



ABC of Pre-Exposure Prophylaxis (PrEP) Ghana Implementation Guide

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MINISTRY OF HEALTH
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Acronyms and Abbreviations

ADR	Adverse drug reaction
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
ARVs	Antiretroviral drugs
ART	Antiretroviral therapy
AMC	Average monthly consumption
CQI	Continuous quality improvement
CMS	Central medical store
CrCl	Creatinine clearance
CSO	Civil society organization
DNA	Deoxyribonucleic acid
ED-PrEP	Event-driven pre-exposure prophylaxis
GAC	Ghana AIDS Commission
FBO	Faith-based organization
FDA	Food and Drugs Authority
FDC	Fixed-dose combination
FEFO	First-in, first-out
FSW	Female sex worker
GFTAM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHS	Ghana Health Service
HIV	Human immunodeficiency virus
HMT	Hospital management team
IBSS	Integrated biobehavioral surveillance survey
JSI	John Snow, Inc.
KP	Key population
MOH	Ministry of Health
MSF	Monthly summary form
MSM	Men who have sex with men
MPSE	Mapping and population size estimation

OPD	Outpatient department
PEP	Post-exposure prophylaxis
PEPFAR	U. S. President’s Emergency Plan for AIDS Relief
PWID	People who inject drugs
NACP	National AIDS/STI Control Program
NSP	National Strategic Plan
PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis
PLHIV	People living with HIV
RMS	Regional medical store
RNA	Ribonucleic acid
SDP	Service delivery point
SSDM	Supplies and Drug Management Division
Trans	Transgender
USAID	United States Agency for International Development
WHO	World Health Organization

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Foreword

Primary prevention of HIV-1 infection among those with ongoing risk may be achieved using antiretroviral drugs (ARVs) either before exposure (pre-exposure prophylaxis [PrEP]) or within 48 hours after exposure (post-exposure prophylaxis [PEP]). Targeting individuals at high risk and providing daily oral PrEP as part of a comprehensive set of prevention services alongside regular monitoring contributes to effective and safe HIV prevention. This need has arisen because most biological and behavioral preventive strategies have failed to decrease HIV acquisition and an effective preventive vaccine has yet to be discovered. In 2015, the World Health Organization (WHO) issued guidance on PrEP use in high HIV incidence settings for people having substantial risk of HIV acquisition. Ghana has adopted PrEP in its Consolidated Guidelines for HIV Care (August 2019) and has captured it as part of the combination prevention package, which includes HIV testing services (HTS), male and female condom and lubricant promotion, ART for HIV-positive partners in serodiscordant couples, and STI prevention and management.

Multiple studies have shown strong evidence for the efficacy and effectiveness of daily oral PrEP using oral tenofovir (TDF) co-formulated with emtricitabine (FTC). These ARVs have demonstrated substantial HIV prevention benefits in clinical trials with TDF having a high genetic barrier to resistance while FTC has a low genetic barrier. Acquired drug resistance is possible if HIV is transmitted and there is also poor adherence level by the client. Another issue of concern is the potential increase in high-risk sexual behavior, such as sex without condoms, among clients on PrEP. This possibility emphasizes the need for regular patient education and monitoring. Behavioral counseling and assurance of safety and efficacy are important components of PrEP. Other factors of PrEP implementation that have been suggested include improving access, averting stigma, cost effectiveness, and education on PrEP to improve knowledge and assure people of the efficacy profile of products used for PrEP.

PEPFAR, via USAID, is funding the Meeting Targets and Maintaining Epidemic Control (EpiC) project, led by FHI 360, Key Population Investment Fund (KPIF), to support a KP-led approach to accelerate progress toward the ambitious 95-95-95 goals in West Africa. The principles guiding the project include client-centered approach, data-driven responses, focus on populations with the highest levels of HIV prevalence, and emphasis on geographical areas (mainly urban) where the HIV epidemic is rooted. The development of this national guide included extensive consultations with various stakeholders through technical working group meetings. It forms the basis for planning, organizing, and implementing PrEP at all levels of service delivery in governmental, nongovernmental, and private health institutions in Ghana.

To promote the effective use of this guide, only trained and authorized persons in certified health care facilities (public and private) are allowed to prescribe PrEP, and HIV commodities are not to be sold to the public unless authorized by the Ghana Health Service, Ministry of Health.



Dr. Stephen Ayisi Addo

Programme Manager, National AIDS/STI Control Programme



Introduction

Ghana is broadening approaches to reach the 2020 goal of reducing new HIV infections by 80 percent. This includes strategies to ensure individuals known to be HIV positive across the 488 ART centers are retained on and adhere to treatment, and to particularly target KPs for a reduction in acquisition of new HIV infections. Closing the critical gaps that exist in KP programming in the country is a priority of these objectives.

These interventions will be championed by the National AIDS/STI Control Program (NACP) and the Ghana AIDS Commission (GAC). Both institutions will use the human and infrastructural resources of Ghana to lead the implementation of oral PrEP with support from the Global Fund, USAID, and country agencies. NACP and GAC will be responsible for policy formulation, operational planning, adoption of technical documents, capacity building, commodity tracking and outcome evaluation, research and resource mobilization, as well as identification of and addressing gaps in service delivery.

To obtain broad-based stakeholder input and participation, NACP and GAC will be assisted by the PrEP task force, a team of oral PrEP program managers and implementers that will provide support at crosscutting levels for smooth program implementation and impact evaluation. The task force will report on their deliberations and activities to NACP and GAC and their partners.

The objective of this guide is to provide a framework for the implementation of Ghana's oral PrEP policy, using PrEP as a combination prevention strategy for HIV. It also includes basic knowledge on HIV and oral PrEP. NACP proposes a stepwise approach to the implementation of oral PrEP service delivery in Ghana, starting with KP members who are at high risk, and then a gradual scale-up to other eligible high-risk groups nationwide. This trajectory will create a trail of local learning and practical adaptation.

1. HIV Basics

What you must know about HIV

AIDS (acquired immune deficiency syndrome) is caused by the human immunodeficiency virus (HIV). This virus was first discovered in 1983, and the first case in Ghana was identified in 1986.

HIV belongs to a group of viruses called retroviruses. There are two main strains of HIV; HIV-1 and HIV-2. HIV has numerous varieties and has been shown to mutate, or change, within an individual during the progression of infection. Both HIV-1 and HIV-2 have the same modes of transmission and are associated with similar opportunistic infections, and both can lead to AIDS.

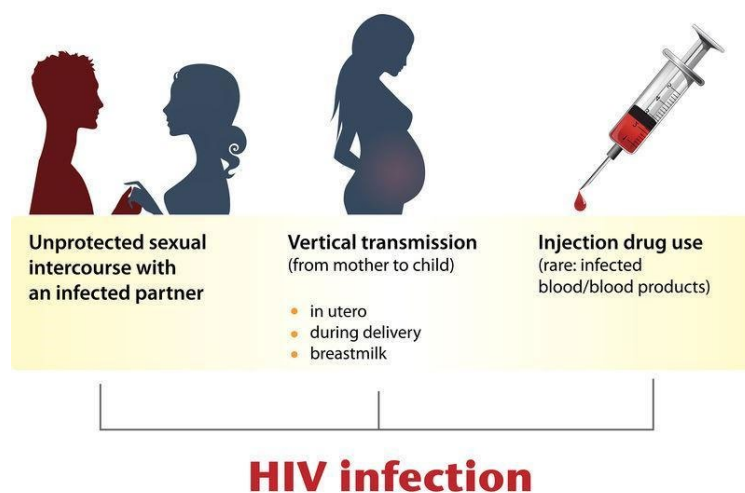
The virus multiplies by replicating in the body at a rate of approximately 10^9 times per day, but frequently fails to produce identical copies of itself. These nonidentical copies are referred to as mutations and may persist in the infected individual as “subtypes,” which are genetically slightly different from the original (parent) virus.

1.1 HIV Transmission

Among adults, HIV is spread mainly through unprotected sexual intercourse with an infected partner. During intercourse, the virus can enter the body through the mucosal linings of the vagina, vulva, penis, rectum, or, rarely, via the mouth and possibly the upper gastrointestinal tract after oral sex.

The likelihood of transmission is increased by factors that may damage these linings, especially other sexually transmitted infections (STIs) that cause ulcers and inflammation. Research suggests that immune cells, which live in the mucosal surfaces such as macrophages and dendritic cells, may begin the infection process after sexual exposure by binding to and carrying the virus from the site of infection to the lymph nodes where other immune system cells become infected.

Figure 1. HIV transmission



Credit: [CK-12 Foundation](#)

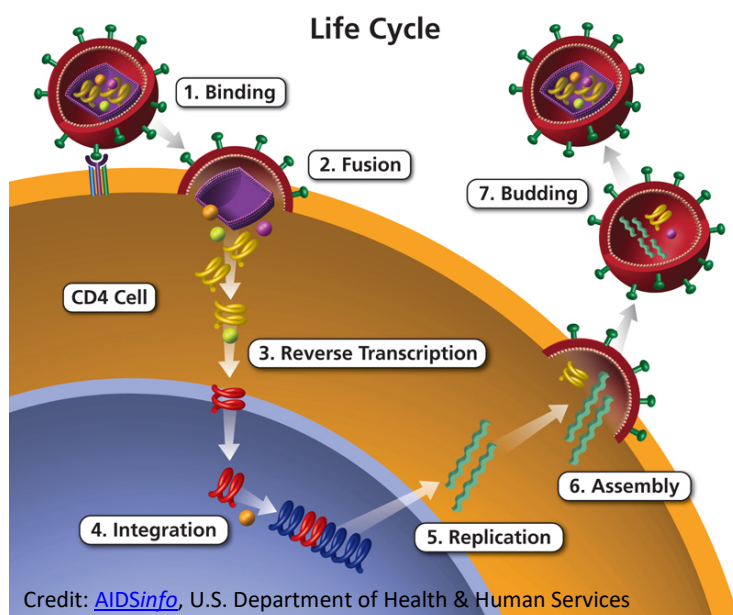
HIV can also be transmitted by contact with infected blood by the sharing of contaminated blades, needles or syringes among people who inject drugs (PWID), after occupational exposure among health workers, and by contaminated blood transfusions.

HIV-positive women can transmit HIV to their babies during pregnancy, at birth, and through breastfeeding. Up to 40 percent of untreated pregnant women infected with HIV have a high likelihood of transmitting the infection to their babies.

1.2 Life Cycle of HIV Infection

HIV begins its infection of a susceptible host by binding to receptors on the CD4 lymphocytes, which are a critical part of the body's immune system. Following fusion of the virus with the host cell, HIV enters the cell. The genetic material of the virus, which is RNA, is released and undergoes reverse transcription into DNA facilitated by the reverse transcriptase.

Figure 2. HIV life cycle



Once the genetic material of HIV has been changed into DNA, this viral DNA enters the host nucleus where it can be integrated into the genetic material of the cell. Once this happens, the cell can either become activated or can remain inactive. Activation of the host cells results in the transcription of viral DNA into messenger RNA, which is translated into viral proteins. The new viral RNA forms the genetic material of the next generation of viruses. The viral RNA and viral proteins assemble at the cell membrane into a new virus. Among the viral proteins is HIV protease, which is required to process other HIV

proteins into their functional forms. Following assembly at the cell surface, the virus then buds off from the cell and is released to infect another cell. Unless the HIV cycle is interrupted by treatment, the viral infection spreads throughout the body and results in the destruction of the body's immune system. The ARVs used in ART, PEP, and PrEP target different aspects of the HIV life cycle.

Those CD4 cells that remain inactive act as a reservoir for HIV. The virus can persist within the cell for many years in a latent form. Because latent virus is not actively replicating, it cannot be targeted by ARVs. Persistence of virus in latently infected cells is the major barrier to eradication or cure of HIV. For this reason, patients who are started on ART must remain on it for life.

HTS is considered an important entry point to HIV prevention, care, treatment, and support in Ghana, and the National Strategic Framework for HIV 2016–2020 highlights the need to strengthen testing interventions to increase the number of individuals who know their HIV status and are able to access ART, PEP, or PrEP services depending on the indication.

1.3 HIV in Ghana

Ghana has a low-level generalized HIV epidemic with an estimated national prevalence of 1.69 percent and an estimated 334,713 persons living with HIV (PLHIV).¹ Of these, 65 percent (217,515) are females in the reproductive age group of 15 to 49 years. The median HIV prevalence in women attending antenatal care in 2018 was 2.4 percent.² In relation to the UNAIDS 90-90-90 target, 74 percent of the estimated 334,713 PLHIV know their status, 61 percent of whom are on lifesaving ART, with 41 percent

¹Joint United Nations Programme on HIV/AIDS (UNAIDS). UNAIDS Data 2019. Geneva: UNAIDS; 2019.

²National AIDS Control Programme (NACP). HIV Sentinel Survey Report, 2018. Accra: NACP, Ghana Health Service; 2018.

of that cohort virally suppressed. The HIV burden in the country is disproportionately distributed across the regions, with the highest in the urban slums of Greater Accra, Ashanti, and the Western regions.

