophylaxis (PrEP) be offered to KPs, including FSWs, MSM, TG people, and PWID, as a component of combination HIV prevention services. PrEP to PWID should be offered as part of a larger prevention package that includes needle exchange, treatment, or opioid substitution therapy.

5 WHO External Review Report, 2014 and Global AIDS Country Response Report 2014

2 OVERVIEW

Since 2012, the World Health Organization (WHO) recommends the use of PrEP containing tenofovir disoproxil fumarate (TDF) alone or in combination with emtricitabine (FTC) or lamivudine (3TC) as a scientifically proven, additional HIV prevention measure for people at substantial risk for HIV infection [6,7,8,9,10,11,12].

WHO recommends two different dosing strategies: daily PrEP and event-driven PrEP (ED-PrEP). Daily PrEP is effective for all populations and consists of taking one pill of PrEP daily. ED-PrEP is only approved for MSM. ED-PrEP consists of taking a double dose (two pills, which serve as the loading dose) of TDF/FTC (or TDF/3TC) between two and 24 hours in advance of sex, then single daily doses until two days after the last potential exposure to HIV. ED-PrEP is for use when an isolated act of sex is involved. If more sex acts take place over the following days, a single PrEP pill can be continued daily for as long as sex continues and until two days after the last potential HIV exposure. 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 MSM. This 2+1+1 dosing is the only ED-PrEP regimen that has been demonstrated to be effective[13].



6 WHO. Appropriate medicines. Options for HIV pre-exposure prophylaxis. Meeting report, 21-22 March 2016. http://apps.who.int/iris/bitstream/handle/10665/273934/WHO-CDS-HIV-18.22- eng.pdf (accessed September 2018). 2016.

7 WHO. Technical update on appropriate medicine options for pre-exposure prophylaxis. A review of the evidence from animal studies, human pharmacology and human clinical trials. 2017

8 WHO. WHO implementation tool for pre-exposure prophylaxis of HIV infection. http://www.who.int/hiv/pub/prep/prep-implementation-tool/en/ (accessed September 2018). 2017.

9 WHO. Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV. http://www.who.int/hiv/pub/guidance_prep/en/ (accessed September 2018).

10 WHO. WHO expands recommendation on oral pre-exposure prophylaxis of HIV infection (PrEP). Policy brief. http://www.who.int/hiv/pub/prep/policy-brief-prep-2015/en/ (accessed September 2018). 2015

11 WHO. Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV

12 Recommendations for use in the context of demonstration projects. https://www.who.int/hiv/pub/guidance_prep/en/ (accessed December, 2018). 2012.

13 WHAT'S THE 2+1+1? TECHNICAL BRIEF EVENT-DRIVEN ORAL PRE-EXPOSURE PROPHYLAXIS TO PREVENT HIV FOR MEN WHO HAVE SEX WITH MEN: UPDATE TO WHO'S RECOMMENDATION ON ORAL PREP, WHO, July 2019

The implementation of PrEP services is recommended as part of combination HIV prevention, which includes

1) behavioral change interventions toward HIV risk reduction,

2) condom and lubricants promotion and provision (CLPP),

3) voluntary medical male circumcision (VMMC) (in settings where the lack of circumcision poses substantial risk);

4) regular HIV/STI testing;

5) treatment as prevention (ART, post-exposure prophylaxis [PEP], PrEP); and

6) harm reduction.

PrEP has been shown to be a highly efficient method to prevent HIV infection when taken consistently. It has an excellent safety profile and has low risk for ARV drug resistance. The risk of resistance to either TDF or FTC is low, occurring in approximately 1 in 1,000 PrEP users in clinical trials, and was mainly seen in those with undetected acute HIV infection at the time of initiating PrEP. Various trials have shown that the overall implementation of PrEP is expected to decrease the public health burden of HIV drug resistance. Additional documents and guidelines on PrEP were produced by WHO, UNAIDS, and the U.S. Centers for Disease Control and Prevention in 2015-2018 to reinforce and expand its implementation.

Many countries have embraced the WHO recommendations and have made PrEP available in combination with early testing and treatment to reduce new cases of HIV infection among populations at sustained risk. In the ASEAN region, most countries have introduced PrEP as a new approach to prevent HIV transmission among high-risk populations: Burma, Cambodia, the Philippines, Thailand, Vietnam are moving to scale-up their PrEP programs. At the time of these guidelines, China and Malaysia are conducting or expanding PrEP demonstration projects.

3 RATIONALE

To end AIDS and eliminate new HIV infections by 2025 in Laos, more collective and intensified strategic efforts are necessary. PrEP offers a complementary biomedical approach to prevent the acquisition of HIV infection and the consequent morbidity and mortality, lower the cost to society, and stop onward transmission. PrEP complements other interventions of the Laos national HIV program, which is already promoting behavioral risk reduction, condom use, and treatment as prevention through its test and treat strategy and early case detection via screening of individuals at high risk.

In Laos, the national HIV program recommends offering PrEP to any clients with ongoing or expected substantial risk for HIV infection, with service delivery focus on key affected populations, such as FSWs, MSM, TG people, and PWID. The Laos national HIV program also recommends provision of ED-PrEP to MSM (men exposed through receptive or insertive anal sex with other men, only).

The following drug regimens are recommended:

- TDF (300 mg) / FTC (200 mg)
- TDF (300 mg) / 3TC (300 mg)
- Tenofovir alafenamide fumarate (TAF) (25 mg) / FTC (200mg)[14]

PrEP has no or minimal drug interactions with commonly prescribed medicines nor significant side effects and has proven to be safe in many randomized controlled trials.

14 TAF/FTC is not currently recommended by WHO for PrEP, while the U.S. Food and Drug Administration has approved its use among MSM only and as a daily regimen

4 GOAL AND OBJECTIVES

The goal of these guidelines is to reduce the spread of HIV infection, with the following specific objectives:

1. **Support the prescription of locally approved and available co-formulations for PrEP of TDF/FTC, TDF/3TC, or TAF/FTC**

2. **Guide providers in recruiting and evaluating clients for PrEP eligibility**

3. **Guide providers in counaselling, initiating, and monitoring clients on PrEP**

5 LEADERSHIP

This section address issues regarding leadership and governance to increase ownership and coordination of PrEP response at all levels. The national-level response, led by the MOH CHAS, is responsible for formulating policy; providing technical assistance to the counties in setting targets, operational planning, and M&E; and research and resource mobilization. This is done with the support of a PrEP technical working group and in consultation with key stakeholder. The national government authorities provide leadership in implementation planning, adaptation and dissemination of guidelines and policies, capacity building, community engagement, and coordination of stakeholders. They are also responsible for M&E and ensuring quality of HIV services in the region.

Community leadership remains key; hence there is need for extensive community engagement in the implementation of this framework. This work may include community and religious leaders, the private sector, media, PLHIV, and the potential PrEP users. This approach allows for increased demand of services, identification and addressing of gaps in service delivery and ownership/adoption of PrEP in the community. All stakeholders have a role in advocating for investment in PrEP as an additional HIV prevention intervention.

For successful implementation of PrEP, there is need to consider human resources for health approaches like :

Task-sharing/ shifting and community-based delivery approaches.

Regulatory authorities should ensure rational use of this ARV both in the public and private sector.

Rational use will therefore be a joint activity with mutual accountability from both public and private sectors.

6 HUMAN RESOURCES

PrEP is a prescription-only drug and hence has restrictions, and these guidelines recommend provision of PrEP services in alignment with the national policy.

A concerted, multidisciplinary effort is needed to promote, prescribe, dispense, and provide PrEP to populations who are most in need as part of a comprehensive HIV prevention package. Doctors, clinical officers, nurses, pharmacists, pharmaceutical technologists, laboratory personnel, peer navigators, peer educators, and community health volunteers will need to work together in planning and updating or revising service provision and supervisory roles delegated to each discipline to fit each population's context. Task-sharing amongst nonclinical (or less specialized) cadres should be considered to support provision of PrEP at health facilities and into the community.

Training on PrEP delivery should be conducted through:

- In-service training

- Pre-service education for health professionals, including doctors, clinical officers, nurses, pharmacists, pharmaceutical technologists, laboratory personnel, and health managers

- In the training for lay workers (e.g., peer navigators, peer educators, community health volunteers).

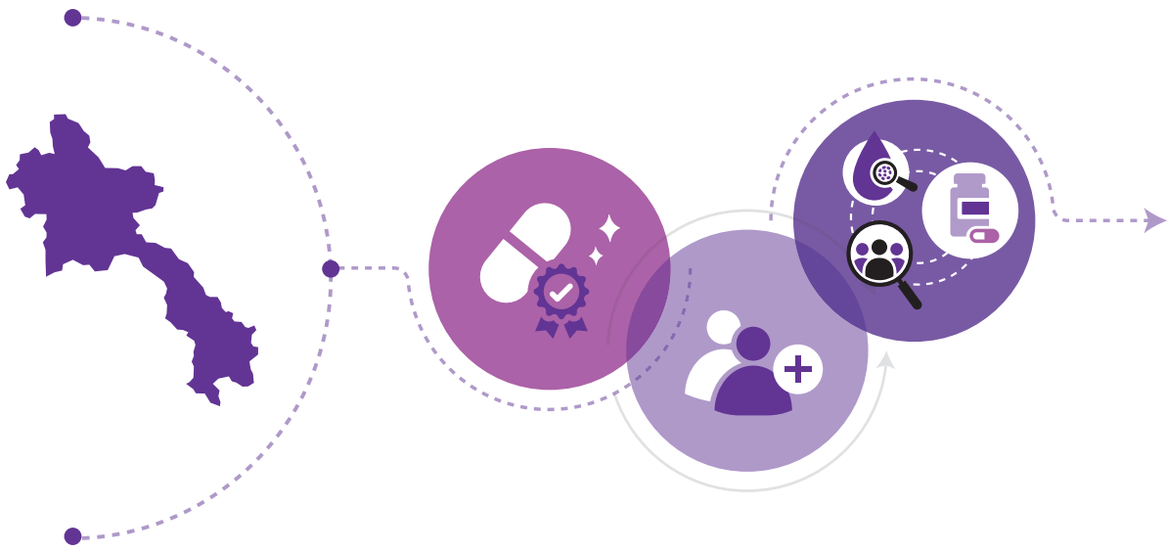
A cascade approach should be used, which involves training master Trainer of Trainers (TOTs) at national and regional levels, who will then build capacity of health workers, peer navigators and educators, and community health volunteers.

PrEP is not a standalone intervention and hence it will be incorporated in other HIV training programs, including HIV testing, care, and treatment; VMMC; and prevention of mother-to-child transmission. Providers of these services will then link beneficiaries who test HIV negative to PrEP. Training, mentorship, and quality improvement should be an on-going process to ensure that service providers are adequately trained and competent.

Health education sessions that include PrEP information should be offered at a variety of facilities (e.g., STI clinics) to inform potential clients about PrEP with the intention of increasing uptake as part of a combination prevention package.

7 PUBLIC-PRIVATE PARTNERSHIPS

PrEP services provided by nongovernmental organizations (NGOs) and the private sector complement the public sector and contribute toward expanding access to quality PrEP services. A structured engagement process of NGOs and the private sector will expand access to HIV testing services and make it easier for potential clients to obtain PrEP. However, an agreed-upon accreditation process that conforms to national guidelines will be followed by NGOs and the private sector.



8 COMMODITY LOGISTICS

PrEP should be managed as part of the national logistics management system. PrEP drugs should be availed by the MOH and distributed to PrEP service delivery points. Procurement is based on national annual quantification and forecasting guided by annual national PrEP targets. Once PrEP commodities are in-country, they should be delivered for warehousing and distribution with other commodities usually supplied to implementing sites. PrEP will be distributed upon requests by facilities, and based on a national distribution plan.

Supply of commodities is based upon reports by the facilities. Facilities' ordering of commodities is to be done during the reporting period, as is routine for other ARVs and HIV commodities. The initial supply of drugs should be delivered (1) based on facility requests for PrEP to CHAS, after a site readiness assessment has been conducted, and PrEP providers have been trained on the new PrEP guidelines and on Logistics Management and Information System (LMIS) tools. New service delivery points should be linked to the national supply system through designated ordering sites to ensure that their have clients access to the commodities.

Pharmacovigilance should be integrated into the follow-up of product use to

(1) monitor adverse drug reactions using national Pharmacovigilance Forms and any hypersensitivity reactions to PrEP and

(2) monitor quality of PrEP commodities annually by conducting post-market surveillance in conjunction with the Department of Food and Drug Administration of MOH, CHAS, and other stakeholders. Poor quality medicines should be documented using the relevant national forms.

9 COMMUNICATIONS, ADVOCACY, AND COMMUNITY ENGAGEMENT

Proactive and meaningful engagement of stakeholders[15] is key for successful PrEP rollout. A communication plan should address perceptions of PrEP with all stakeholders through a positive narrative about PrEP, effective and timely dissemination of information, and a transparent relationship with all stakeholders. Furthermore, the communication plan should help ensure that there is increased knowledge of PrEP as a part of HIV combination prevention; ensure that there is improved positive perceptions/attitudes about the benefits of PrEP; relay accurate information about PrEP; and create demand for PrEP. The plan should also help to address the issue of stigma and discrimination that can negatively affect uptake of and adherence to PrEP. The objectives of the communication plan are to:

- Increase knowledge of PrEP and PrEP services, provide information on where PrEP can be accessed, and counter misinformation about PrEP with accurate and trusted messages

- Create a positive perception and improve the attitude toward PrEP amongst all stakeholder groups

- Increase demand for PrEP amongst the target audience

Communications messages for each audience group are anchored on the positioning statements, and the modes or channels of communication should depend on the nature of the audience. Communications messages are aimed at creating knowledge, awareness, and demand and are based on the following broad topics: what PrEP is and what it is not, evidence of PrEP efficacy and why PrEP is important, the role of PrEP, who PrEP is for, misuse /abuse of PrEP, PrEP side effects, safely starting and stopping PrEP, changing between PrEP daily and ED-PrEP safely, and the importance of regular HIV and STI testing. Deliver of these messages should be tailored to suit each audience segment. Careful consideration should be given to the choice of communication channels to be used to reach specific populations (e.g., social media platforms to reach young people or key populations as opposed to policy makers, who need more formal channels; hotlines; websites).

The success or failure of PrEP rollout will depend on advocacy work undertaken at all levels in society. There is need for aggressive advocacy at the grassroots level, including with community advisory boards, influencers, and opinion leaders, among others, to increase acceptability of PrEP and reduce stigma toward PrEP users. Policy and advocacy forums at county and national levels are instrumental in ensuring advocacy toward adequate resource allocation for PrEP delivery and response to implementation needs. Through their testimonials, current PrEP users are powerful advocates of PrEP.

Structured, systematic, and constructive engagement of stakeholders is critical from the pre-rollout stage, throughout the rollout of PrEP, and beyond. Ongoing stakeholder engagement helps to improve people's knowledge, perceptions, and attitudes, and provides information about when it may be necessary re-strategize.

15 Stakeholders refers to government officials at central, regional/provincial and district level, local and international partners, supporting facility as well community level services; civil society organizations, non-governmental organizations; beneficiaries of the PrEP service and the community within which such service is offered, such as local community leaders

10 SERVICE DELIVERY MODELS

Delivery of PrEP through the health system provides the opportunity to strengthen existing services and reinforce linkages between complementary services, such as STI and reproductive health services. With HIV testing as the gateway to PrEP initiation, novel approaches such as the use of HIV self-testing can also provide an additional strategy to support continued PrEP use.

This section describes service delivery modalities in terms of demand creation and venues where PrEP can be offered. All providers offering PrEP demand creation, clinical services, and monitoring should have been trained through the national curriculum.

10.1 DEMAND CREATION

Community-based outreach workers and health care providers should work closely with the targeted communities to create awareness of and demand for PrEP. In-person and virtual contacts should be used to educate communities about the availability of PrEP and help to navigate people to PrEP services. Health care providers are responsible for identifying eligible clients for PrEP among serodiscordant couples at ART clinics and among those testing HIV negative at facility-based testing and counselling services and STI clinics.

Knowledge about PrEP has grown enormously in the past year, though community-level stigma and misconceptions sometimes surround PrEP's introduction[16]. Furthermore, male partner violence has been documented as a barrier to start and/or continue PrEP, with individuals sometimes prioritizing coping with the relationship over HIV prevention[17]. The refore, it is recommended to address these issues as part of the demand creation activities.

Community based outreach worker and the health care worker should refer to PrEP sites those individuals who are at substantial risk of HIV infection and who test HIV negative in the event such test can be done prior the referral.

10.2 FACILITY- AND COMMUNITY-BASED APPROACHES

A facility-based approach refers to PrEP services provided at a public, NGO, or private clinic where potential clients either come on their own or are referred by a community-based outreach worker. Community-based approach refers to PrEP services provided at a community site. Both venues should meet safety, privacy, and confidentiality standards.

Before they prescribe and initiate clients on PrEP, health care workers at facility and community sites should assess clients against the PrEP eligibility criteria and offer counselling.

16 Sevelius JM, Keatley J, Calma N, Arnold E. "I am not a man": trans-specific barriers and facilitators to PrEP acceptability among transgender women. Glob Public Health. 2016;11(7-8):1060-75.

17 Murire M, Ridgeway K, Lanham M, Shamu P, Pillay D, Shoko N et al. Service provider insights: implications for national training and support for PrEP provision in South Africa. Tenth International AIDS Society Conference, Mexico City, 21–24 July 2019. Abstract TUPEC 420

Any health facility that is part of the national health system and is included in the national supply chain management system is eligible to offer PrEP provided that:

- The health facility is within the list of sites to be supplied with the PrEP medications
- The health care providers / community-based health care providers who are in charge of creating demand and prescribing and dispensing PrEP have been trained on the national curriculum and are accredited to offer HIV testing services
- HIV testing services are available
- PrEP M&E tools have been printed and distributed
- A laboratory facility or a rapid diagnostic test is available or a transportation system to a reference laboratory is in place, for hepatitis serology and a creatinine test [18].

If PrEP services are offered at the community level where clients are initiated and receive refills, the medications should be supplied by the reference health facility to which the community service is linked. The lab test should be either done at the community level through point of care/rapid test or the samples should be collected and transported to the laboratory of the reference health facility.