1.4 Key Populations

KPs are groups of individuals who have specific high-risk behaviors that increase their chances of becoming infected with HIV. Between 40 to 50 percent of all new infections worldwide occur among KPs and their immediate partners. Available data suggest that the risk of HIV acquisition among gay men and other men who have sex with men (MSM) was 22 times higher in 2018 than it was among all adult men. Similarly, the risk of acquiring HIV for PWID was 22 times higher than for people who do not inject drugs, 21 times higher for female sex workers (FSWs) than adults aged 15–49 years, and 12 times higher for transgender women than adults aged 15–49 years.³

KPs also have a substantially higher HIV prevalence and are a major driver of the HIV epidemic in Ghana. The average HIV prevalence among FSWs is 4.6 percent while prevalence among MSM is 18.1 percent. There are about 51,900 FSWs and 54,800 MSM in Ghana. In 2018, an estimated 28 percent⁴ of new infections in Ghana were among KPs. Despite the high HIV risk among

Table 1. National Strategic Plan (NSP) projection 2017-2020

Impact Results	Indicator	Sources IBBSS 2011	2018	2020
% KP living with HIV – FSWs	HIV Prevalence FSWs – General	11.1%	8.3%	5.6%
	HIV Prevalence FSWs – Seaters	21.4%	16%	10.7%
	HIV Prevalence FSWs – Roamers	6.8%	5.1%	3.4%
% KP living with HIV – MSM	HIV Prevalence MSM	17.5%	13.1%	8.8%

KPs, ART coverage remains very low due to structural and environmental factors including laws, policies, cultural myths, and stigma and discrimination that have a huge effect on their ability to confidently access health care. For instance, in Ghana, ART coverage among KPs is about 3.7 percent. This may be related to the public criminalization of female sex work and MSM behavior, and the associated high stigma and discrimination among health workers toward KPs. WHO recommends that populations with high vulnerability to HIV, including KP groups, should be assisted to initiate oral PrEP. Research has shown that PrEP significantly reduces the risk of HIV acquisition by as much as 92 percent when taken as prescribed. The implementation of oral PrEP in Ghana is consistent with the objectives of the national strategic plan for KPs.

³UNAIDS; 2019.

⁴Human Sciences Research Council. Mapping and population size estimation (MPSE) and integrated bio-behavioral surveillance survey (IBBSS) among men who have sex with men in Ghana. Accra: Ghana AIDS Commission, National HIV and AIDS Research Conference; 2018.

Step-by-step implementing PrEP

NACP plans to implement oral PrEP in two phases.

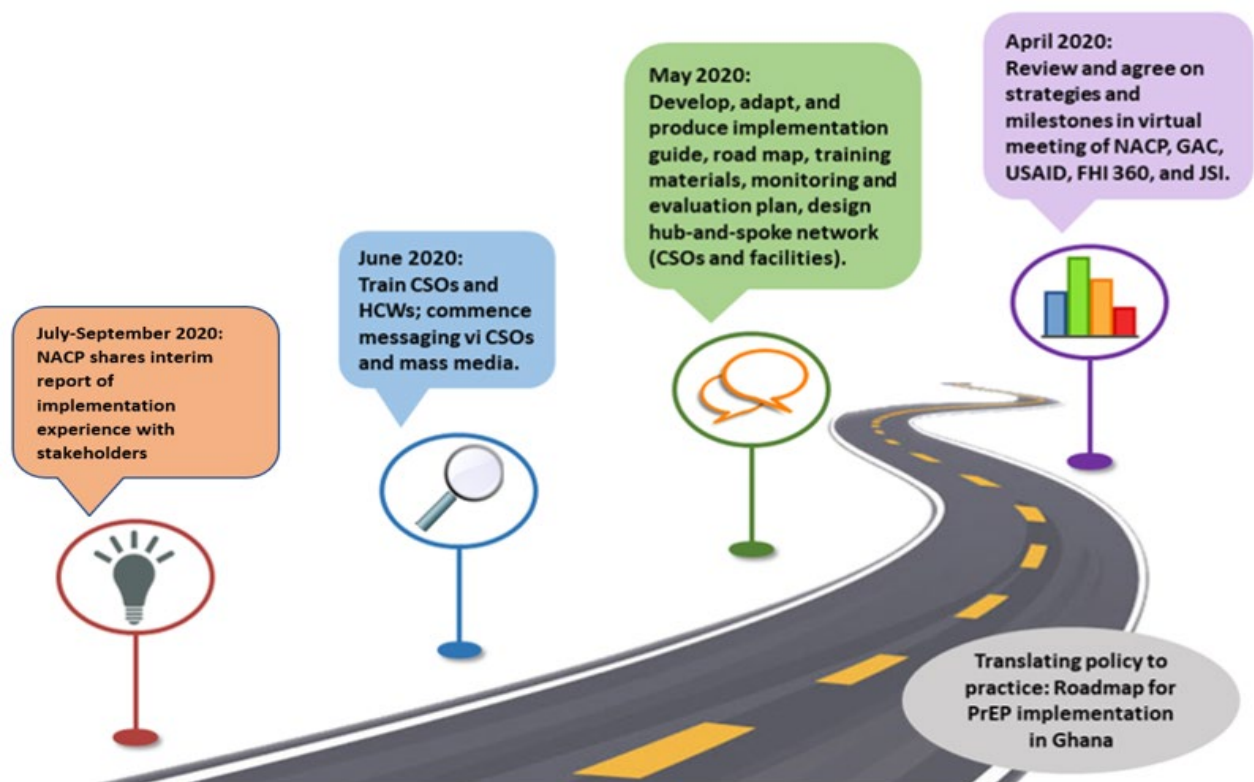
- **Phase one (jump-start):** To cover established areas of high HIV prevalence that have relative access to persons with potentially high-risk behavior. Even though PrEP could be offered to all members of eligible populations who seek it, the focus will be on KPs. Regions earmarked include:
 - Greater Accra
 - Ashanti
 - Western
- **Phase two (scale-up):** To follow an initial evaluation of the jump-start phase and cover all eligible populations around the country.

In both phases, PrEP will be implemented as part of a combination prevention package, a mix of biomedical, behavioral, and structural interventions that decreases risk of HIV acquisition. Combined approaches will produce a greater impact than using a single intervention alone. The elements of combination prevention are shown in Table 2.

Table 2. Components of combination HIV prevention

Structural	Behavioral	Biomedical
<ul style="list-style-type: none"> • Policies • Laws • Regulatory environment • Culture • Cash transfers 	<ul style="list-style-type: none"> • Education • Counseling • Stigma reduction • Harm reduction • Adherence interventions 	<ul style="list-style-type: none"> • HIV testing • Condoms • PMTCT • STI treatment • ART • PEP • PrEP

Figure 3. PrEP jump-start road map



2. Oral PrEP for HIV Prevention

What you must know about PrEP

Oral PrEP for HIV prevention is the use of ARVs by HIV-negative persons to prevent them from acquiring HIV. It is mostly recommended in populations with a high HIV incidence of about 3% or among people who, through the assessment of a trained health provider, are determined to be at high risk of acquiring HIV. KPs in Ghana—including FSWs, MSM, transgender people, and PWID—fall into this category. Persons who independently seek to access oral PrEP are also deemed eligible. Other categories of people considered eligible to access oral PrEP according to risk are listed in the Ghana 2019 Consolidated HIV Treatment Guidelines (pp. 117–120). They include:

- HIV-negative persons in serodiscordant relationships
- Sexual partners of unknown HIV status
- Individual with recent or recurrent STIs
- Multiple or concurrent sexual partners
- History of inconsistent or no condom use
- Recurrent PEP users
- History of sex while under the influence of alcohol or recreational drugs

2.1 Location and Demand Strategies for PrEP Beneficiaries

Potential PrEP beneficiaries may be found in the facility and within the community. PrEP programs should work with other health systems to design strategies that identify people both in health facilities and the community who are at high risk of acquiring HIV:

2.1.1 Health facility.

Common service delivery points where potential PrEP users may be found include:

- STI clinic
 - Many KP members accessing health service for STIs may not identify as a KP member. Careful use of the PrEP eligibility screening form will help define the indication.
 - STI clinic attendees may also be used for estimation of likely PrEP users in a facility and within a region where subnational and local HIV incidence rates are not available.
- Outpatient department (through active referrals from outpatient clinic or department)
 - HIV testing (the most common)
 - Testing for STIs
- Family planning clinic
 - To identify women in serodiscordant partnerships
- Antenatal clinic
 - Women in serodiscordant partnerships
 - HIV-negative pregnant and breastfeeding women in high prevalence HIV settings
- Sexual and gender-based violence services

- Harm reduction and other drug treatment services
- PEP services
 - Clients completing PEP services may be referred for PrEP
 - PrEP offers more consistent protection against HIV than repeated PEP

2.1.2 Community.

Notable locations to find potential PrEP users include:

- KP civil society organizations
- Hot spots
 - MSM and FSW hot spots should be targeted with appropriate messaging
- Drop-in centers (DICs)
 - Safe space for KP community activities with their peer navigators and educators
- Community-based and outreach HIV testing
 - Clients tested may be referred for PrEP
- Accredited community pharmacies
 - Screening tool used for multiple users of contraceptive pills and clients requesting PrEP or HIV self-testing kits

2.2 Indications for Oral PrEP

PrEP should only be given to HIV-negative persons at substantial risk of acquiring HIV, usually based on history in the past six months. WHO also recommends that oral PrEP taken before and after sex in some subgroups of MSM can prevent HIV infection (this is known as event-driven oral PrEP).

Only clients who have been offered and received HIV testing services from an NACP-accredited center or community outreach site (including DICs) should access PrEP services. It is advisable that the providers of PrEP be trained on HTS protocol using the Ghana HTS algorithms and guidelines to minimize losses of clients to incomplete referrals.

2.3 PrEP Eligibility Criteria (see Appendix 6 for risk assessment)

<ul style="list-style-type: none"> • HIV seronegative
<ul style="list-style-type: none"> • No suspicion of acute HIV infection
<ul style="list-style-type: none"> • At substantial risk of HIV infection
<ul style="list-style-type: none"> • Creatinine clearance (eGFR) >60ml/min
<ul style="list-style-type: none"> • Willingness to use PrEP as prescribed
<ul style="list-style-type: none"> • Client is requesting PrEP

Figure 4. Oral PrEP clinic algorithm

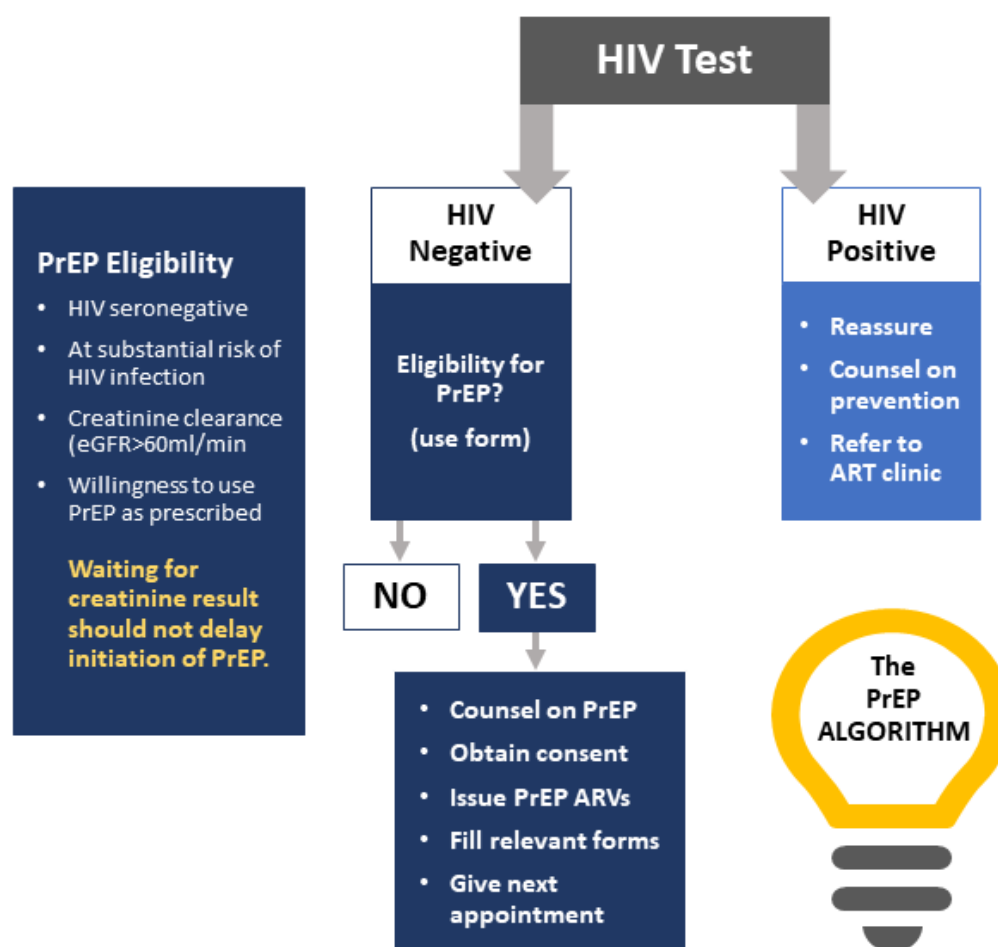


Table 3: Screening for substantial risk among sexual or injecting-use partners

Steps to follow to determine indication of a potential PrEP user among sexual partners and/or injecting-use partners
Client reports a history of sharing injection material and/or equipment with another person in the past six months.
Client reports having a sexual partner in the past six months who is HIV positive <i>and</i> who has not been on effective HIV treatment.
If the HIV-negative partner is not confident of the HIV-positive partner's adherence to treatment or has other sexual partners besides the partner on treatment.
If the couple is not communicating openly about treatment adherence and viral load test results.
If the HIV-negative partner is aware of gaps in the HIV-positive partner's treatment adherence.
If the HIV-positive partner has been on ART for less than six months. <ul style="list-style-type: none"> It takes three to six months on ART to suppress viral load. In studies of serodiscordant couples, PrEP has provided a useful bridge to full viral suppression during this time.

2.4 Laboratory Support for PrEP Administration

In addition to the initial HIV test and the subsequent three-month test to assure HIV status, the following tests are recommended to ensure PrEP service delivery is of high quality.