Some service delivery locations may include:

- One-stop shops
- Drop-in centers (including in community and facility settings)
- HIV clinics (for HIV-negative partners before the HIV-positive partner has a suppressed viral load or when viral suppression is unknown)
- Antenatal care and maternal, newborn, and child health clinics
- Family planning, reproductive health, and STI clinics and mobile health clinics
- Community settings meeting the criteria for initial client assessment and evaluation, e.g., integrated prevention centers and youth-friendly outlets
- Primary care settings
- Virtual settings

18 Creatinine and hepatitis test are recommended only to those who have signs/symptoms and/or increased chances of renal/liver impairment or creatinine elevation

11 DEMAND CREATION

It is recommended that PrEP be offered to HIV-negative individuals who are at substantial risk of acquiring HIV and lack contraindications for PrEP. Risk assessment questions can aid in assessing individual risk level as part of the pre- or post-HIV test counselling process but should not be used to ration PrEP or serve as the only criteria for determining whether someone should take PrEP. Risk assessments are considered tools and should not be required. If someone asks for PrEP, they should be given PrEP regardless of whether a risk assessment is completed or what the result of the risk assessment was. **Requesting PrEP has been shown to be an indicator of substantial risk.**

• Risk assessment

- HIV-uninfected individuals[19] with body weight >35 kg AND at ongoing or expected substantial risk for HIV infection as per (but not limited to) the following examples:
  - Sexual partner of person living with HIV who is not virally suppressed OR
  - Sexual partner of a person living with HIV whose viral load is unknown OR
  - History of condomless anal, vaginal, or neovaginal sex with more than one partner in the past 6 months OR
  - History of a STI in the past 6 months (by laboratory-confirmed diagnosis or by symptoms) OR
  - Received PEP one or more times in the past 6 months OR
  - Sexual partner has one or more of the HIV risk factors listed above OR
  - Refuses to report a risk category but still requests PrEP

• Clinical eligibility

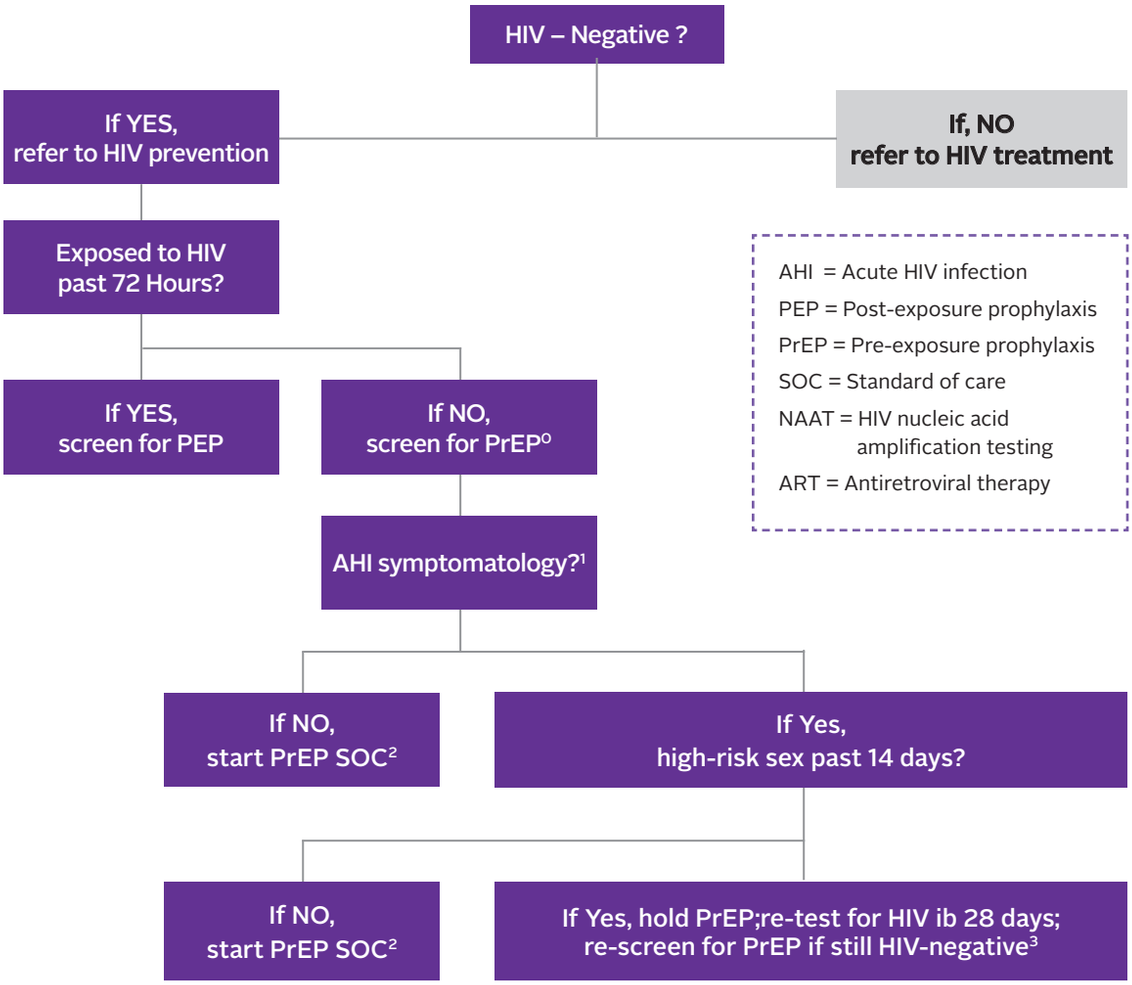
- Free of symptoms of acute HIV infection (AHI)[20] and no recent possible exposure
- Good renal function (creatinine clearance > 60 mL/min), if known
- Free of any allergy to TDF, TAF, 3TC, or FTC
- Willing to consent to and use PrEP as prescribed, including periodic HIV testing and enhanced adherence counselling sessions

19 HIV negative using a rapid antibody test as per the National HIV testing algorithm

20 No suspicion of Acute HIV infection (AHI), that is, following possible exposure to HIV, clients with any of the following in the past 72 hours Fever, Lymphadenopathy, Mucocutaneous ulceration, Rash, Headaches, sore throat, aches and pains

The first step in determining whether someone is clinically able to take PrEP is to determine whether there has been HIV exposure in the past 72 hours and rule out AHI. See Figure 1.

Figure 1: PrEP initiation – HIV exposure and AHI assessment[21]



[O] An answer of "NO" to question "Exposed to HIV past 72 hours?" means no known past exposure to HIV at all or known HIV exposure that was 73+ hours ago.

[1] Signs/symptoms mimicking acute HIV infection (sore throat, fever, sweats, swollen glands, mouth ulcers, headache, rash, muscle aches) are commonly due to illnesses other than HIV; providers need to use discretion in determining whether the symptomatology is consistent with HIV, or whether an alternative cause may explain them.

[2] PrEP standard of care: clinical eligibility screening and risk assessment per WHO/national guidelines, e.g., creatinine clearance, medical history, hepatitis screening, etc.

[3] If NAAT (nucleic acid amplification testing) is available, PrEP may be started earlier than 28 days, if NAAT negative. Clinician may consider fully suppressive ART in 28-day interim if waiting 28 days to re-test for HIV.

21 Developed by Jhpiego in collaboration with Jared Baeten (Univ of Washington) and Rachel Baggaley (WHO)

If the client is determined to be at risk for HIV and AHI is ruled out, clinical eligibility for PrEP should be assessed.

The following are contraindications for daily PrEP:

- HIV infection
- Signs/symptoms of acute HIV infection with probable recent exposure to HIV
- Estimated creatinine clearance of less than 60 ml/min (if known)
- Concurrent nephrotoxic medication
- Allergy or contraindication to any medicine in the PrEP regimen

For MSM, oral daily PrEP and ED-PrEP can be offered as options, and the choice can be based on a person's circumstances and preferences, including the frequency and predictability of sex and whether sex is anticipated. Men who have sex with men on PrEP can switch from daily dosing to ED-PrEP (and vice versa). Switching between daily and ED-PrEP can be done easily and safely. MSM should be provided with information during their first visit on how to safely start, stop, and change regimens if they choose.

In the context of ED-PrEP, following are the recommended eligibility criteria for MSM:

- Has infrequent sex (for example, sex less than two times per week on average)
- Can plan for sex at least 2 hours in advance, or can delay sex for at least 2 hours

Following are contraindications for ED-PrEP dosing among MSM:

- HIV infection
- Signs/symptoms of acute HIV infection with probable recent exposure to HIV
- Estimated creatinine clearance of less than 60 ml/min (if known)
- Concurrent nephrotoxic medication
- Chronic hepatitis B infection

Health care workers should help clients decide on the most suitable dosing and duration of PrEP, as described in Table 1.

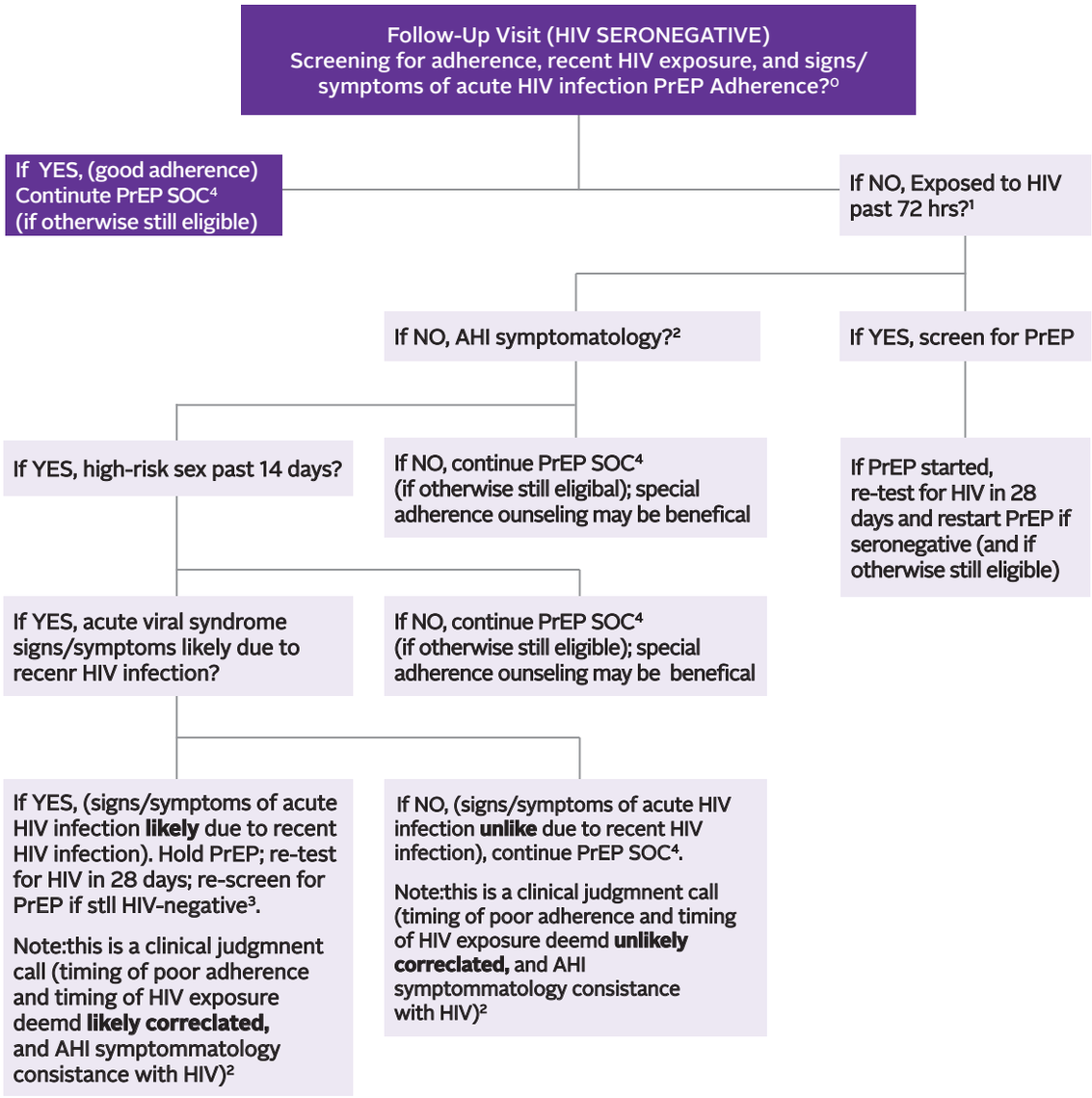
Table 1. Dosing and duration of PrEP

Dosing	Remarks	Loading dose to achieve protection from HIV infection	Dose from last exposure if coming off PrEP
Daily	It should be taken daily at the same time and each day	Everyone (except men who only have sex with men) needs one pill for at least seven days prior to potential exposure.	Everyone (except men who only have sex with men) needs one pill daily for 28 days after last potential exposure.
		Men who only have sex with men need two pills at 2 to 24 hours before potential exposure	Men who only have sex with men need one pill daily for two days after last potential exposure
Single event (Men who only have sex with men)	First dose: two pills at 2 to 24 hours before the first sexual intercourse. Second dose: one pill at 24 hours after the first dose. Third dose: one pill at 24 hours after the second dose. If risk continues beyond one event, the individual should continue taking one pill per day until 2 days after the last risk event. Pills should be taken each day at the same time.	Men who only have sex with men need two pills at 2 to 24 hours prior to potential exposure.	Men who only have sex with men need one pill daily for 2 days after last potential exposure.

Initially, PrEP should be prescribed for one month. After the first month, at the first follow-up visit, the client should receive a three-month supply. Three months' supply can also be considered at initiation, on a case-by-case basis and based on client–provider discussion and according to heath facilities' drug supply conditions.

At each follow-up visit, review of PrEP adherence, recent HIV exposure, and signs/symptoms of AHI should continue. The flow diagram shown below (Figure 2) can be used to assist with this process.

Figure 2: PrEP follow-up – HIV exposure, AHI, and adherence assessment[22]



[0] If adherence was so poor as to constitute PrEP discontinuation, then refer back to Initiation Visit.

[1] An answer of "NO" to question "Exposed to HIV past 72 hours?" means no known past exposure to HIV at all or known HIV exposure that was 73+ hours ago.

[2] Signs/symptoms mimicking acute HIV infection (sore throat, fever, sweats, swollen glands, mouth ulcers, headache, rash, muscle aches) are commonly due to illnesses other than HIV; providers need to use discretion in determining whether the symptomatology is consistent with HIV, or whether an alternative cause may explain them.

[3] If NAAT is available, PrEP may be started earlier than 28 days, if NAAT negative. Clinician may consider fully suppressive ART in 28-day interim if waiting 28 days to re-test for HIV.

[4] PrEP standard of care: clinical eligibility screening and risk assessment per WHO/national guidelines, e.g., creatinine clearance, medical history, hepatitis screening, etc.

22 Developed by Jhpiego in collaboration with Jared Baeten (Univ of Washington) and Rachel Baggaley (WHO)

Clinical and laboratory monitoring requirement of PrEP / ED-PrEP clients are listed in Table 2.

Table 2. Clinical and laboratory monitoring requirements

Monitoring	Baseline	Frequency at follow-up
Medical history	YES	Every visit
Clinical assessment	YES	Every visit
Assessment of need for contraceptives and/or pregnancy testing	YES	Every visit
Assess for adverse drug reactions	YES	Every visit
Mental health, gender-based violence (GBV), including intimate partner violence (IPV), and substance use screening and counselling	YES	Every visit
STI screening and counselling[23]	YES	Every visit
Counselling on safer sex practices during the window periods; condom and lubricants promotion and provision	YES	Every visit
AHI screening	YES	Every visit
HIV test[24]	YES	Every visit
Creatinine clearance[25]	YES If signs/symptoms or risk for and/or increased chances of renal impairment or creatinine elevation	Semi-annually
HBV serology[26]	YES	Annually
Hepatitis C virus (HCV) serology[27]	YES	Annually

23 STI screening (syphilis, N gonorrhea and C trachomatis) should be offered through syndromic approach or using a laboratory diagnostic test

24 A fourth generation HIV Ag/Ab test is recommended

25 After month 3, assess creatinine clearance on a 6-monthly basis. Estimated Creatinine Clearance: For men: (((140 - age in years) x (wt in kg)) x 1.23) / (serum creatinine in micromol/l). For women: 0.85 x (((140 - age in years) x (wt in kg)) x 1.23) / (serum creatinine in micromol/l).

26 Hepatitis B serology is indicated to MSM opting for ED-PrEP. HBsAg negative: offer hepatitis B vaccination (as per national hepatitis guidelines). HBsAg positive: see section on clients with a hepatitis B infection.

27 Hepatitis C serology should not be a barrier for daily PrEP initiation and continuation; if available, consider it for MSM and PWID; If positive, refer for assessment and treatment for hepatitis C

Important considerations

- For clients with **pre-existing risk factors for renal impairment**, every effort should be made to obtain a serum creatinine before initiation of PrEP. Risk factors include age >50, hypertension, diabetes mellitus, body weight ≤55kg, other nephrotoxic medication, any symptoms or signs suggestive of renal impairment.

- If estimated creatinine clearance is <60 ml/min, it is recommended to repeat the serum creatinine levels on a separate sample, on a separate day because creatinine measurements vary from day to day, depending on hydration, exercise, diet, and other factors. If estimated creatinine clearance is confirmed to be <60 ml/min, it is recommended to interrupt PrEP, repeat serum creatinine in one month, and restart once creatinine clearance is restored to >60 ml/min. Consider more frequently if there is a history of conditions affecting the kidney, such as diabetes or hypertension; consider less frequently if aged less than 45 years, baseline estimated creatinine clearance >90 ml/min, and weight more than 55 kg. Stopping TDF-containing PrEP is typically sufficient to restore baseline renal function. Additional causes and management of creatinine elevations can be considered, 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.

  Common causes of chronic or severe renal insufficiency are diabetes mellitus, uncontrolled systemic hypertension, HCV infection, liver failure from any cause and pre-eclampsia during pregnancy.