1. Creatinine clearance (CrCl): Should be ≥ 60 ml/min (Cockcroft-Gault) to safely use tenofovir. An online calculator can be found here: <http://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation/>). However, there is no need to wait for the result of the creatinine test before initiating PrEP. Where there is no access to the test, PrEP should not be unreasonably withheld.
2. Hepatitis B surface antigen: TDF/FTC or TDF/3TC is active against hepatitis B virus (HBV). Patients with chronic HBV can use TDF/FTC or TDF/3TC for PrEP but should have liver function tests monitored regularly during PrEP use and after discontinuing PrEP.
 - a. Such PrEP users should be cautioned that hepatitis can flare if PrEP ARVs is discontinued.
 - b. Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.

2.5 Oral PrEP Dosage

Following WHO recommendations, the approved regimens containing tenofovir disoproxil fumarate (TDF) for oral PrEP in Ghana are:

- A fixed-dose combination of TDF 300mg/FTC 200mg (emtricitabine) per oral daily, or
- A fixed-dose combination of TDF 300mg/3TC 300mg (lamivudine) per oral daily⁵

2.6 How to Give PrEP

- Give PrEP after eligibility determination and evaluation
- Give one (1) bottle of 30 pills in the first instance. This should cover a period of one month on average. Increase the number of bottles to three to cover about three months if client is adherent and expresses demand.
- Event-driven PrEP: Although efficacy is not guaranteed, give PrEP when demanded in anticipation of a high-risk exposure. (Providers should always avoid being judgmental).
- WHO updated its recommendation for PrEP to include event-driven PrEP (ED PrEP) taken before and after sex (also called on-demand PrEP or the 2+1+1 schedule) as an HIV prevention option for MSM. The 2+1+1 schedule entails taking TDF 300mg/FTC 200mg or TDF 300mg/3TC 300mg between two and 24 hours before sex is anticipated, and then 24 hours after sex has occurred, and after another 24 hours.
 - For whom is ED-PrEP appropriate?
 - Men who have sex with men
 - Men who find ED-PrEP more effective and convenient
 - Men who have infrequent sex (for example, less than two times per week on average)

⁵ARV class: Nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs). Mechanism of action: interferes with a process called reverse transcription (when HIV turns its RNA into DNA, using building blocks called nucleotides). NRTIs contain faulty building blocks that stop DNA from being made properly.

- Men who are able to plan for sex at least two hours in advance, or who can delay sex for at least two hours
- For whom is ED-PrEP NOT appropriate?
 - Cisgender women or transgender women
 - Transgender men having vaginal/frontal sex
 - Men having vaginal or anal sex with women
 - People with chronic hepatitis B infection

2.7 Side Effects of Oral PrEP

Every medication has side effects. Always weigh the benefit of a medication against the risk of a side effect. With PrEP, the benefit is staying HIV negative weighed against the minor, often transient, side effects. One in 10 PrEP users report minor side effects which usually last for no longer than a month. These include:

- Nausea
- Abdominal cramps
- Headache

2.8 Where PrEP Is Offered

PrEP may be accessed in various places that are KP-friendly and where other people with high risk of acquiring HIV commonly access health services. In Ghana, the following places are approved to provide PrEP services:

- STI clinics
- Family planning clinics
- ART clinics
- Drop-in centers
- Drug treatment centers
- Accredited community pharmacies





















2.9 Who Should Prescribe PrEP

The following categories of individuals are recommended to be trained to provide PrEP services:

- Clinicians (Doctors, Physician Assistants, etc.)
- Nursing cadres
- Pharmacy cadres (Pharmacists, Dispensing Assistants)
- Counsellors
- Case Managers
- Peer Educators

2.10 PrEP Clinic Schedule

Table 4. Oral PrEP clinic schedule

Period in PrEP administration	Day 1	Month 0	Month 3	Month 6	Visit clinic every other 3 months
Services at visit to PrEP facility	Review HIV-negative status				
	Confirm hepatitis B status		-		-
	Check serum creatinine		-		-
	Medication-adherence counseling				
	Risk-reduction counseling				
	Prescribe: TDF 300mg/3TC 300mg FDC or TDF 300mg/FTC 200mg per oral				

2.11 Oral PrEP Adherence Counseling

- Evidence shows that, when taken consistently and correctly, PrEP reduces the chances of HIV infection to near zero.
- PrEP is cost effective and acceptable to people at higher risk of HIV infection.
- PrEP does not protect against other STIs; therefore PrEP needs to be delivered as part of a comprehensive package of HIV and STI prevention services.
- PrEP effectiveness decreases rapidly if not taken regularly as prescribed, so addressing adherence barriers is key for success.
- Confirm that the client has understood the following:
 - PrEP is being offered as an informed choice.
 - PrEP is highly effective when used as prescribed.
 - Effectiveness is linked to consistency of use.
 - Condom use and other positive behavioral attitudes should be implemented alongside PrEP (e.g., avoidance/reduction in alcohol and substance abuse).
 - Adherence is improved when taken as part of daily routine, e.g., when waking up, going to sleep, or at regular mealtimes.
 - Access to join PrEP-user support groups; available social media groups can be found here: <https://www.facebook.com/groups/PrEPFacts>
 - Commitment to use PrEP if risk exposure persists
 - Discontinuing PrEP
 - If the person taking PrEP is no longer at substantial risk of HIV acquisition
 - If the person experiences complications related to the drugs
 - Discuss the decision to stop with the facility PrEP provider

- Possibly discuss plans to stop PrEP with your partners) and get tested for HIV (use 4th generation test)
- Advisable to continue taking PrEP for one month following the last possible exposure to HIV
- Period of risk may be associated with a relationship, alcohol and drug use, leaving school or home, trauma, or other events
- Dosage and interval of taking PrEP ARVs
- Potential minor side effects and average duration when they happen
- Date of next appointment
- To achieve optimal adherence, PrEP providers should be thorough in the adherence counseling process and provide follow-up support at every scheduled visit. Providers should ask at every clinical assessment visit:
 - What challenges have you had taking your oral PrEP ARVs?
 - What days/time of day are you most likely to forget taking your meds? (weekends, weekdays, mornings, evenings?)
- Remind PrEP users of the importance of perfect adherence at every clinic visit, while providing risk-reduction counseling.
- Give practical strategies on how to achieve optimal adherence:
 - Build ARVs into the daily routine (e.g., before washing face, after evening meal)
 - Ask a trusted peer to remind you
 - Set a daily alarm on the cell phone
 - Keep a “drug diary” and mark every tablet taken
- Encourage honest dialogue. Avoid giving the impression of “policing” the client. Work with them to help them achieve good adherence.

2.12 PrEP Program Management



PrEP implementation among KPs and other users requires strong team building for effective coordination of internal and external referrals with the community. An integrated program management approach for each PrEP facility and among CSOs that generate and sustain demand is critical for monitoring, evaluation, and sustainability.

A. PrEP focal person

1. Reports to ART focal person or hospital management team (HMT).
2. In small facilities, the ART focal person or facility head could also serve as the PrEP focal person.
3. Collect and collate all records on daily PrEP use in the facility and aggregate on the monthly summary form (MSF) for submission to NACP and the implementing partner through the HMT.
4. Ensure a minimum stock of two months of ARVs for PrEP use in the facility.

5. Provide contacts and be the lead person for liaison with CSOs and users of PrEP in the community.
6. Facilitate and coordinate tracking and home visits of PrEP users where need arises.
7. Leads the monthly joint facility PrEP program review meeting with the linked CSOs.

B. Facility PrEP dispensing officer

1. Receive and warehouse all PrEP ARV allocation for the facility.
2. Generate PrEP ARV facility supply through quantification from projection records with PrEP use in the facility over the quarter.
3. Ensure a minimum stock of two months of ARVs for PrEP use in the facility, and alert PrEP focal person for requisition submission to the regional medical store (RMS).
4. Fill and submit all pharmaco-vigilance forms in the rare event of an adverse reaction or side effect with use of PrEP.
5. Complete and submit PrEP specific commodity consumption reports to inform forecasting and quantification.

C. CSO PrEP representative

1. Serve as community focal person for PrEP liaison with the health facility.
2. Form the community hub for PrEP education and demand creation for PrEP.
3. Coordinate with peer navigators and educators to sustain good adherence among KPs.
4. Co-facilitate monthly review meeting with the PrEP focal person to review PrEP uptake, monitoring, and issues related to commodity availability, seroconversion, etc.

3. PrEP Demand and Delivery System

Housekeeping to start a PrEP program

3.1 Community Engagement and Communication

Ensure community participation and leadership by the CSOs. Effective engagement and planning with the management of CSOs in the implementation process will address demand and adherence questions. The messaging and awareness creation should also have a broad audience, including faith-based organizations (FBOs) and other community gatekeepers, the private sector, mass media, PLHIV, and potential oral PrEP users. All communication and messaging should provide knowledge and create awareness that will reflect in generating high demand from the eligible target population.

3.2 Service Delivery

Oral PrEP could be delivered using facility-based delivery models in outpatient department (OPD), antenatal care (ANC), ART, family planning (FP), and STI clinics, as well as through community-based locations that are considered safe and where confidentiality can be maintained to meet the minimum standard for service delivery. DICs supported by projects are good community outlets for oral PrEP.

The delivery of PrEP should be done through a hub of a PrEP facility linked to spokes of CSOs (especially for KPs). This will facilitate ease of referrals and follow-up. When the management of CSOs and a PrEP-supporting health facility collaborate, they create a KP-friendly pathway and facility ambience for PrEP service delivery, access, and retention. In addition, this creates opportunities to reinforce links between complementary services such as reproductive health and STI.

HIV testing is the gateway to oral PrEP initiation. All HTS providers should be mobilized to ensure everyone identified to be at substantial risk of HIV acquisition through a behavioral risk assessment during HIV pre-test and post-test counseling are linked to oral PrEP services. This is in addition to persons who independently seek to access PrEP (in alignment with WHO recommendations that people requesting PrEP are likely at substantial risk).

A directory of oral PrEP services should be developed as part of the national program and shared with all HTS service delivery points across the country. Novel HTS approaches such as outreach testing at hot spots and the use of HIV self-testing provide additional opportunities for more eligibility assessments for PrEP in the community. Self-testing is currently included in the Ghana HIV Testing Guidelines.

3.3 Capacity Building

Ensure appropriate training on the science and use of PrEP is provided to all would-be providers to keep its use within the boundaries of prescription restrictions. The training should be in a centralized comfortable environment to encourage open and relaxed communication; ensure all anxieties and ambiguities related to the use of PrEP are cleared. The participants should include the list of potential oral PrEP prescribers. Peer educators at CSOs, community health volunteers, members of youth networks who will also promote oral PrEP use at the community level should be trained. A central training of trainers (TOT) could be conducted ahead of PrEP implementation to produce a large pool of master trainers for country use. Staff at PrEP facilities will require continuous on-the-job training using case scenarios.

3.4 Monitoring and Evaluation

In phase one, PrEP implementation may be demonstration projects, hence relevant indicators and data collection may be more intense. In the scale-up phase, the national PrEP monitoring and evaluation framework will only collect data that will be relevant to guide and measure performance of the program. Supportive supervision and mentorship for oral PrEP uptake and use will be done quarterly and on demand to ensure continuous quality control and improvement (CQI) of the program. Relevant PrEP program recording and reporting tools in the Appendices will be used in the monitoring and evaluation of the program.

3.5 Supply Chain for PrEP Commodities

In phase one, oral PrEP commodities for the target population will depend on available stocks and will be distributed directly to the selected oral PrEP facilities after prior on-site assessment to guarantee proper storage and safety of the commodities. This will be based on agreed and documented targets to avoid challenges with availability of commodities. Commodity managers will be trained in good inventory management practices to equip them with the knowledge and skills to ensure commodities are managed appropriately. Logistics reporting tools will be developed to ensure that enough data is available to support the full-scale rollout. This process will be synchronized with the national logistics management system to ensure accurate documentation using appropriate PrEP logistics tools. This will produce accurate and reliable data for national consumption projection, quantification, and documentation of lessons learned.

3.6 Pharmacovigilance

The Food and Drugs Authority (FDA) is the National Pharmacovigilance Centre and coordinates pharmacovigilance activities in Ghana. Monitoring and reporting of adverse drug events should be done according to their guidelines. Adverse drug reactions reporting forms (blue forms) as well as other means recommended by the FDA can be used to submit reports. Health facilities must record adverse drug reactions and report them to the FDA. Furthermore, facilities are encouraged to use the information to monitor patients.



4. Pharmacovigilance

Pharmacovigilance refers to the activities set up for the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

- Adverse drug reactions (ADRs) can be detected by either a drug user, guardian, or health care practitioner.
- Report all ADRs (minor and serious) that are a concern to either a patient or guardian (e.g., persistent fever) and to the health care provider (e.g., jaundice).
- Serious ADRs should be reported as soon as possible to the Ghana Food and Drug Regulatory Authority.
- ADRs are considered serious if they result in any of the following: death, life-threatening, disability, hospitalization/prolonged hospitalization, congenital anomaly, require intervention to prevent impairment/damage, and any other important medical event. Serious ADRs (e.g., death) must be reported within 24 hours.

4.1 How to Fill Out the ADR Reporting Form

All sections of the form must be filled in with adequate details. The following basic information is required:

- Identifiable source of information or reporter
- Identifiable patient
- Name(s) of the suspected product(s)
- Description of the suspected reaction



5. Supply Chain

This section describes the supply chain management system that will support continuous availability of ARVs for PrEP use in Ghana. At the national level, PrEP commodity procurement and distribution will be a component of the HIV program supply chain management. Commodity procurement, warehousing, and distribution for HIV programs is described in the 2019 Consolidated Guidelines for HIV Care in Ghana (Section 10.1.3–10.1.8). These sections emphasize the due diligence required in record keeping in HIV commodity utilization, forecasting, supply planning, procurement, warehousing, and distribution.