- **Side effects:** major toxicities associated with TDF/FTC are rare in PrEP exposure to date. Minor side effects are relatively common but are mild and self-limiting if they do occur (approximately 1 in 10 individuals in the first 1 to 2 months), and do not require discontinuation of PrEP
  - **Major side effects:** renal toxicity and metabolic complications (decreased bone mineral density, which is reversible in adults upon stopping PrEP), extremely small risk of lactic acidosis and hepatic steatosis or steatohepatitis; in such circumstances, PrEP can be interrupted.
  - **Minor side effects:** gastrointestinal symptoms (diarrhoea, nausea, vomiting, and flatulence), headache and skin problems or itching, which are self-limiting and typically end within first month of use (start-up syndrome); unintentional weight loss.
  - **Less predictable side effects:** hypersensitivity reactions and flares of hepatitis B in those who are chronic carriers if they stop TDF/FTC.

- **If adverse drug reaction,** complete the national form and report as per national standard operating procedures.

- **Clients with hepatitis B infection wanting PrEP:**
  - ED-PrEP is contraindicated in clients with chronic hepatitis B infection.
  - Daily PrEP is not contraindicated in clients with hepatitis B infection; if the HBsAg result is positive, the client can initiate daily PrEP.
  - Additional assessment can be considered for people with hepatitis B infection who are considering PrEP.
  - Clients with hepatitis B infection who are not interested in PrEP or stopping PrEP should be referred to relevant management/treatment services. Daily PrEP can be given to clients with active HBV infection with a warning that stopping PrEP can cause a flare-up of HBV.
  - Clients starting PrEP who have hepatitis B infection may benefit from additional counselling to ensure they are aware of the need for ongoing treatment should they wish to stop taking PrEP for HIV prevention.

- There are no known interactions between PrEP medications and **alcohol or recreational drugs**. However, if a PrEP user thinks that his or her use of alcohol or other substances is interfering with taking PrEP regularly, the PrEP provider should discuss and support behavior change and offer additional prevention options, including condoms.

- PrEP can be used safely by most people including **pregnant or breastfeeding women**, women using hormonal drugs for contraception, and transgender people on **gender-affirmative hormone therapy**.

- Standard TB medication does not interact with PrEP drugs and there is no need for dose adjustments. Clients on MDR-TB medications may have increased risk of renal side effects. Therefore, a clinician should determine if PrEP can be used on a case-by-case basis. Other prevention methods should be recommended, and PrEP screening should be delayed until the end of MDR-TB treatment.

- **HIV seroconversion** after initiating PrEP can occur and may be due to nonadherence or being in the window period at the time of testing. As soon as an HIV-positive test has been confirmed, ART should be immediately initiated using first-line regimens, and the client must be linked to HIV care and treatment. Document seroconversion and possible reason for seroconversion (nonadherence, stopped taking PrEP, or PrEP failure, i.e., breakthrough infection while adherent to PrEP).

Stopping PrEP

Ideally, clients should inform their service provider when they want to discontinue PrEP. The duration of PrEP use may vary, and individuals are likely to start and stop PrEP depending on their individual risk assessment at different periods in their lives, including changes in sexual relationship status, behaviors, and ability to adhere to a PrEP maintenance program.

Health care workers should discuss the options of when to discontinue PrEP with their clients. PrEP may be stopped for the following reasons:

- Client request
- Positive HIV test (clients who seroconvert while on PrEP should be immediately linked to care and initiated on ART in line with national guidelines)
- Safety concerns, such as persistent creatinine clearance <60 mL/min
- No longer at substantial risk
- Decision to switch from PrEP to a different HIV prevention method(s)
- Persistent side effects

In addition, the provider should be sure to:

- Explore risks and alternative prevention/risk reduction strategies
- Advise the client that an HIV test is required to re-start PrEP
- Remind the client of PrEP use that is required after the last potential exposure (at least two days for men whose only potential exposure to HIV is through sex with other men and at least 28 days for other clients)
- Encourage ongoing links to appropriate HIV prevention and contraceptive services, as well as the use of other HIV prevention strategies, as needed

Restarting PrEP

Individuals restarting PrEP will need to be tested again for HIV and be free of any contraindications for PrEP.

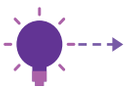
12 EDUCATION AND COUNSELING FOR PrEP

Education and counselling for clients considering PrEP, or clients already on PrEP, are important to ensure that it is used effectively.

PrEP counselling should be based on the following principles:

- Be client-driven, based on clients' needs, resources, and preferences

- Be based on a foundation of respect and include an open and honest relationship between provider and client



- Recognize that behavior change is not easy, and human beings are not perfect

- Validate and normalize client concerns and seek to affirm and encourage client efforts and not be prescriptive or judgmental

- Focus on identifying small wins and achievable next steps in reducing risk and/or making pill-taking easier

- Include contingency planning when common barriers are encountered

Risk Reduction Counselling

Risk reduction counselling is a behavioral intervention that attempts to decrease an individual's chances of acquiring HIV and other STIs. It includes counselling about HIV and other STI prevention, prevention of unintended pregnancy, GBV/IPV prevention and mitigation, and other sexual and reproductive health issues and should be provided at all follow-up visits for PrEP users.

The main objective of risk reduction counselling is for clients to assess individual risk, acknowledge self-risk, and set realistic goals for behavior change that could reduce their risk of acquiring HIV and other STIs, as well as prevent unintended pregnancies.

This counselling, which is most effective when nonjudgmental and user-centered, can be provided by any trained health care provider and should:

- Explore the context of the client's specific sexual practices and psychosocial status and help the client recognize any of their behaviors that are associated with higher risks for HIV infection or unintended pregnancy. Health care providers should also be aware that clients might not always perceive their own risk or may be in denial about it.

- If the client discloses that they have experienced or are at risk of GBV, including IPV, provide first-line support and make referrals as appropriate. Discuss how violence and fear of violence affects their risk and prevention behaviors and discuss ways to stay safe and protect themselves in the context of their relationship(s).

- Identify the sexual health protection needs of the potential PrEP user and reflect on what his or her main concerns appear to be.

- Strategize with the client about how they can manage these concerns or needs.

- Agree on which strategies the client is willing to explore and provide guidance on how to implement them.

See Table 3 for additional counselling and education messages for clients about PrEP.

Table 3. Counselling and Education Messages for Clients about PrEP

Topic	Key Messages
What is PrEP?	PrEP is one of several HIV prevention options and, where possible, should be used in combination with condoms and other prevention methods. PrEP does not protect against other STIs or prevent unintended pregnancy.
PrEP works if taken as prescribed	For PrEP to be effective, you must take PrEP as prescribed, which for most people is every day throughout their time at risk.
PrEP is not for life	You should take PrEP for as long as you feel you are at risk of HIV infection. Some people only need to take PrEP during certain times in their lives, while others have an ongoing need.
Starting and stopping PrEP	For everyone other than men whose only exposure to HIV is through sex with other men: One pill of PrEP must be taken daily for seven consecutive days before exposure to have maximum efficacy, and the pills must be taken at approximately the same time every day. To discontinue PrEP safely, one pill of PrEP must be continued daily for 28 days after the last potential exposure. For men whose only exposure to HIV is through sex with other men: For those taking a daily regimen: Two pills of PrEP must be taken at least two hours before sex to have maximum efficacy. One pill should be taken daily at approximately the same time thereafter. To discontinue PrEP safely, one pill of PrEP should be taken daily until two days after last potential exposure. For those taking an ED regimen: Two pills of PrEP (the loading dose) must be taken 2-24 hours before having sex. One pill of PrEP should be taken daily at the same time as the loading dose until two days after last potential exposure. This process should be repeated for each period of potential exposure to HIV.

Ways to support adherence	PrEP can be taken any time of the day, preferably at the same time every day, with or without food. If you forget a dose on daily PrEP, take it as soon as you remember. Some people find it easy to remember to take their PrEP when they integrate it into a daily routine and take it the same time each day. For example, you could take PrEP when you brush your teeth (either in the morning or evening), or when watching a favorite TV show or listening to a favorite radio program. It is helpful to pair taking PrEP with a routine that makes you feel good. ED-PrEP: If the loading dose is taken less than two hours before sex, or forgotten, the client may be a candidate for PEP.
PrEP and GBV/IPV	Male partner violence has been documented as a barrier to start and/or continue PrEP, with individuals sometimes prioritizing coping with the relationship over HIV prevention. Therefore, it is recommended to screen for violence and address these issues as part of the PrEP service.
PrEP and alcohol or other recreational drugs	Taking PrEP while you are using alcohol or other recreational drugs will not hurt you. However, alcohol or other recreational drugs may cause you to forget to take your PrEP, so be sure to take it in advance of any substance use. (Note to provider: emphasize adherence and pill-taking reminders.)
PrEP, pregnancy, and breastfeeding	PrEP does not prevent pregnancy. Be sure to use a modern method of contraception to avoid an unintended pregnancy. Taking PrEP while you are pregnant or breastfeeding will not hurt you or your baby. You can use PrEP throughout pregnancy and breastfeeding. (Note to provider: assess family planning needs and offer, as appropriate.) (Note to provider: offer PrEP to pregnant women at high risk of HIV as a priority after all the risks and benefits have been explained to the client.)
PrEP and other medications	PrEP is safe and effective. It can be taken with hormonal contraceptives, gender-affirming hormones, or nonprescription drugs.
No STI protection other than HIV	PrEP does not prevent any other STIs. Use a condom correctly whenever you have sex to protect against other STIs.
Side effects	Over 90% of people will not experience any side effects. Those who do, experience only mild side effects, including: • Gastrointestinal symptoms (diarrhea and nausea, decreased appetite, abdominal cramping, and flatulence) • Dizziness • Headaches Most of those side effects disappear within one month. However, your health care provider can help you manage them.

Other ways to lower risk of HIV	To lower your risk of HIV: • Adopt safer sexual practices, including consistent condom use • Ensure an HIV-positive partner in a serodiscordant couple has been on effective ART for at least six months, has an undetectable viral load, and remains adherent • Receive voluntary medical male circumcision • Reduce number of sexual partners • Access drug harm reduction services
Switching between HIV prevention options	It is okay to start PrEP and decide later that you want to use another option to prevent HIV infection, like condoms. Many people switch between methods as their needs change. I am here to help you to make the best decision for you.

13 PROMOTE CLIENT RETENTION AND FOLLOW-UP

Effective use of a PrEP dosing regimen is imperative for users to maintain an HIV-negative status while using PrEP. Monitoring drug adherence is therefore an important function to ensure rational use of PrEP drugs. Whenever possible, those who are supporting and monitoring PrEP continuation should use existing structures and systems. The effectiveness of oral PrEP is contingent upon continued use during periods of risk for HIV, and the high discontinuation at month one and persistent discontinuation at later points can have a negative impact on epidemic control. Therefore, it is vital to establish a robust M&E system and peer-led support to monitor and help clients continue PrEP through periods of risk.

PrEP users may face challenges in attending regular follow-up visits required for PrEP services. Strategies should be used to address the specific challenges faced by individuals to support retention in PrEP services and adherence. For example, sex workers may be highly mobile, may not consistently visit the same clinic or service provider over an extended period, and may find it difficult to attend clinic services during regular working hours.

The following strategies for supporting retention and communication are recommended:

- Schedule times for taking medication that correspond with the user's daily routine activities.
- Use reminders, e.g. cell phone, alarms, calendars.
- Follow up with clients who have consented; if they miss appointments, offer them another appointment at a convenient time.
- Use pillboxes.
- Review disclosure issues to identify those who can support the user's intentions to adhere or barriers to adherence due to lack of disclosure/privacy at home.
- Offer community-based PrEP.
- Offer support groups[28].
- Offer telehealth[29].

28 PrEP support groups should have the objective to support PrEP clients on identifying strategies of adhering to PrEP; prevent / mitigate violence; supporting each other; continue education; build the capacity of PrEP clients to become PrEP ambassadors etc

29 Refers to virtual support to mitigate barriers and continue PrEP medications; prevent/ mitigate violence; continue education

Assessing adherence should be based on the dosing regimen used. Adherence to PrEP should be assessed at every follow-up visit by self-report.

Those who are not adherent but are willing and eligible to continue PrEP should be given additional adherence counselling or they should be referred to peer-based adherence support services.

Several approaches can be used to promote adherence: motivational interviewing , informed choice counselling , and integrated next step counselling , among others.

Persistent poor adherence to PrEP medications should be managed on a case-by-case basis.

14 MONITORING AND EVALUATION

Strategic information is vital to track and measure progress, program impact and inform decision-making. Systems should be in place to support routine data capture and surveillance data that will inform programming. This section details how national PrEP roll-out will be incorporated into the mainstream HIV M&E health sector reporting.

The objectives of the PrEP M&E framework are:

- Incorporate PrEP monitoring as part of routine HIV program in the health sector reporting by defining core set of indicators that are relevant to the program; and developing the relevant data collection tools
- Utilize routinely collected data to improve PrEP programming through routine data analysis and feedback to the stakeholders; and the use of program data to determine targets and measure impact

Key principles for PrEP M&E:

- Use of standard M&E tools to ensure consistency and reliability of data collected across time and location.
- Standard data elements to be defined for PrEP monitoring through a consultative process. The data collation and reporting to the upper aggregation levels is also to be defined.
- Unique dynamics of target population in regard to non-static risk and high mobility of some populations; use of electronic systems incorporating a unique identifier is recommended

The tools in annex 1 and annex 2 represent the PrEP Facility record and the PrEP Follow up visit records; annex 3 is the PrEP Clients register; Annex 4 and annex 5 represent the PrEP monthly summary form and the PrEP quarterly cohort report.

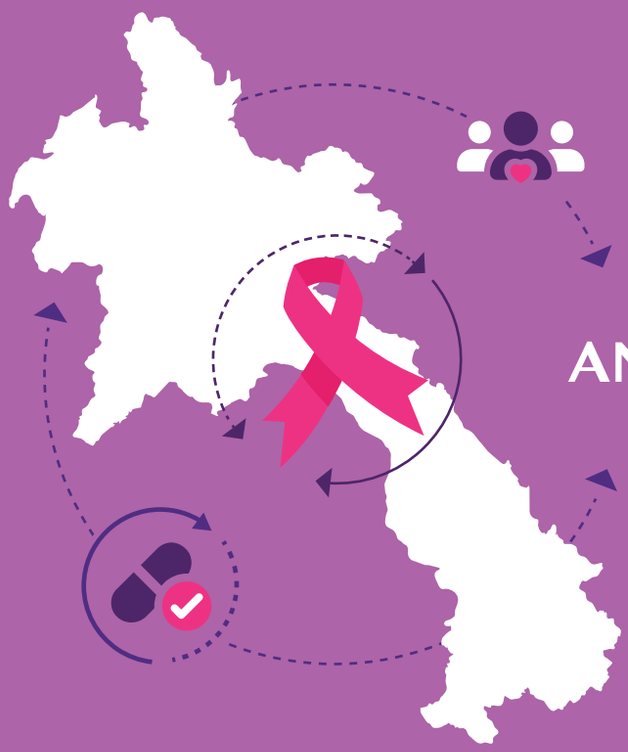
This PrEP implementation framework is to be monitored regularly to track performance towards achievement of targets and objectives. This is to be done through the M&E framework that outlines the targets to be achieved, indicators to be measured, process of data collection, frequency of collection, data source and the responsible person. Data should be routinely collected through standard MOH tools.

It is recommended to collect and report on the following indicators (Table 4).

Table 4. Recommended PrEP indicators[30]

Indicators		Disaggregation
PrEP_SCREEN	Number of individuals who have been screened for eligibility for PrEP	KP Type; Age/Sex
PrEP_ELIGIBLE	Number of individuals who are eligible for PrEP during the reporting period	KP Type; Age/Sex
PrEP_NEW	Number of individuals who have been newly enrolled on oral ARV PrEP to prevent HIV infection in the reporting period	KP Type; Age/Sex
PrEP_1 MONTH	Number of clients returning for 1-month (initial) follow-up visit (includes all clients returning per month for 1-month visit)	KP Type; Age/Sex
PrEP_RESTART	Number of clients who have taken oral PrEP in the past and discontinued (for any reason) or who were delayed for their return visit beyond the locally defined window who are re-initiated on PrEP	KP Type; Age/Sex
PrEP_SERO	Number of PrEP clients who received an HIV-positive test result during a period of continuous PrEP use (excluding those who were HIV-positive at PrEP initiation or when restarting PrEP)	KP Type; Age/Sex
PrEP_CURR	Number of individuals, inclusive of those newly enrolled, who received oral ARV PrEP to prevent HIV at least once in the reporting period	KP Type; Age/Sex

30 These indicators are based on the PEPFAR Monitoring, Evaluation, and Reporting (MER) indicators for PrEP programming.



ANNEXES

Annex 1.
PrEP Facility Record

PrEP file no:

A. Facility information		
Facility Name	District	District clinician/team
Date of initial client visit (dd/mm/yy) ____ /____ /____		Person Completing Form

B. Person Completing Form		
First Name	Middle Name	Surname
Address	Telephone	
Date of Birth (dd/mm/yy) ____ /____ /_____	Unique ID number	
Date of last HIV test: ____ /____ /____ (dd/mm/yy) Last eGFR Result :_____ Date: ___/___ /___(dd/mm/yy)	Marital status ☐ Single ☐ Married ☐ Divorced ☐ Widowed ☐ Separated ☐ Refused	

C. Sexual and Drug Injection Core Risk Classification

1. Do you consider yourself: male, female, transgender, or other?

☐ Male ☐ Female

☐ Transgender woman

☐ Transgender man

☐ Something else: _____]

☐ Refuses to answer

2. What was your sex assigned at birth?

☐ Male

☐ Female

☐ Other: _____

☐ Refuses to answer

3. Do you have sex with: ☐ Men only ☐ Women only ☐ Refuses to answer ☐ Both men and women

4. Have you exchanged sex as your ☐ Yes ☐ No ☐ Refuses to answer

5. In the last six months, have you injected illicit or illegal drugs? ☐ Yes ☐ No ☐ Refuses to answer

6. HIV + Couple and (Mark all that apply)

☐ No ARV

☐ On ARV < 6 month

☐ Poor adherence for ARV

☐ VL un suppression

☐ Hight risk & Not know HIV status couple

☐ IPV/GBV

☐ STI (in past 6 month)