An effective national supply chain system requires close in-country coordination among the Procurement and Supply Directorate (P&S) of the Ministry of Health and the Supplies and Drug Management Division (SSDM) of the Ghana Health Service, the National AIDS Control and STI Program (NACP), central medical store (CMS), regional medical stores (RMSs), and service delivery points (SDPs). A typical sequence of responsibility is described below:

- Health facility staff will ensure filling and timely reporting of commodity use on appropriate LMIS forms.
- The NACP supply chain team reviews submitted forms, and then works with appropriate stakeholders (P&S, SSDM, CMS, RMS, and implementing partners) to ensure timely and uninterrupted supply of health commodities.
- Collaboration between the NACP and key stakeholders is required before authorization of the following activities involving movement of ARVs and HIV test kits:
 - Requesting additional supplies from CMS
 - Disposing of expired/damaged stocks
 - Emergency distribution, particularly for replenishment between distribution cycles to ensure continuous availability of ARVs and test kits at facilities to provide uninterrupted HIV services to clients
- The ARVs and medical supplies move downward from the CMS to the regions.
- The supply chain system implements a regular distribution cycle from the RMSs.

The PrEP dispensing officer is responsible for determining commodity order or re-order quantities based on consumption patterns and available stocks and submits same to the logistics management information system (LMIS) for review by the regional health directorate and other stakeholders.

5.1 Preparing the Stock Report

The health facility PrEP dispensing officer uses the following information to complete logistics reports:

- Consumption data from PrEP dispensing register (DR)
- Stock-on-hand data from stock card or physical count report
- Losses and adjustments data from stock card

PrEP logistics report should be completed at the end of every month for timely requisition and resupply of PrEP drugs. The following activities should be implemented before completing the LMIS tool:

- Confirm each commodity is sorted by the expiry date
- Ensure all stocks are available to be counted, including those in bulk or store, at the clinic store and at HIV testing rooms, etc.
- Do a physical count of available stocks to determine the stock on hand (SOH)

5.2 Receiving ARVs and Medical Supplies at Facility Store

- PrEP ARV supplies should be received by the facility stores according to the recommended practices of the MOH.
- The person receiving the commodities at the facility should inspect the entire consignment based on facility regulations:
 - Physically count all re-packed/loose units. Originally sealed boxes do not need to be opened for counting of units.
 - Check expiry date for all ARV packs.
 - Write the physical count for each item into the respective box on the delivery document. Write zero (0) for any items not received – do not leave any check box empty.
- Sign, date, and stamp the delivery note to confirm receipt of the items as indicated.
- The person signing on the delivery note is accountable for all items s/he has signed for. The PrEP dispensing officer will be held responsible for any discrepancies noted later.

5.3 Moving ARVs and Medical Supplies to Storage

- Immediately move the ARVs received into a secure storage area at the facility (clean, dry, cool, and off the floor).
- Enter quantity and date of receipts on *stock cards* without delay.
- Arrange items by expiry date to make it easy to follow the “first expiry, first out” (FEFO) principle.

5.4 Issuing ARVs and Medical Supplies to Clinic or Pharmacy

- Fill requisition and issue vouchers for all commodities requested from the clinic.
- Follow the FEFO principle ALWAYS.
- Update stock card immediately when moving items out of the pharmacy/clinic.

5.5 Requesting Adjustment and Stock Redistribution

Good planning and coordination will prevent PrEP ARV expiry and stock-out, however, in the unlikely event of a risk of PrEP ARV stock expiry or stock-out, PrEP focal persons should establish contacts with the regional health directorate immediately and contact a neighboring facility for stock redistribution. Before establishing the contact, prepare the following information:

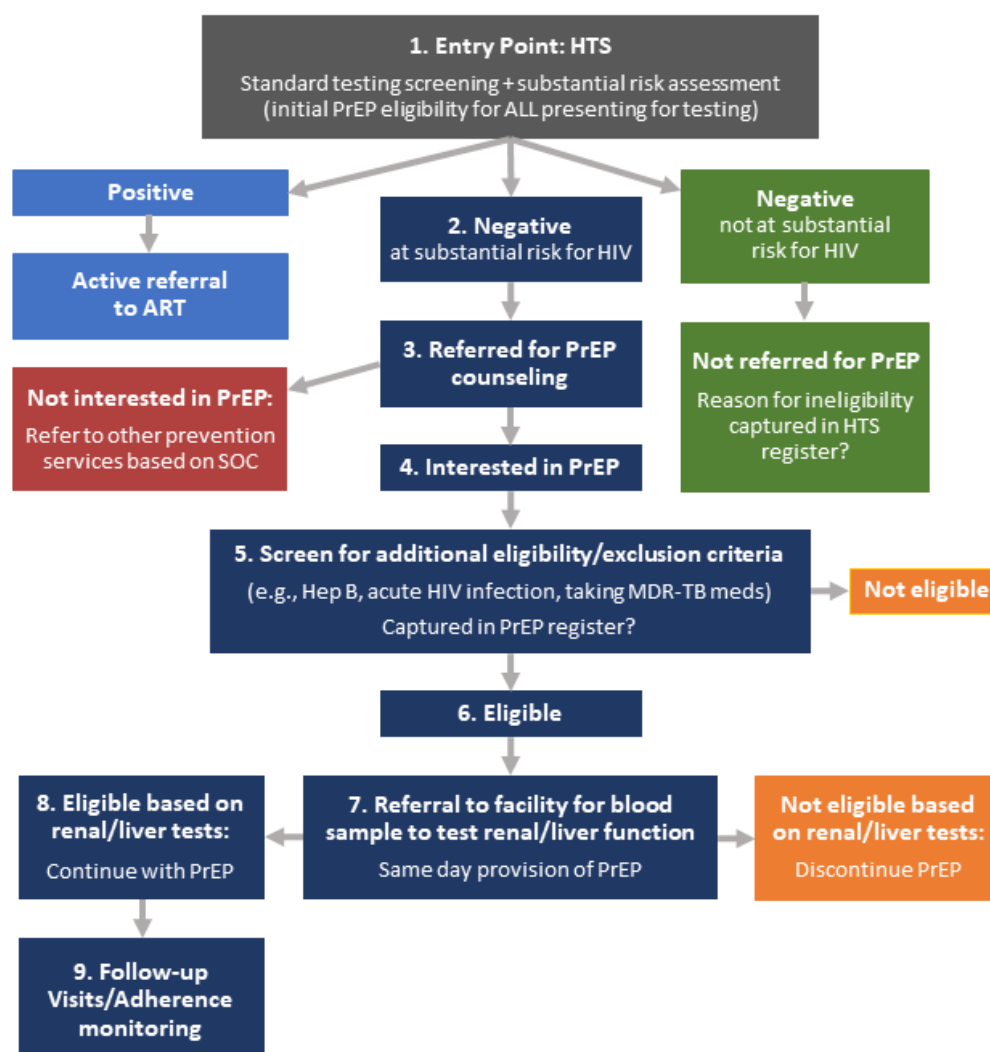
- Number of packs/bottles of PrEP ARVs required
- Expiry date for each ARV drug
- Number of PrEP users on the regimen at your facility and approximate average monthly consumption (AMC)

6. Monitoring and Evaluation

NACP relies heavily on accurate and timely data for program evaluation, strategic planning, and research. Cleaned data will be shared with donors and stakeholders for drug quantification and procurement. PrEP data analysis and reporting will be done from client PrEP dispensing cards and facility registers at selected PrEP facilities.

- Reporting is done monthly for PrEP, even though daily and weekly summaries are advisable to track missed appointments and losses to follow-up.
- All PrEP reports are to form part of the integrated HMIS reporting form to the MOH.
- Reports from facilities are to be completed within five working days after the end of the reporting period.
- PrEP monitoring and evaluation will be part of the comprehensive PrEP training schedule.
- Follow the PrEP eligibility algorithm and client flow (Appendix 2) to identify the appropriate tool for reporting.

Figure 5. Flow chart for oral PrEP data collection



6.1 Commonly Used Tools for PrEP Monitoring and Evaluation

- PrEP screening for substantial risk and eligibility
- PrEP facility register
- PrEP follow-up register (PrEP client card)
- PrEP screening log
- PrEP monthly summary form
- Seroconverter tracker
- PrEP quarterly cohort report

6.2 Screening for Substantial Risk and Oral PrEP Indication

- Administered at the HIV testing site to HIV-negative clients who are potential candidates for PrEP.
- Screening looks at the following:
 - Verification of substantial risk for HIV infection
 - Possibility of acute HIV infection
 - Weight
 - History of liver disease
 - Taking MDR TB drugs

6.3 PrEP Facility Record

- Administered at PrEP dispensing point
- Documents enrollment data from the PrEP enrollment registers
- Captures all follow-up information:
 - Adherence (pill count, missed doses)
 - HIV test results
 - Side effects
 - Next appointment
- Complete the PrEP Facility Record (Appendix 8) with the client using the PrEP Screening for Substantial Risk and Eligibility form (Appendix 6) and guided by the standard operating procedures (Appendices 3–5).
- Complete the PrEP Follow-Up Visits section of this form at each follow-up visit.

6.4 PrEP Follow-Up Register

- Administered at PrEP dispensing point
- Documents enrollment data from PrEP facility registers
- Captures all follow-up information:
 - Adherence (pill count, missed doses)
 - HIV test results
 - Side effects
 - Next appointment

6.5 PrEP Screening Log

The PrEP screening log is completed after the initial PrEP screening. It should include *everyone* screened for PrEP, regardless of whether they are eligible for PrEP or decline it.

The log shows how many of those screened are eligible for PrEP, and among those eligible, how many accept or decline PrEP.

Consult the PrEP Screening for Substantial Risk and Eligibility form.

- The data help to inform clinics and NACP of the PrEP eligibility and acceptability rate and the main reasons that individuals are ineligible for or decline PrEP.
- The data can inform increased outreach and education efforts and information, education, and communication (IEC) materials.
- The fact that many people screened are ineligible can inform how the screening form might be revised—for example, by adding additional KP or vulnerable groups.

6.6 Seroconverter Tracker

The tracker is completed during follow-up visits for PrEP clients who seroconvert to HIV positive.

Source documents to complete this form: PrEP client register and ART records.

Refer to the variable and code definitions as needed when completing the tracker. The tracker will help ensure appropriate linking and follow-up of clients diagnosed with HIV and can facilitate reporting of seroconversions for surveillance.

6.7 PrEP Monthly Summary Form

Optimally, all data from all HIV testing points referring individuals for PrEP within a facility should be combined and reported here.

- The number of clients testing HIV negative is the “denominator” for assessing coverage of who is eligible for PrEP screening. Data for the HIV testing and results table should be taken from clinic HIV testing services registers.
- Source documents to complete this form: Use the PrEP screening log and PrEP client register.

6.8 PrEP Quarterly Cohort Report

This form is used to collect and track data per quarter and PrEP cohort.

Source document to complete this form: PrEP client register.

6.9 Confidentiality of Patient Records

- All PrEP client cards and clinic registers are property of the NACP/GHS and may be kept only at the respective facilities or at the National Archives.
- Client cards and clinic registers must be kept in a locked room and are to be accessed only by clinic staff responsible for providing the respective service and by the national supervision team. PrEP clients and named partners may have access to their own individual cards.

6.10 Use of PrEP Facility Registers

- Use only one PrEP facility register in each facility; all multipoint PrEP services must be documented in this single register.
- Turn to a new page when starting to register clients in a new month. Leave any unused rows at the bottom of the previous page empty. This is to separate the month when adding page totals.
- Assign continuous registration numbers (by sequence of registration). Take care not to duplicate registration numbers.
 - Continue assigning cumulative registration numbers in the PrEP facility register. These number series are never re-started.

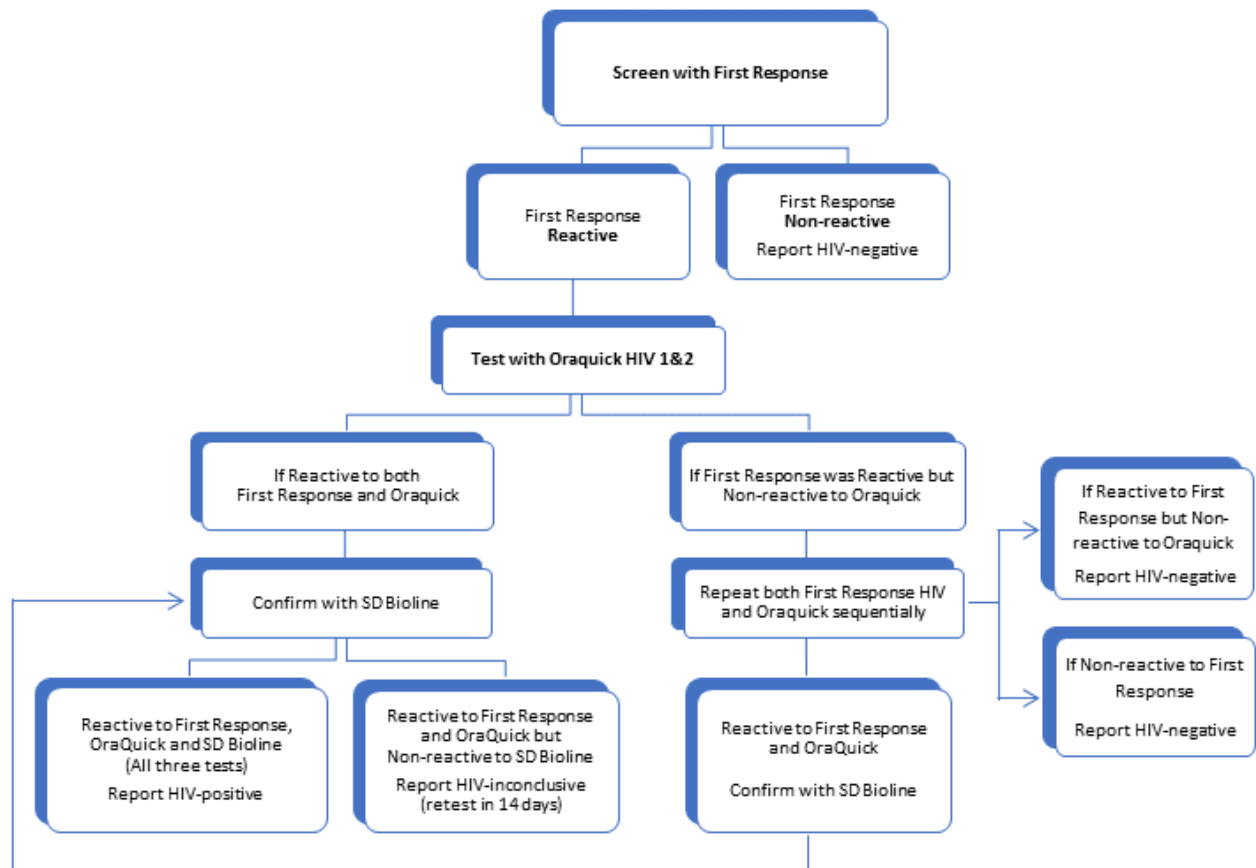
7. Appendices

Appendix 1: Training and Certification

All eligible PrEP providers, irrespective of educational level and capacity, must be trained on PrEP service delivery, including the science of PrEP, eligibility determination, platform for service delivery, medication adherence strategies, and monitoring and evaluation. The PrEP Training Package developed by ICAP at Columbia University has been adapted to align with specific policies, the health system, and epidemic context for use with KPs in Ghana. The three-day training package includes:

Day One	Day Two	Day Three
<ul style="list-style-type: none">• HIV and PrEP basics• ARVs for PrEP and PrEP misconception• PrEP screening and eligibility• Adapted clinical scenarios	<ul style="list-style-type: none">• Initial and follow-up PrEP visits• Understanding adherence• Integrated next-steps counseling• Clinical role-plays• Monitoring and managing PrEP side effects	<ul style="list-style-type: none">• PrEP follow-up visits• Entry points for PrEP• PrEP monitoring and evaluation• Commodity management and reporting

Appendix 2: National HIV Testing Algorithm for Non-Pregnant Women and General Population in Ghana



Appendix 3: Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility

1. Facility Information		
Facility Name		
Date of Initial Client Visit (dd/mm/yyyy) ____ / ____ / ____		Person Completing Form
2. Client Information		
First Name	Middle Name	Surname
Address	Telephone #	
Client ID Number		
3. Client Demographics		
What was your sex at birth?	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> No response	
What is your current gender?	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender (male to female) <input type="checkbox"/> Transgender (female to male) <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> No response	
What is your age? (Specify number of years.)	_____	
4. Screening for Substantial Risk for HIV Infection		
Client is at substantial risk if he/she belongs to categories ①, ②, or ③ below	Question Prompts for Providers	
① If client is sexually active in a high HIV prevalence population PLUS reports ANY one of the below in the last 6 months	Have you been sexually active in the last 6 months?	
<input type="checkbox"/> Reports vaginal or anal intercourse without condoms with more than one partner	In the last 6 months, how many people did you have vaginal or anal sex with? In the last 6 months, did you use condoms consistently during sex?	
<input type="checkbox"/> Has a sex partner with one or more HIV risk:	In the last 6 months, have you had a sex partner who: <ul style="list-style-type: none"> • Is living with HIV? • Injects drugs? • Has sex with men? • Is a transgender person? • Is a sex worker? • Has sex with multiple partners without condoms? 	
<input type="checkbox"/> History of a sexually transmitted infection (STI) based on self-report, lab test, syndromic STI treatment	In the last 6 months, have you had an STI?	
<input type="checkbox"/> History of use of post-exposure prophylaxis (PEP)	In the last 6 months, have you taken post-exposure prophylaxis (PEP) following a potential exposure to HIV?	
② If client reports history of sharing injection material or equipment in the last 6 months <input type="checkbox"/> History of sharing injection material or equipment	In the last 6 months, have you shared injecting material with other people?	
③ If client reports having a sexual partner in the last 6 months who is HIV positive AND who has not been on effective* HIV treatment (i.e., the partner has been on ART for fewer than 6 months or has inconsistent or unknown adherence) <input type="checkbox"/> History of HIV-positive sex partner not on effective treatment	Is your partner HIV positive? Is he/she on ART? What was the last viral load result?	

5. PrEP Eligibility

Client is eligible if he/she fulfills ALL the criteria below:

<input type="checkbox"/> HIV negative	Date client tested: (dd/mm/yyyy): ____ / ____ / ____ Date client received test results: (dd/mm/yyyy): ____ / ____ / ____ Test result: <input type="checkbox"/> Negative <input type="checkbox"/> Positive (Refer to HIV medical care.) <input type="checkbox"/> Inconclusive (Re-test in 14 days.) Type of test used: <input type="checkbox"/> First Response <input type="checkbox"/> Combo <input type="checkbox"/> OraQuick <input type="checkbox"/> SD Bioline
<input type="checkbox"/> At substantial risk of HIV	At least one item/risk in Section #4 above is ticked
<input type="checkbox"/> Has no signs/symptoms of acute HIV infection	See Section #6 below to confirm no recent exposure to HIV
<input type="checkbox"/> Has creatinine clearance (eGFR) >60 ml/min	Result: _____ Date of creatinine test (dd/mm/yyyy): ____ / ____ / ____

If all boxes in Section 5 are ticked, offer PrEP.

6. Recent Exposure to HIV

Ask the client: In the past 72 hours, have you had sex without a condom with someone whose HIV status is positive or not known to you, or have you shared injection equipment with someone whose HIV status is positive or unknown to you?	<input type="checkbox"/> Yes*	<input type="checkbox"/> No	<input type="checkbox"/> Don't know
In the past 28 days, have you had symptoms of a cold or flu, including fever, fatigue, sore throat, headache, or muscle pain or soreness?	<input type="checkbox"/> Yes**	<input type="checkbox"/> No	<input type="checkbox"/> Don't know
<p>* If the client reports potential exposure to HIV within past 72 hours, do NOT offer PrEP. Follow facility procedures to evaluate further or refer for evaluation for post-exposure prophylaxis (PEP).</p> <p>** If the client reports flu-like symptoms or other signs of acute HIV infection, do NOT offer PrEP and evaluate further, following facility procedures to diagnosis acute HIV infection.</p>			

7. Services Received by Client

<input type="checkbox"/> PrEP offered. <ul style="list-style-type: none"> <input type="checkbox"/> PrEP accepted. <input type="checkbox"/> PrEP declined. (If declined, see Reasons for Declining PrEP, below).
Date eligible (dd/mm/yyyy): ____ / ____ / ____ Date initiated (dd/mm/yyyy): ____ / ____ / ____ Same-day initiation recommended.
Reasons for Declining PrEP (Check all that apply.) <ul style="list-style-type: none"> <input type="checkbox"/> No need for PrEP <input type="checkbox"/> Does not wish to take a daily medication <input type="checkbox"/> Concerns about side effects <input type="checkbox"/> Concerns about what others might think <input type="checkbox"/> Concerns about time required for clinic follow-up <input type="checkbox"/> Concerns about safety of medication <input type="checkbox"/> Concerns about effectiveness of medication <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/> Referred for PEP evaluation
<input type="checkbox"/> Referred for PCR/HIV Ag test or follow-up HIV re-testing (if suspicion of acute HIV infection)

Appendix 4: STANDARD OPERATING PROCEDURES

Pre-Exposure Prophylaxis (PrEP) Facility Record

Purpose: Document and track clients initiated on PrEP

For whom: All clients initiated on PrEP

When to use: After completing the PrEP Screening for Substantial Risk and Eligibility form

Responsible staff: Health care worker who is initiating the client on PrEP

Source document: Completed with the client; PrEP Screening for Substantial Risk and Eligibility form

DESCRIPTION OF VARIABLES

The PrEP Facility Record is completed with the client. Consult the PrEP Screening for Substantial Risk and Eligibility form and client's medical record when indicated below.

- **Date:** Date this form is completed, day (dd), month (mm), and year (yyyy); e.g., 30/04/2018
- **Person Completing Form:** First and last name of the health care worker completing this form

A. FACILITY INFORMATION

- **Facility Name:** Name of the facility
- **District:** District where the facility is located
- **Date of Initial PrEP Client Screening Visit:** Date that the client was screened for PrEP eligibility, from the PrEP Screening for Substantial Risk and Eligibility form: day (dd), month (mm), and year (yyyy)
- **PrEP Client Number:** Unique number assigned to the client when he or she accepts PrEP. If no PrEP-specific number is assigned, leave this space blank.

B. CLIENT DEMOGRAPHICS

- **First/Given Name:** Client's first (given) name
- **Middle Name:** Client's middle name (if any)
- **Surname:** Client's surname or family name
- **Address:** Client's current address (where the client lives now)
- **Telephone:** Client's primary telephone number
- **Telephone (alternative):** Any other number (if any) that may be used to contact the client

- **Date of Birth:** Day (dd), month (mm), and year (yyyy)
- **Age (*years*):** Client's age at most recent birthday, in years
- **Client ID Number:** Number assigned to the client at clinic registration
- **Marital Status:** Ask the client and tick the box for the client's current legal status: Single, Married, Divorced, Widowed, Separated, or No response.

C. SEXUAL AND DRUG INJECTION CORE RISK CLASSIFICATION

- **1. Do you consider yourself: male, female, transgender, or other?** Client's current gender as self-identified by the client, regardless of the client's sex at birth. Consult the PrEP Screening for Substantial Risk and Eligibility form and tick the appropriate box. If Other, specify in the space provided.
- **2. What was your sex at birth?** Ask the client's sex at birth and tick Male, Female, Other (specify in the space provided), or No response.
- **3. Do you have sex with:** Ask the client and tick the appropriate box: Men only, Women only, Both men and women, or No response.
- **4. Have you exchanged sex as your main source of income in the last 6 months?** Ask the client if her or his main monetary or non-monetary source of income comes from sex work and tick the appropriate box: Yes, No, or No response.
- **5. In the last 6 months, have you injected illicit or illegal drugs?** Ask the client and tick the appropriate box: Yes, No, or No response.
- **6. Are you incarcerated?** Ask the client and tick the appropriate box, Yes, No, or No response.

D. KEY POPULATION CLASSIFICATION

- Use information from section C to determine the client's key population classification(s). For example, if the client answers "Male" to section C question 1, and answers "Men only" or "Both men and women" to section C question 3, categorize the client as "MSM." Then tick the right-hand box AND the box for MSM in the Final Classification column.
- Repeat this process for the transgender (TG), sex worker (SW), person who injects drugs (PWID), and person in prison (PP) classifications, ticking both the right-hand boxes AND the boxes under the Final Classification column.

E. IF FEMALE: PREGNANCY AND BREASTFEEDING

- **Client currently pregnant?** Ask the client for the date of her last normal menstrual period and do a pregnancy test if needed. Tick Yes or No.
- **Client currently breastfeeding?** Ask the client if she is currently breastfeeding and tick Yes or No.

F. BASELINE LABORATORY TESTS

Consult the client's medical record and/or PrEP Screening for Substantial Risk and Eligibility form for all baseline laboratory tests.

- **Date of last HIV test:** Date of the client's last HIV test; day (dd), month (mm), and year (yyyy)
- **Date of creatinine test:** Date the client's baseline serum creatinine test was performed; day (dd), month (mm), and year (yyyy). If the test not done, tick Not done.
- **Calculated creatinine clearance (CrCl):** Write the result. If the test was not done, tick Not done.
- **Date of creatinine clearance:** Date that the client's creatinine clearance was determined; day (dd), month (mm), and year (yyyy)

G. HEPATITIS B TESTING, VACCINATION, AND TREATMENT

Consult the client's medical record where appropriate.

- **Date of HBsAg test:** Day (dd), month (mm), and year (yyyy). If the facility does not offer hepatitis B testing, leave the test date blank.
- **Test result:** Tick Negative, Positive, or Not Done
- **If positive, is client on treatment?** Tick the appropriate box according to client's report. Yes = client is initiated on Hepatitis B treatment; No = client is not initiated on Hepatitis B treatment; Unknown = client does not know.
- **If negative, dates HBV vaccination provided (if available):** Record the 1st, 2nd, and 3rd dates of the client's HBV vaccinations, day (dd), month (mm), and year (yyyy). If vaccinations are not provided, tick Not done.

H. SEXUALLY TRANSMITTED INFECTIONS (STIs)

Consult the client's medical record where appropriate.

- **STI symptom screen date:** Day, (dd), month (mm), and year (yyyy)
- **Result (see codes):** Write the appropriate codes: U = Urethral discharge; G = Genital ulcers or lesions; V = Vaginal discharge; I = Itching; L = Lower abdominal pain (women only); S = Scrotal swelling; B = Bubo in inguinal area; D = Dysuria (pain with urination); P = Pain with intercourse (women only); O = Other (specify in the space provided). If screening was not done, tick Not done.
- **If STI syndromic management, syndrome treated (see codes):** Write all codes that apply: GUS = Genital ulcer syndrome; VDS = Vaginal discharge syndrome; LAP = Lower abdominal pain; MUS = Male urethritis syndrome; SSW = Scrotal swelling; O = Other (specify in the space provided).
- **STI treatment start date:** Day (dd), month (mm), and year (yyyy). If the client has not started STI treatment, tick Not started treatment.

I. INITIATION OF PrEP TREATMENT

- **PrEP start date: Date initiated:** Date the client was started on PrEP at the facility; day (dd), month (mm), and year (yyyy).
- **PrEP (ARVs) prescribed:** Tick the client's PrEP regimen or tick Other and specify the regimen prescribed in the space provided.
- **PrEP discontinued:** Complete this section if the facility clinician stops PrEP or is informed that the client has stopped PrEP. **Date discontinued:** Record the date that discontinuation was documented by the facility; day (dd), month (mm), and year (yyyy).
- **Reasons for stopping PrEP:** Ask the client and tick all reasons given: Tested HIV+; No longer at substantial risk; Side effects; Client preference; Abnormal creatinine result; and/or Other (specify in the space provided).
- **HIV status at time of discontinuation:** Tick Negative, Positive, or Unknown.