☐ Use PEP

☐ Have sex while drunk/use drug

☐ Improperly use of condom

If Yes

Fill the information into this part if couple HIV +

UIC of couple HIV+: _____

Or ☐ No information (not register UIC)

or ☐ UIC/not know register UIC

Couple HIV+ start ARV treatment,

Date of register:___/____/_____

Or ☐ not start ART due the first visit

Know HIV+: ___ year _ _ month

Not use condom with couple HIV+ in past 30 day: ☐ Yes ☐ No

Number of Children: _____person

D. Key Population Classification (an individual can belong to more than one category)	
If client answers "Male" to question 1 and answers "Men only" or "Both men and women" to question 3, then categorize as MSM	☐
If client answers "Transgender woman" or "transgender man" to question 1, then categorize as transgender (cross-check with question 2, if 1 & 2 are different, categorize as transgender)	☐
If client answers "Yes" to question 4, then categorize as sex worker	☐
If client answers "Yes" to question 5, then categorize as person who injects drugs	☐

Final Classification: (mark ALL that apply*)

☐ Man who has sex with men (MSM) ☐ Transgender (TG) ☐ Sex worker (SW)

☐ Person who injects drugs (PWID)

* categorize based on client self-identify where multiple are possible

E. Pregnancy and breastfeeding status			F. Baseline Laboratory Tests:
Client currently pregnant?	☐ Yes	☐ No	Creatinine (eGFR): _____
Client currently breastfeeding?	☐ Yes	☐ No	

G. Hepatitis B Testing, Vaccination, and Treatment	
Date of HBsAg test: ___/___/____ (dd/mm/yy)	Test result: ☐ Negative ☐ Positive ☐ Not Done
If positive, is patient on treatment?	If negative, dates HBV vaccination provided: (dd/mm/yy) 1) ____ /____ /____ 2) ____ /____ /____ 3) ____ /____ /____

H. Sexually Transmitted Infections (STI)

VDRL/Syphilis test date: ___/___/____ (dd/mm/yy)

Result: ☐ Negative ☐ Positive ☐ Not done ☐ Other _____

Syndromic STI screen date: ____ /____ /____ (dd/mm/yy)

Result: _____

STI syndromes (select all that apply): U=Urethral discharge / G=Genital ulcers / V=Vaginal discharge / L=Lower abdominal pain / S=Scrotal swelling / I=Inguinal bubo / O=Other-specify

STI ecological diagnosis: _____

If STI diagnosis, date started treatment: ___/___/___ (dd/mm/yy)

I. Initiation of PrEP	
PrEP start date	___/___/____ (dd/mm/yy)
Dosing regimen	☐ daily ☐ ED-PrEP
PrEP (ARVs) prescribed	☐ TDF/FTC ☐ TDF/3TC ☐ TAF /FTC ☐ Other: _____
PrEP discontinued	Date discontinued: ___/___/____ (dd/mm/yy)
	Reasons for stopping PrEP: ☐ Tested HIV+ ☐ No longer at substantial risk ☐ Side effects ☐ Client preference ☐ Other: _____ HIV status at the time of discontinuation: ☐ Negative ☐ Positive ☐ Unknown

Annex 2. PrEP Follow-up Visits

Follow-up date (dd/mm/yy)	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
Dosing regimen used	☐ ED-PrEP ☐ Daily PrEP	☐ ED-PrEP ☐ Daily PrEP	☐ ED-PrEP ☐ Daily PrEP	☐ ED-PrEP ☐ Daily PrEP	☐ ED-PrEP ☐ Daily PrEP	☐ ED-PrEP ☐ Daily PrEP	☐ ED-PrEP ☐ Daily PrEP
Repeat HIV test Test result: Tests Used:	☐ Negative ☐ Positive 1st :______ Confirmatory: ______ Other:______	☐ Negative ☐ Positive 1st :______ Confirmatory: ______ Other:______	☐ Negative ☐ Positive 1st :______ Confirmatory: ______ Other:______	☐ Negative ☐ Positive 1st :______ Confirmatory: ______ Other:______	☐ Negative ☐ Positive 1st :______ Confirmatory: ______ Other:______	☐ Negative ☐ Positive 1st :______ Confirmatory: ______ Other:______	☐ Negative ☐ Positive 1st :______ Confirmatory: ______ Other:______
Asked about signs and symptoms of acute HIV infection?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Side-effects (see codes)							
eGFR estimate							
New STI diagnosed?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Adherence (daily PrEP): Number of missed pills in past 7 days	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed
Adherence (ED- PrEP): Number of missed pills in past 7 days	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed	☐ O missed ☐ 1 missed ☐ 2 missed ☐ 3 missed ☐ 4 or more missed
Adherence counselling provided? (tick box if yes)	☐	☐	☐	☐	☐	☐	☐
Risk reduction counselling provided?	☐	☐	☐	☐	☐	☐	☐
Condoms and lubricants provided?	☐	☐	☐	☐	☐	☐	☐
Currently pregnant or breastfeeding?	☐	☐	☐	☐	☐	☐	☐
Repeat PrEP prescription ARVs prescribed: Number of pills:	☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC # of pills: __	☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC # of pills: __	☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC # of pills: __	☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC # of pills: __	☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC # of pills: __	☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC # of pills: __	☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC # of pills: __
Next scheduled visit date: (dd/mm/yy)	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
Notes:							

Side effects: A= Abdominal pain; S=Skin rash; Nau=Nausea; V=Vomiting; D=Diarrhea; F=Fatigue; H=Headache; L = Enlarged lymph nodes; R= Fever ; O= Other (specify)

Annex 3.
PrEP Clients Register

							Initial HIV Test							Follow-up Visit 1						Follow-up Visit 2, 3, 4, 5 etc.						Stopped PrEP	
															HIV Re-testing						HIV Re-testing						
Date	Patient ID Number	Name & Surname	Contact Number (Cell/Tel)	Age (years)	Key populations client?	If key population (KP): KP group classification (tick all that apply)	Date tested	Result: (R/NR/Inc)	Date Client Received Result	Creatinine (eGFR)	STI syndrome (see codes). If STI: Date started treatment	PrEP (ARVs) prescribed	Number of pills	Date	Date Re-tested	Result (R/NR/Inc)	Side effects (see codes)	PrEP (ARVs) prescribed	Number of pills	Date	Date Re-tested	Result (R/NR/Inc)	Side effects (see codes)	PrEP (ARVs) prescribed	Number of pills	Date	Reasons (see codes)
					☐ Yes ☐ No	☐ MSM ☐ TG ☐ SW ☐ PWID						☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC						☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC						☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC			
					☐ Yes ☐ No	☐ MSM ☐ TG ☐ SW ☐ PWID						☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC						☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC						☐ TDF/FTC ☐ TDF/3TC ☐ TAF/FTC			

Annex 4
Monthly Summary Form

Facility Name	Level of Facility	Facility Code
District		Province/Region
Month of Report	Year of Report	

Section 1: All New PrEP Candidates

1.1 #of new clients who received HIV testing for PrEP screening during month, by gender & age

	Age group (in years)					
Gender	**15-19**	**20-24**	**25-29**	**30-49**	**50+**	**Total**
Female						
HIV-negative						
HIV-positive						
Male						
HIV-negative						
HIV-positive						
TGW						
HIV-negative						
HIV-positive						
TGM						
HIV-negative						
HIV-positive						
Total						
HIV-negative						
HIV-positive						

1.2 #of new clients who received HIV testing for PrEP screening during month, by KP group only

	Key Population (KP) group				
	Men who have sex with men (MSM)	**Transgender (TG)**	**Sex worker (SW)**	**Person who injects drugs (PWID)**	**Total**
HIV-negative					
HIV-positive					
Total					

1.3 #of clients who started PrEP during the month, by gender & age

	Age group (in years)					
Gender	**15-19***	**20-24**	**25-29**	**30-49**	**50+**	**Total**
Female						
Male						
TGW						
TGM						
Total						

*No global recommendation for PrEP among adolescents has been developed

1.4 #of clients who started PrEP during the month, by KP group only

KP group	MSM	TG	SW	PWID	Total
Number starting PrEP					

Section 2: PrEP Follow-up Services

2.1 #of returning PrEP clients receiving follow-up HIV testing during the month, by gender & age

	Age group (in years)					
Gender	**15-19**	**20-24**	**25-29**	**30-49**	**50+**	**Total**
Female						
HIV negative						
HIV positive						
Male						
HIV negative						
HIV positive						
TGW						
HIV negative						
HIV positive						
TGM						
HIV negative						
HIV positive						
Total						
HIV negative						
HIV positive						

2.2 #of returning PrEP clients receiving follow-up HIV testing during the month, by KP only

KP group	MSM	TG	SW	PWID	Total
HIV-negative					
HIV-positive					
Total					

2.3 Total Number of clients currently receiving PrEP from this facility, by gender and age:

	Age group (in years)					
Gender	**15-19**	**20-24**	**25-29**	**30-49**	**50+**	**Total**
Female						
Male						
TGW						
TGM						
Total						

2.4 Total Number of clients currently receiving PrEP from this facility, by KP ONLY:

KP group	MSM	TG	SW	PWID	Total
# currently receiving PrEP					

Form completed by:	Title:	Date: (dd/mm/yy)
Form verified by:	Title:	Date: (dd/mm/yy)

Annex 5.
PrEP Quarterly Cohort report

Facility Name	Level of Facility	Facility Code
District		Province/Region
Quarter of Report *(Ending month)*: _____		Year of Report (YYYY):

Instructions: Complete each of the tables below for the full PrEP client population, and each subpopulation as specified. Client cohorts should be defined based on the month clients first started PrEP (for example, clients starting PrEP between June 1 - June 30, 2017 should be assigned to the June 2017 cohort).The client cohorts to include can be identified via the "Months ago started on PrEP" column, as well as the specific year and month of PrEP initiation to be documented in the subsequent column (for example, if the current month is **June 2017**, cohorts 1-5 would be defined and recorded as shown below.) Illustrative data are shown in the tables below to demonstrate how data are to be recorded and indicators calculated.