I. Continued: RE-START PrEP TREATMENT

Complete this section for clients who discontinued PrEP but have decided to re-initiate at a later date. When the client decides to re-initiate PrEP, another PrEP Screening for Substantial Risk and Eligibility form is completed.

- **PrEP re-start date:** Write the **Date re-started** on PrEP, day (dd), month (mm), and year (yyyy).
- **PrEP (ARVs) prescribed:** Tick the client's PrEP regimen or tick Other and specify the regimen prescribed in the space provided.
- **PrEP discontinued:** Complete this section if the facility clinician stops PrEP or is informed that the client has stopped PrEP. **Date discontinued:** Record the date that discontinuation was documented by the facility; day (dd), month (mm), and year (yyyy).
- **Reasons for stopping PrEP:** Ask the client and tick all reasons given: Tested HIV+; No longer at substantial risk; Side effects; Client preference; Abnormal creatinine result; and/or Other (specify in the space provided).
- **HIV status at time of discontinuation:** Tick Negative, Positive, or Unknown.

J. TRANSFER OUT, DEATH, AND LOSS TO FOLLOW-UP

Leave this section blank unless the client transfers out, is lost to follow-up, or dies. Consult the client's medical record where appropriate.

- If the client transfers out, tick **Transferred out (TO)**, write the **date TO**, day (dd), month (mm), and year (yyyy), e.g. 30/04/18. Write the **Name of facility transferred to** in the space provided.
- If the client dies, tick **Died** and write the **Date of death**, (dd), month (mm), and year (yyyy).

- Tick **Lost to follow-up (LTFU)** if the client is lost to follow-up, i.e. the client has missed a PrEP follow-up appointment by more than 90 days. Write **Date confirmed LTFU**, day (dd), month (mm), and year (yyyy).

PrEP FOLLOW-UP VISITS

Clients started on PrEP will be followed at 3-month intervals after the 1st month on PrEP. Complete this section during each follow-up visit. Use one column for each follow-up visit. Use the Provider Checklist for Follow-Up PrEP Visits as a guide for conducting follow-up visits.

- **Date of visit (starting with screening visit):** Date the client attends the appointment, day (dd), month (mm), and year (yyyy)
- **HIV test:** Tick the HIV **Test result**, Negative or Positive or Inconclusive. Write the tests used in the spaces provided for First HIV test and Confirmatory test.
- **Signs and symptoms of acute HIV infection?** Assess for acute HIV infection and tick Yes or No.
- **Side effects:** Ask the client if he or she has experienced any side effects from the PrEP medication and write all codes (listed on the bottom of the form). If the client has no side effects, write a dash in the space. A = Abdominal pain; S = Skin rash; Nau = Nausea; V = Vomiting; D = Diarrhea; F = Fatigue; H = Headache; L = Enlarged lymph nodes; R = Fever; and O = Other (specify in the space provided).
- **CrCl calculation:** Record the client's serum creatinine and calculated creatinine clearance (baseline and every six months).
- **Risk-reduction counseling and commodities provided?** Tick box to indicate that risk-reduction counseling and commodities have been provided.
- **PrEP prescription:** Tick the client's PrEP regimen or tick Other and specify the regime in the space provided.
- **Next scheduled visit date:** Date of the client's next appointment; day (dd), month (mm), and year (yyyy)
- **Additional notes:** Write any other lab investigations or clinical findings in the space provided.

Appendix 5: Pre-Exposure Prophylaxis (PrEP) Facility Record

Date (dd/mm/yyyy)		Person Completing Form																	
A. Facility Information																			
Facility Name		District																	
Date of Initial PrEP Client Screening Visit (dd/mm/yyyy): / /		PrEP Client Number (if applicable)																	
B. Client Demographics																			
First/Given Name:		Middle Name:	Surname:																
Address:		Telephone: Telephone (alternative):																	
Date of Birth (dd/mm/yyyy) / /		Age (years):																	
Client ID Number:		Marital Status: <input type="checkbox"/> Single <input type="checkbox"/> Married <input type="checkbox"/> Divorced <input type="checkbox"/> Widowed <input type="checkbox"/> Separated <input type="checkbox"/> No response																	
C. Sexual and Drug Injection Core Risk Classification																			
1. Do you consider yourself: male, female, transgender, or other? <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender, male to female (MTF) <input type="checkbox"/> Transgender, female to male (FTM) <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> No response		2. What was your sex at birth? <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> No response																	
3. Do you have sex with: <input type="checkbox"/> Men only <input type="checkbox"/> Women only <input type="checkbox"/> Both men and women <input type="checkbox"/> No response																			
4. Have you exchanged sex as your main source of income in the last 6 months? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No response																			
5. In the last 6 months, have you injected illicit or illegal drugs? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No response																			
6. Are you incarcerated? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No response																			
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 man who has sex with men (MSM)			<input type="checkbox"/>																
If client answers "Transgender MTF" or "FTM" to question 1, then categorize as transgender (TG) (cross-check with question 2)			<input type="checkbox"/>																
If client answers "Yes" to question 4, then categorize as sex worker (SW)			<input type="checkbox"/>																
If client answers "Yes" to question 5, then categorize as person who injects drugs (PWID)			<input type="checkbox"/>																
If client answers "Yes" to question 6, then categorize as person in prison (PP)			<input type="checkbox"/>																
If client is not transgender (TG) and answers "No" or "No response" to questions 3-7, classify as None			<input type="checkbox"/>																
Final Classification: (Mark ALL that apply*) <table border="0"> <tr> <td>Man who has sex with men (MSM)</td> <td><input type="checkbox"/> MSM</td> <td rowspan="6"> <i>*Some clients may belong to more than one category due to overlapping risk behavior.</i> </td> </tr> <tr> <td>Transgender (TG)</td> <td><input type="checkbox"/> TG</td> </tr> <tr> <td>Sex worker (SW)</td> <td><input type="checkbox"/> SW</td> </tr> <tr> <td>Person who injects drugs (PWID)</td> <td><input type="checkbox"/> PWID</td> </tr> <tr> <td>Person in prison (PP)</td> <td><input type="checkbox"/> PP</td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/> Other(specify): _____</td> </tr> <tr> <td>None</td> <td><input type="checkbox"/> None</td> <td></td> </tr> </table>				Man who has sex with men (MSM)	<input type="checkbox"/> MSM	<i>*Some clients may belong to more than one category due to overlapping risk behavior.</i>	Transgender (TG)	<input type="checkbox"/> TG	Sex worker (SW)	<input type="checkbox"/> SW	Person who injects drugs (PWID)	<input type="checkbox"/> PWID	Person in prison (PP)	<input type="checkbox"/> PP	Other	<input type="checkbox"/> Other(specify): _____	None	<input type="checkbox"/> None	
Man who has sex with men (MSM)	<input type="checkbox"/> MSM	<i>*Some clients may belong to more than one category due to overlapping risk behavior.</i>																	
Transgender (TG)	<input type="checkbox"/> TG																		
Sex worker (SW)	<input type="checkbox"/> SW																		
Person who injects drugs (PWID)	<input type="checkbox"/> PWID																		
Person in prison (PP)	<input type="checkbox"/> PP																		
Other	<input type="checkbox"/> Other(specify): _____																		
None	<input type="checkbox"/> None																		

E. IF FEMALE: Pregnancy & Breastfeeding		F. Baseline Laboratory Tests	
Client currently pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No		Date of last HIV test (dd/mm/yyyy): ____ / ____ / ____	
Client currently breastfeeding? <input type="checkbox"/> Yes <input type="checkbox"/> No		Date of creatinine test (dd/mm/yyyy): ____ / ____ / ____ <input type="checkbox"/> Not done	
		Calculated creatinine clearance (CrCl): _____ <input type="checkbox"/> Not done	
		Date of creatinine clearance (CrCl) (dd/mm/yyyy): ____ / ____ / ____	

G. Hepatitis B Testing, Vaccination, and Treatment	
Date of HBsAg test (dd/mm/yyyy): ____ / ____ / ____	Test result: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not done
If positive, client on treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If negative, dates HBV vaccination provided (if available): (dd/mm/yyyy) 1) ____ / ____ / ____ 2) ____ / ____ / ____ 3) ____ / ____ / ____ <input type="checkbox"/> Not done

H. Sexually Transmitted Infections (STI)	
STI symptom screen date (dd/mm/yyyy): ____ / ____ / ____	Result (*see codes): _____ <input type="checkbox"/> Not done
* STI symptom codes (select all that apply): U=Urethral discharge. G=Genital ulcers or lesions. V=Vaginal discharge. I=Itching. L=Lower abdominal pain (women only). S=Scrotal swelling. B=Bubo in inguinal area. D=Dysuria (pain with urination). P=Pain with intercourse (women only). O=Other (specify)	
If STI syndromic management, syndrome treated (**see codes): _____ <input type="checkbox"/> Not done	
** STI syndrome codes (select all that apply): GUS=Genital ulcer syndrome. VDS=Vaginal discharge syndrome. LAP=Lower abdominal pain. MUS=Male urethritis syndrome. SSW=Scrotal swelling. O=Other (specify)	
STI treatment start date (dd/mm/yyyy): ____ / ____ / ____	<input type="checkbox"/> Not started treatment

I. Initiation of PrEP Treatment	
PrEP start date	Date initiated (dd/mm/yyyy): ____ / ____ / ____
PrEP (ARVs) prescribed	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC (tick)
PrEP discontinued	Date discontinued (dd/mm/yyyy): ____ / ____ / ____
	Reasons for stopping PrEP: <input type="checkbox"/> Tested HIV+ <input type="checkbox"/> No longer at substantial risk <input type="checkbox"/> Side effects <input type="checkbox"/> Client preference <input type="checkbox"/> Abnormal creatinine result <input type="checkbox"/> Other (specify): _____
	HIV status at time of discontinuation: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Unknown
Re-start of PrEP	
PrEP re-start date	Date re-initiated (dd/mm/yyyy): ____ / ____ / ____
PrEP (ARVs) prescribed	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC (tick)
PrEP discontinued	Date discontinued (dd/mm/yyyy): ____ / ____ / ____
	Reasons for stopping PrEP: <input type="checkbox"/> Tested HIV+ <input type="checkbox"/> No longer at substantial risk <input type="checkbox"/> Side effects <input type="checkbox"/> Client preference <input type="checkbox"/> Abnormal creatinine result <input type="checkbox"/> Other (specify): _____
	HIV status at time of discontinuation: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Unknown

J. Transfer Out, Death, and Loss to Follow-Up	
<input type="checkbox"/> Transferred out (TO)	Date TO (dd/mm/yyyy): ____ / ____ / ____ Name of clinic transferred to: _____
<input type="checkbox"/> Died	Date of death (dd/mm/yyyy): ____ / ____ / ____
<input type="checkbox"/> Lost to follow-up (LTFU)	Date confirmed LTFU (dd/mm/yyyy): ____ / ____ / ____

Pre-Exposure Prophylaxis (PrEP) Follow-Up Visits							
Date of visit (dd/mm/yyyy) (starting with screening visit)	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
HIV test Test result: Tests Used:	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Inconclusive First: _____ Confirmatory: _____	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Inconclusive First: _____ Confirmatory: _____	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Inconclusive First: _____ Confirmatory: _____	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Inconclusive First: _____ Confirmatory: _____	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Inconclusive First: _____ Confirmatory: _____	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Inconclusive First: _____ Confirmatory: _____	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Inconclusive First: _____ Confirmatory: _____
Signs and symptoms of acute HIV infection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
PrEP Side effects (see codes – insert a dash if none)							
CrCl calculation (baseline and every 6 months)							
Risk reduction counseling and commodities provided? (tick if yes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SIDE EFFECT CODES: **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*)

PrEP prescription <i>ARVs prescribed (tick)</i>	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC	<input type="checkbox"/> TDF/FTC <input type="checkbox"/> TDF/3TC
Next scheduled PrEP visit date <i>(dd/mm/yyyy)</i>	____/____/____	____/____/____	____/____/____	____/____/____	____/____/____	____/____/____	____/____/____
Additional notes							

Appendix 6: STANDARD OPERATING PROCEDURES

Pre-Exposure Prophylaxis (PrEP) Monthly Summary Form

Purpose: Track all clients screened for PrEP (eligible and not eligible)

For whom: All clients screened for PrEP (eligible and not eligible)

When to use: Monthly

Responsible staff: The designated provider of PrEP service delivery (provider in-charge and/or data or monitoring and evaluation team member)

Source documents: PrEP Screening Log and PrEP Client Register

DESCRIPTION OF VARIABLES

*Use data from the **PrEP Screening Log** and **PrEP Client Register** to complete this form.*

- **Facility Name:** Name of the facility
- **Level of Facility:** Level of the facility, e.g. Regional Hospital
- **Facility Code:** Health facility code (if applicable)
- **District:** District where this facility is located
- **Region:** Region where this facility is located
- **Month of Report:** Month (mm) this report is being completed
- **Year of Report:** Year (yyyy) this report is being completed

SECTION 1: ALL NEW PrEP CANDIDATES

*Use data from the **PrEP Screening Log** and **PrEP Client Register** to complete this section.*

1.1 Number of new clients who received HIV testing for PrEP screening during the period, by gender and age

- Take data from the PrEP Screening Log and calculate totals by gender and age for all NEW clients who received HIV testing for PrEP screening during this month.
- Record each total in the appropriate cell. For example, if there are 10 HIV-negative females aged 30-34 for this month, write “10” in that cell.
- **Total (last column of Table 1.1):** For each row, add all the numbers across the row and write the total in the Total cell.
- **Total (last 2 rows of Table 1.1):** When you have completed totals for all age groups and genders, add the totals for HIV negative and HIV positive down each column and write those totals in the last 2 rows of each column.