EXAMPLE:

Cohort	Baseline			Follow-up									
	Months ago started on PrEP	Calendar Year/Month started PrEP (YYYY/MM)	# started PrEP at this clinic (original cohort)	# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	# received PrEP at current follow-up time	# tested for HIV	# stopped: tested HIV+	# stopped: no longer at substantial risk	# stopped: other reason	# lost	# died
			Col: 1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
1	1 mo.	2017/05	47	0	0	47	45	45	0	0	0	2	0
2	3 mos.	2017/03	28	0	1	27	23	23	1	2	0	1	0
3	6 mos.	2016/12	21	1	0	22	17	17	0	3	0	2	0
4	9 mos.	2016/09	8	0	1	7	5	5	1	1	0	0	0
5	12 mos.	2016/06	10	0	0	10	4	4	0	4	0	2	0

Summary of Cohort Outcomes:

Cohort	Months ago started on PrEP	Calendar year/month started PrEP (YYYY/MM)	Percent of cohort alive and on PrEP [col. 5/col. 4] *100	Percent receiving HIV test [col 6./col. 4] *100	Percent testing HIV+ [col 7./col. 6] *100	Percent no longer at substantial risk [col 8./col. 4] *100	Percent lost [col 10./col. 4] *100
1	1 mo.	2017/05	96%	100%	0	0	4%
2	3 mos.	2017/03	85%	100%	4%	7%	4%
3	6 mos.	2016/12	77%	100%	0	14%	9%
4	9 mos.	2016/09	71%	100%	20%	14%	0%
5	12 mos.	2016/06	40%	100%	0	40%	20%

1. **ALL PrEP clients (including key populations clients and ALL other clients)**

Cohort	Baseline			Follow-up									
	Months ago started on PrEP	Calendar Year/Month started PrEP (YYYY/MM)	# started PrEP at this clinic (original cohort)	# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	# received PrEP at current follow-up time	# tested for HIV	# stopped: tested HIV+	# stopped: no longer at substantial risk	# stopped: other reason	# lost	# died
			Col: 1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
1	1 mo.												
2	3 mos.												
3	6 mos.												
4	9 mos.												
5	12 mos.												

Summary of ALL Cohort Outcomes:

Cohort	Months ago started PrEP	Calendar Year/Month started PrEP (YYYY/MM)	Percent of cohort alive and on PrEP [col. 5/col. 4] *100	Percent receiving HIV test [col 6./col. 4] *100	Percent testing HIV+ [col 7./col. 6] *100	Percent no longer at substantial risk [col 8./col. 4] *100	Percent lost to follow-up [col 10./col. 4] *100
1	1 mo.						
2	3 mos.						
3	6 mos.						
4	9 mos.						
5	12 mos.						

KEY POPULATIONS CLIENTS

2. Men who have Sex with Men (MSM)

Cohort	*Baseline*			*Follow-up*								
	Months ago started on PrEP	Calendar Year/Month started PrEP (YYYY/MM)	# started PrEP at this clinic (original cohort)	# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	# received PrEP at current follow-up time	# tested for HIV	# stopped: tested HIV+	# stopped: no longer at substantial risk	# stopped: other reason	# lost	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11
1	1 mo.												
2	3 mos.												
3	6 mos.												
4	9 mos.												
5	12 mos.												

Summary of MSM Cohort Outcomes:

Cohort	Months ago started PrEP	Calendar Year/Month started PrEP (YYYY/MM)	Percent of cohort alive and on PrEP [col. 5/col. 4] *100	Percent received HIV test [col 6./col. 4] *100	Percent tested HIV+ [col 7./col. 6] *100	Percent no longer at substantial risk [col 8./col. 4] *100	Percent lost to follow-up [col 10./col. 4] *100
1	1 mo.						
2	3 mos.						
3	6 mos.						
4	9 mos.						
5	12 mos.						

3. Transgender Persons (TG)

Cohort	Baseline			Follow-up								
	Months ago started on PrEP	Calendar Year/Month started PrEP (YYYY/MM)	# started PrEP at this clinic (original cohort)	# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	# received PrEP at current follow-up time	# tested for HIV	# stopped: tested HIV+	# stopped: no longer at substantial risk	# stopped: other reason	# lost	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11
1	1 mo.												
2	3 mos.												
3	6 mos.												
4	9 mos.												
5	12 mos.												

Summary of TG Cohort Outcomes:

Cohort	Months ago started PrEP	Calendar Year/Month started PrEP (YYYY/MM)	Percent of cohort alive and on PrEP [col. 5/col. 4] *100	Percent received HIV test [col 6./col. 4] *100	Percent tested HIV+ [col 7./col. 6] *100	Percent no longer at substantial risk [col 8./col. 4] *100	Percent lost to follow-up [col 10./col. 4] *100
1	1 mo.						
2	3 mos.						
3	6 mos.						
4	9 mos.						
5	12 mos.						

4. **Sex Workers (SW)**

Cohort	Baseline			Follow-up								
	Months ago started on PrEP	Calendar Year/Month started PrEP (YYYY/MM)	# started PrEP at this clinic (original cohort)	# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	# received PrEP at current follow-up time	# tested for HIV	# stopped: tested HIV+	# stopped: no longer at substantial risk	# stopped: other reason	# lost	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11
1	1 mo.												
2	3 mos.												
3	6 mos.												
4	9 mos.												
5	12 mos.												

Summary of SW cohort outcomes:

Cohort	**Months ago started PrEP**	**Calendar Year/Month started PrEP** (YYYY/MM)	**Percent of cohort alive and on PrEP** [col. 5/col. 4] *100	**Percent received HIV test** [col 6./col. 4] *100	**Percent tested HIV+** [col 7./col. 6] *100	**Percent no longer at substantial risk** [col 8./col. 4] *100	**Percent lost to follow-up** [col 10./col. 4] *100
1	1 mo.						
2	3 mos.						
3	6 mos.						
4	9 mos.						
5	12 mos.						

5. **Persons Who Inject Drugs (PWID)**

Cohort	Baseline			Follow-up								
	Months ago started on PrEP	Calendar Year/Month started PrEP (YYYY/MM)	# started PrEP at this clinic (original cohort)	# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	# received PrEP at current follow-up time	# tested for HIV	# stopped: tested HIV+	# stopped: no longer at substantial risk	# stopped: other reason	# lost	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11
1	1 mo.												
2	3 mos.												
3	6 mos.												
4	9 mos.												
5	12 mos.												

Summary of PWID cohort outcomes:

Cohort	**Months ago started PrEP**	**Calendar Year/Month started PrEP** (YYYY/MM)	**Percent of cohort alive and on PrEP** [col. 5/col. 4] *100	**Percent received HIV test** [col 6./col. 4] *100	**Percent tested HIV+** [col 7./col. 6] *100	**Percent no longer at substantial risk** [col 8./col. 4] *100	**Percent lost to follow-up** [col 10./col. 4] *100
1	1 mo.						
2	3 mos.						
3	6 mos.						
4	9 mos.						
5	12 mos.						

6. **ALL PrEP Key Populations Clients (MSM+TG+SW+PWID)**

Cohort	Baseline			Follow-up									
	Months ago started on PrEP	Calendar Year/Month started PrEP (YYYY/MM)	# started PrEP at this clinic (original cohort)	# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	# received PrEP at current follow-up time	# tested for HIV	# stopped: tested HIV+	# stopped: no longer at substantial risk	# stopped: other reason	# lost	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11
1	1 mo.												
2	3 mos.												
3	6 mos.												
4	9 mos.												
5	12 mos.												

Summary of ALL cohort outcomes:

Cohort	Months ago started PrEP	Calendar Year/Month started PrEP (YYYY/MM)	Percent of cohort alive and on PrEP [col. 5/col. 4] *100	Percent receiving HIV test [col 6./col. 4] *100	Percent testing HIV+ [col 7./col. 6] *100	Percent no longer at substantial risk [col 8./col. 4] *100	Percent lost to follow-u[[col 10./col. 4] *100
1	1 mo.						
2	3 mos.						
3	6 mos.						
4	9 mos.						
5	12 mos.						

Form completed by:	Title:	Date:
Form verified by:	Title:	Date:

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