Table 1.1 Sample Data

Gender	Age Group (years)								
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	Total
Female									
<i>HIV negative</i>	5	4	15	10	8	7	3	1	53
<i>HIV positive</i>	3	8	10	6	6	5	1	0	39
Male									
<i>HIV negative</i>	7	10	16	12	9	6	4	0	64
<i>HIV positive</i>	4	11	5	3	5	2	2	1	33
Transgender									
<i>HIV negative</i>	1	2	0	3	1	0	0	0	7
<i>HIV positive</i>	0	1	1	1	2	1	0	0	6
Total									
<i>HIV negative</i>	13	16	31	25	18	13	7	1	124
<i>HIV positive</i>	7	20	16	10	13	8	3	1	78

1.2 Number of new clients who received HIV tests for PrEP screening during the period, among key populations (KPs), by age

- Take data from the PrEP Screening Log and calculate totals by KP and age for all NEW clients who received HIV testing for PrEP screening during this month.
- Record each total in the appropriate cell. For example, if there are 23 HIV-positive men who have sex with men (MSM) aged 25-29 for this month, write “23” in that cell.
- Total** (*last column of Table 1.2*): For each row, add all the numbers across the row and write the total in the Total cell. For example:

Table 1.2 Sample Data

KP Group	Age Group (years)								
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	Total
MSM									
<i>HIV negative</i>	5	8	16	6	5	4	1	0	45
<i>HIV positive</i>	9	15	23	2	3	5	1	0	58

- Do not include clients who are not members of key populations.
- MSM = Men who have sex with men; PWID = People who inject drugs; PP = Persons in prison
- Total** (*last 2 rows of Table 1.2*): When you have completed totals for all age groups and key populations, add the totals for HIV negative and HIV positive down each column and write those totals in the last 2 rows of each column.

1.3 Number of new clients determined to be **eligible for PrEP** during the period, **by gender and age**

- Take data from the PrEP Screening Log and calculate totals by gender and age for all NEW clients who received HIV testing and were determined to be eligible for PrEP during this month.
- Record each total in the appropriate cell. For example, if there are three females aged 20-24 who were tested for HIV and are eligible to receive PrEP for this month, write “3” in that cell.
- *No global recommendation for PrEP among adolescents has been developed.
- **Total (last column of Table 1.3):** For each row, add all the numbers across the row and write the total in the Total cell.
- **Total (last row of Table 1.3):** When you have completed totals for all age groups and genders, add the totals down each column and write those totals in the last row of each column. For example:

Table 1.3 Sample Data

Gender	Age Group (years)								Total
	15-19*	20-24	25-29	30-34	35-39	40-44	45-49	50+	
Female	4	3	10	8	3	2	1	0	31
Male	5	11	15	5	4	3	1	0	44
Transgender	1	2	0	3	1	0	0	0	7
Total	10	16	25	16	8	5	2	0	82

* Note: No global recommendation for PrEP among adolescents has been developed.

1.4 Number of clients determined to be **eligible for PrEP** during the period, **by KP group and age**

- Take data from the PrEP Screening Log and calculate totals by key population and age for all NEW clients who received HIV testing and were determined to be eligible for PrEP during this month.
- Record each total in the appropriate cell. For example, if there are two transgender people aged 15-19 who were tested for HIV and are eligible to receive PrEP for this month, write “2” in that cell.
- **Total (last column of Table 1.4):** For each row, add all the numbers across the row and write the total in the Total cell. For example:

Table 1.4 Sample Data

KP Group	Age Group (years)								Total
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	
MSM	5	7	14	6	3	2	1	0	38
Transgender	2	5	4	1	1	0	0	0	13

- Do not include clients who are not members of key populations.
- MSM = Men who have sex with men; PWID = People who inject drugs; PP = Persons in prison
- **Total** (*last row of Table 1.4*): When you have completed totals for all age groups and key populations, add the totals down each column and write those totals in the last row of each column.

1.5 Number of clients who **started PrEP** during the period, **by gender and age**

- Take data from the PrEP Client Register and calculate totals by gender and age for all NEW clients who started PrEP during this month.
- Record each total in the appropriate cell. For example, if there are 12 males aged 25-29 who started PrEP for this month, write “12” in that cell.
- **Total** (*last column of Table 1.5*): For each row, add all the numbers across the row and write the total in the Total cell. For example:

Table 1.5 Sample Data

Gender	Age Group (years)								Total
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	
Female	3	3	8	8	2	1	1	0	26
Male	4	9	12	5	3	3	1	0	37

- **Total** (*last row of Table 1.5*): When you have completed totals for all age groups and genders, add the totals down each column and write those totals in the last row of each column.

1.6 Number of clients who **started PrEP** during the period, **by KP group and age**

- Take data from the PrEP Client Register and calculate totals by key population and age for all NEW clients who started PrEP during this month.
- Record each total in the appropriate cell. For example, if there are 12 men who have sex with men (MSM) aged 25-29 who started PrEP for this month, write “12” in that cell.
- **Total** (*last column of Table 1.6*): For each row, add all the numbers across the row and write the total in the Total cell. For example:

Table 1.6 Sample Data

KP Group	Age Group (years)								Total
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	
MSM	5	7	12	4	2	2	1	0	33
Transgender	2	4	3	1	1	0	0	0	11

- Do not include clients who are not members of key populations.
- MSM = Men who have sex with men; PWID = People who inject drugs; PP = Persons in prison
- **Total** (*last row of Table 1.6*): When you have completed totals for all age groups and key populations, add the totals down each column and write those totals in the last row of each column.

SECTION 2: PrEP FOLLOW-UP SERVICES

Use data from the *PrEP Client Register* to complete this form.

2.1 Number of returning PrEP clients **receiving follow-up HIV testing** during the period, by **gender and age**

- Take data from the PrEP Client Register and calculate totals by gender and age for all returning PrEP clients who received follow-up HIV testing during this month.
- Record each total in the appropriate cell. For example, if there are eight HIV-negative females aged 30-34 for this month, write “8” in that cell.
- Total (last column of Table 2.1):** For each row, add all the numbers across the row and write the total in the Total cell. For example:

Table 2.1 Sample Data

Gender	Age Group (years)								
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	Total
Female									
<i>HIV negative</i>	3	2	6	8	2	1	1	0	23
<i>HIV positive</i>	0	1	2	0	0	0	0	0	3

- Total (last 2 rows of Table 2.1):** When you have completed totals for all age groups and genders, add the totals for HIV negative and HIV positive down each column and write those totals in the last 2 rows of each column.

2.2 Number of returning PrEP clients **receiving follow-up HIV testing** during the period, by **KP group and age**

- Take data from the PrEP Client Register and calculate totals by key population and age for all returning PrEP clients who received follow-up HIV testing during this month.
- Record each total in the appropriate cell. For example, if there are six HIV-negative men who have sex with men (MSM) aged 20-24 for this month, write “6” in that cell.
- Total (last column of Table 2.2):** For each row, add all the numbers across the row and write the total in the Total cell. For example:

Table 2.2 Sample Data

KP Group	Age Group (years)								
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	Total
MSM									
<i>HIV negative</i>	4	6	10	4	2	1	1	0	28
<i>HIV positive</i>	1	1	2	0	0	1	0	0	5

- Do not include clients who are not members of key populations.

- MSM = Men who have sex with men; PWID = People who inject drugs; PP = Persons in prison
- **Total** (*last 2 rows of Table 2.2*): When you have completed totals for all age groups and key populations, add the totals for HIV negative and HIV positive down each column and write those totals in the last 2 rows of each column.

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

- Take data from the PrEP Client Register and calculate totals by gender and age for all clients currently receiving PrEP during this period.
- Record each total in the appropriate cell. For example, if there are nine males aged 20-24 who are currently receiving PrEP in this facility for this month, write “9” in that cell.
- **Total** (*last column of Table 2.3*): For each row, add all the numbers across the row and write the total in the Total cell. For example:

Table 2.3 Sample Data

Gender	Age Group (years)								Total
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	
Female	3	3	8	8	2	1	1	0	26
Male	4	9	12	5	3	3	1	0	37

- **Total** (*last row of Table 2.3*): When you have completed totals for all age groups and genders, add the totals down each column and write those totals in the last row of each column.

2.4 Number of clients **currently receiving PrEP** from this facility, **by KP group and age**

- Take data from the PrEP Client Register and calculate totals by key population and age for all clients currently receiving PrEP during this month.
- Record each total in the appropriate cell. For example, if there are 12 men who have sex with men (MSM) aged 25-29 currently receiving PrEP for this month, write “12” in that cell.
- **Total** (*last column of Table 2.4*): For each row, add all the numbers across the row and write the total in the Total cell. For example:

Table 2.4 Sample Data

KP Group	Age Group (years)								Total
	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	
MSM	5	7	12	4	2	2	1	0	33
Transgender	2	4	3	1	1	0	0	0	11

- Do not include clients who are not members of key populations.
- MSM = Men who have sex with men; PWID = People who inject drugs; PP = Persons in prison
- **Total** (*last row of Table 2.4*): When you have completed totals for all age groups and key populations, add the totals down each column and write those totals in the last row of each column.

BOTTOM OF FORM

- **Form completed by:** Name of the person completing this form (first name and surname)
- **Title:** Title of the person completing this form
- **Date:** Date that this form is completed; day (dd), month (mm), and year (yyyy), e.g., 30/04/18
- **Form verified by:** Name of the person verifying this form (first name and surname)
- **Title:** Title of the person verifying this form
- **Date:** Date that this form is verified; day (dd), month (mm), and year (yyyy)

Appendix 7: STANDARD OPERATING PROCEDURES

Pre-Exposure Prophylaxis (PrEP) Quarterly Cohort Report

Purpose: Track all clients initiated on PrEP per PrEP cohort

For whom: All clients initiated on PrEP

When to use: Quarterly (every three months)

Responsible staff: The designated provider of PrEP service delivery (provider in-charge, and/or data or monitoring and evaluation team member)

Source document: PrEP Client Register

DESCRIPTION OF VARIABLES

*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, 2019 should be assigned to the June 2019 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 2019**, cohorts 1–5 would be defined and recorded as shown below. Note: (1) individuals newly testing HIV positive (column 7) will not receive PrEP at the current visit, so the **# tested for HIV** (column 6) may exceed the **# received PrEP** (column 5); and (2) results in the **# stopped, lost to follow-up, and died** columns (columns 8–12) after the Cohort 1 time point are cumulative and must incorporate any results from previous time points for the cohort. Illustrative data are shown in the tables below to demonstrate how data are to be recorded and indicators calculated.*

*Use data from the **PrEP Client Register** to complete this report.*

- **Facility Name:** Name of the facility
- **Level of Facility:** Level of the facility, e.g. Regional Hospital
- **Facility Code:** Health facility code (if applicable)
- **District:** District where this facility is located
- **Region:** Region where this facility is located
- **Quarter of Report (ending month):** The ending month (mm) for the quarter. For example, if the quarter is April–June, the ending month is 06.
- **Year of Report (yyyy):** Year (yyyy) this report is being completed, e.g., 2019

BASELINE AND FOLLOW-UP TABLE FOR ALL PrEP CLIENTS

Include key population clients and ALL other clients.

EXAMPLE: Baseline and Follow-up Table for ALL PrEP Clients

Cohort	Baseline						Follow-Up							
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.	2019/05	47	0	0	47	45	45	0	0	0	0	2	0
2	3 mos.	2019/03	28	0	1	27	22	23	1	2	2	0	1	0
3	6 mos.	2018/12	21	1	0	22	17	17	0	1	2	0	2	0
4	9 mos.	2018/09	8	0	1	7	4	5	1	1	1	0	1	0
5	12 mos.	2018/06	10	0	0	10	4	4	0	1	1	0	4	0

Original Cohort

- Calendar year/month started on PrEP (yyyy/mm):** For each cohort, write the year (yyyy) and month(s) (mm) ago from the ending month for this quarter. For example, if this report is being completed in June 2019, write “2019/05” in the 1-month space. For 3, 6, 9, and 12 months ago, write: “2019/03,” “2018/12,” “2018/09,” and “2018/06.”
- Column 1 – # started PrEP at this clinic:** Consult the Date of PrEP Initiation column in the PrEP Client Register. Count all clients who started PrEP during each cohort month and write the totals in column 1. For example, if 47 clients started PrEP during May 2015, write “47” in the 1-month space in column 1. If 28 clients started PrEP during March 2019, write “28” in the 3-months space in column 1. Include in each cohort ONLY clients who started PrEP during those months. (For example, do not include clients who started PrEP in April or February.)
- Column 2 – # transfers in:** Consult the PrEP Client Register. For each cohort, use the date of clients’ first PrEP visits in this facility to determine the number of clients who have been added to the cohort in the register since the initial cohort month. For example, if a client who started PrEP 6 months ago (the 2018/12 cohort) had their first PrEP visit 2 months ago, count this client as transferred in.
- Column 3 – # transfers out:** Consult the Transfer Out column in the Outcome section of the PrEP Client Register. For each cohort, count all clients who transferred out and write the total in column 3. For example, if 0 clients transferred out during May 2019, write “0” in the 1-month space in column 3.
- Column 4 – # net current cohort (col. 1+2-3):** For each cohort, add columns 1 and 2, subtract column 3, and write the results in column 4. For example, if among 28 clients who started PrEP in March 2019, 0 clients transferred in, and 1 client transferred out, $28 + 0 - 1 = 27$. Write “27” in the 3-months space for column 4.

At Current Follow-Up Visit

- **Column 5 – # received PrEP:** Consult the Follow-Up Visit section of the PrEP Client Register. For each cohort, use clients' most recent follow-up visits to count all clients who were prescribed PrEP. Write the totals in column 5. For example, if among clients who started PrEP in March 2019, 22 were prescribed PrEP during their most recent follow-up visits, write “22” in the 3-months space for column 5.
- **Column 6 – # tested for HIV:** Consult the Follow-Up Visit section of the PrEP Client Register. For each cohort, use clients' most recent follow-up visits to count all clients who were tested for HIV. Write the totals in column 6. For example, if among clients starting PrEP in March 2019, 23 were tested for HIV during their most recent follow-up visits, write “23” in the 3-months space for column 6.
- **Column 7 – # newly tested HIV+:** Consult the Follow-Up Visit section of the PrEP Client Register. For each cohort, use clients' most recent follow-up visits to count all clients whose HIV test results were positive at those visits – code Pos in the Register. Write the totals in column 7. For example, if among clients starting PrEP in March 2019, 1 client's HIV test result was positive, write “1” in the 3-months space for column 7.

Cumulative for Cohort

Use the most recent data for each client. For example, if a client stopped PrEP and then re-initiated, do not count that client as having stopped PrEP. If a client stopped PrEP, then re-initiated, and then stopped again, count that client as having stopped PrEP.

- **Column 8 – # stopped: HIV+ test:** Consult the Stopped PrEP and Re-initiated PrEP sections of the PrEP Client Register. For each cohort, count all clients who stopped PrEP because they tested positive for HIV – code H in the Register. Write the totals in column 8. For example, if among clients starting PrEP in March 2019, 2 clients stopped PrEP due a positive HIV test (code H) – at any previous point in time – write “2” in the 3-months space for column 8.
- **Column 9 – # stopped: no longer at substantial risk:** Consult the Stopped PrEP and Re-initiated PrEP sections of the PrEP Client Register. For each cohort, count all clients who stopped PrEP because they were no longer at substantial risk – code R in the Register. Write the totals in column 9. For example, if among clients starting PrEP in March 2019, 2 clients stopped PrEP because they were no longer at substantial risk – at any previous point in time – write “2” in the 3-months space for column 9.
- **Column 10 – # stopped: other reason:** Consult the Stopped PrEP and Re-initiated PrEP sections of the PrEP Client Register. For each cohort, count all clients who stopped PrEP for other reasons – codes S, C, AB, and O in the Register. Write the totals in column 10. For example, if among clients starting PrEP in March 2019, no clients stopped PrEP for other reasons – at any previous point in time – write “0” in the 3-months space for column 10.
- **Column 11 – # lost to follow-up:** Consult the Outcome section of the PrEP Client Register. For each cohort, count all clients who were lost to follow-up and write the total in column 11. For example, if among clients starting PrEP in March 2019, 1 client was lost to follow-up – at any previous point in time – write “1” in the 3-months space for column 11.
- **Column 12 – # died:** Consult the Outcome section of the PrEP Client Register. For each cohort, count all clients who died and write the total in column 12. For example, if among clients starting PrEP in March 2018, 0 clients died – at any previous point in time – write “0” in the 3-month space for column 12.

SUMMARY OF COHORT OUTCOMES TABLE FOR ALL PrEP CLIENTS

Round up or down to the nearest whole number for all percentages.

EXAMPLE: Summary of ALL 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.	2019/05	96%	100%	0	0	0	4%
2	3 mos.	2019/03	85%	100%	4%	7%	7%	4%
3	6 mos.	2018/12	77%	100%	0	5%	9%	9%
4	9 mos.	2018/09	71%	100%	20%	14%	14%	14%
5	12 mos.	2018/06	40%	100%	0	10%	10%	40%

- **Calendar year/month started on PrEP (yyyy/mm):** For each cohort, write the year (yyyy) and month (mm) from the previous table.
- **Percent of cohort alive and on PrEP:** For each cohort, divide Baseline/Follow-Up Table column 5 by column 4, multiply by 100, and write the result in the appropriate space. For example, if for the 3-months cohort 23 clients received PrEP (column 5) among the net current cohort of 27 clients (column 4), $23/27 \times 100 = 85\%$. Write “85%” in the 3-months space in this column.
- **Percent of cohort receiving HIV test:** For each cohort, divide Baseline/Follow-Up Table column 6 by column 5 plus column 7, multiply by 100, and write the result in the appropriate space. For example, if for the 3-months cohort 23 clients were tested for HIV (column 6), 22 clients received PrEP (column 5) and 1 client tested positive for HIV (column 7), $23/22 + 1 \times 100 = 100\%$. Write “100%” in the 3-months space in this column.
- **Percent testing HIV+ this visit:** For each cohort, divide Baseline/Follow-Up Table column 7 by column 5 plus column 7, multiply by 100, and write the results in the appropriate space. For example, if for the 3-months cohort 1 client tested positive for HIV (column 7) among 22 clients who received PrEP (column 5), $1/22 + 1 \times 100 = 4\%$. Write “4%” in the 3-months space in this column.
- **Percent stopped: HIV+:** For each cohort, divide Baseline/Follow-Up Table column 8 by column 4, multiply by 100, and write the results in the appropriate space. For example, if for the 3-months cohort 2 clients stopped PrEP because they tested positive for HIV (column 8) among the net current cohort of 27 clients (column 4), $2/27 \times 100 = 7\%$. Write “7%” in the 3-months space in this column.
- **Percent no longer at substantial risk:** For each cohort, divide Baseline/Follow-Up Table column 9 by column 4, multiply by 100, and write the results in the appropriate space. For example, if for the 3-months cohort 2 clients stopped PrEP because they were no longer at substantial risk (column 9) among the net current cohort of 27 clients (column 4), $2/27 \times 100 = 7\%$. Write “7%” in the 3-months space in this column.
- **Percent lost to follow-up:** For each cohort, divide Baseline/Follow-Up Table column 11 by column 4, multiply by 100, and write the results in the appropriate space. For example, if for the 3-months cohort 1

client was lost to follow-up (column 11) among the net current cohort of 27 clients (column 4), $1/27 \times 100 = 4\%$. Write “4%” in the 3-months space in this column.

KEY POPULATION CLIENTS

1. **Men Who Have Sex with Men (MSM):** Use the process and calculations described above to complete this table and the **Summary of MSM Cohort Outcomes** table. Include only clients listed as MSM in the Key Populations column of the PrEP Client Register.
2. **Transgender Persons (TG):** Use the process and calculations described above to complete this table and the **Summary of TG Cohort Outcomes** table. Include only clients listed as TG in the Key Populations column of the PrEP Client Register.
3. **Sex Workers (SW):** Use the process and calculations described above to complete this table and the **Summary of SW Cohort Outcomes** table. Include only clients listed as SW in the Key Populations column of the PrEP Client Register.
4. **People Who Inject Drugs (PWID):** Use the process and calculations described above to complete this table and the **Summary of PWID Cohort Outcomes** table. Include only clients listed as PWID in the Key Populations column of the PrEP Client Register.
5. **Persons in Prison (PP):** Use the process and calculations described above to complete this table and the **Summary of PP Cohort Outcomes** table. Include only clients listed as PP in the Key Populations column of the PrEP Client Register.
6. **ALL PrEP Key Population Clients (MSM+TG+SW+PWID+PP):** Combine data from tables #1 – #5 (MSM, TG, SW, PWID, PP) to complete this table. For example, if in the 3-months cohort eight men who have sex with men (MSM), two transgender persons (TG), three sex workers (SW), five persons who inject drugs (PWID), and zero persons in prison (PP) started PrEP (column 1 in the baseline section of the table), $8+2+3+5+0 = 18$. Write “18” in the 3-months space for Column 1 of this table.
7. **Summary of ALL Key Population Client Cohort Outcomes:** Enter cohort dates and calculate percentages using the calculations described above (and indicated in column headings). Include only MSM, TG, SW, PWID, and PP clients.

BOTTOM OF FORM

- **Form completed by:** Name of the person completing this report (first name and surname)
- **Title:** Title of the person completing this report
- **Date:** Date the report is completed; day (dd), month (mm), and year (yyyy), e.g., 30/04/2019
- **Form verified by:** Name of the person verifying this report (first name and surname)
- **Title:** Title of the person verifying this report
- **Date:** Date the report is verified; day (dd), month (mm), and year (yyyy)

Appendix 8: Pre-Exposure Prophylaxis (PrEP) Quarterly Cohort Report

Facility Name	Level of Facility	Facility Code
District	Region	
Quarter of Report (<i>ending month</i>):		Year of Report (<i>yyyy</i>):

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, 2019 should be assigned to the June 2019 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 2019**, cohorts 1–5 would be defined and recorded as shown below. Note: 1) Individuals newly testing HIV+ (Column 7) will not receive PrEP at the current visit, so the *# tested for HIV* (Column 6) may exceed the *# received PrEP* (Column 5); and 2) Results in the *# stopped, lost to follow-up*, and *died* columns (Columns 8–12) after the Cohort 1 time point are cumulative and must incorporate any results from previous time points for the cohort. Illustrative data are shown in the tables below to demonstrate how data are to be recorded and indicators calculated.

EXAMPLE: ALL PrEP CLIENTS

Cohort	Baseline						Follow-Up							
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.	2019/05	47	0	0	47	45	45	0	0	0	0	2	0
2	3 mos.	2019/03	28	0	1	27	22	23	1	2	2	0	1	0
3	6 mos.	2018/12	21	1	0	22	17	17	0	1	2	0	2	0
4	9 mos.	2018/09	8	0	1	7	4	5	1	1	1	0	1	0
5	12 mos.	2018/06	10	0	0	10	4	4	0	1	1	0	4	0

EXAMPLE: Summary of ALL 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.	2019/05	96%	100%	0	0	0	4%
2	3 mos.	2019/03	85%	100%	4%	7%	7%	4%
3	6 mos.	2018/12	77%	100%	0	5%	9%	9%
4	9 mos.	2018/09	71%	100%	20%	14%	14%	14%
5	12 mos.	2018/06	40%	100%	0	10%	10%	40%

Quarter of Report (*ending month/year*): _____/_____

ALL PrEP CLIENTS

(Including Key Populations Clients and All Other Clients)

Cohort	Baseline			Follow-Up										
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.													
2	3 mos.													
3	6 mos.													
4	9 mos.													
5	12 mos.													

Summary of ALL 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.							
2	3 mos.							
3	6 mos.							
4	9 mos.							
5	12 mos.							

Quarter of Report (ending month/year): _____/_____

Key Populations Clients

1. Men Who Have Sex with Men (MSM)

Cohort	Baseline			Follow-Up										
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.													
2	3 mos.													
3	6 mos.													
4	9 mos.													
5	12 mos.													

Summary of MSM 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.							
2	3 mos.							
3	6 mos.							
4	9 mos.							
5	12 mos.							

Quarter of Report (ending month/year): _____/_____

2. Transgender Persons (TG)

Cohort	Baseline						Follow-Up							
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.													
2	3 mos.													
3	6 mos.													
4	9 mos.													
5	12 mos.													

Summary of TG 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.							
2	3 mos.							
3	6 mos.							
4	9 mos.							
5	12 mos.							

Quarter of Report (ending month/year): _____/_____

3. Sex Workers (SW)

Cohort	Baseline			Follow-Up										
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.													
2	3 mos.													
3	6 mos.													
4	9 mos.													
5	12 mos.													

Summary of SW 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.							
2	3 mos.							
3	6 mos.							
4	9 mos.							
5	12 mos.							

Quarter of Report (ending month/year): _____/_____

4. Persons Who Inject Drugs (PWID)

Cohort	Baseline						Follow-Up							
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.													
2	3 mos.													
3	6 mos.													
4	9 mos.													
5	12 mos.													

Summary of PWID 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.							
2	3 mos.							
3	6 mos.							
4	9 mos.							
5	12 mos.							

Quarter of Report (ending month/year): _____/_____

5. Persons in Prison (PP)

Cohort	Baseline			Follow-Up										
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.													
2	3 mos.													
3	6 mos.													
4	9 mos.													
5	12 mos.													

Summary of PP 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.							
2	3 mos.							
3	6 mos.							
4	9 mos.							
5	12 mos.							

Quarter of Report (ending month/year): _____/_____

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

Cohort	Baseline						Follow-Up							
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.													
2	3 mos.													
3	6 mos.													
4	9 mos.													
5	12 mos.													

Summary of ALL Key Populations Client 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.							
2	3 mos.							
3	6 mos.							
4	9 mos.							
5	12 mos.							

Quarter of Report (ending month/year): _____/_____

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

General Population Clients

7. Serodiscordant Heterosexual Couples (SHC)

8. Coh	Baseline						Follow-Up							
	Original Cohort			# transfers in	# transfers out	# net current cohort (Col. 1+2-3)	At Current Follow-Up Visit			Cumulative for Cohort				
	Months ago started on PrEP	Calendar year/month started PrEP (yyyy/mm)	# started PrEP at this clinic				# received PrEP	# tested for HIV	# newly tested HIV+	# stopped: HIV+ test	# stopped: no longer at substantial risk	# stopped: other reason	# lost to follow-up	# died
			Col: 1	2	3	4	5	6	7	8	9	10	11	12
1	1 mo.													
2	3 mos.													
3	6 mos.													
4	9 mos.													
5	12 mos.													

Summary of SHC 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. 5 + Col. 7)] * 100	Percent testing HIV+ this visit [Col. 7/(Col. 5 + Col. 7)] * 100	Percent stopped: HIV+ [Col. 8/Col. 4] * 100	Percent no longer at substantial risk [Col. 9/Col. 4] * 100	Percent lost to follow-up [Col. 11/Col. 4] * 100
1	1 mo.							
2	3 mos.							
3	6 mos.							
4	9 mos.							
5	12 mos.							

Quarter of Report (ending month/year): _____/_____

