

TECHNICAL INSTRUCTIONS
PROGRAM MANAGEMENT
PRE-EXPOSITION PROPHYLAXIS
(PREP) ORAL FOR PEOPLE
HIGH RISK OF INFECTION
HIV IN INDONESIA

Indonesian Ministry of Health
Revised 2023



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HIV INFECTED
IN INDONESIA**

Ministry of Health of the Republic of Indonesia
Revised 2023

TECHNICAL INSTRUCTIONS FOR PROGRAM ADMINISTRATION
ORAL PRE-EXPOSITION PROPHYLAXIS (PREP) FOR
PEOPLE ARE AT HIGH RISK OF HIV INFECTION
IN INDONESIA

Indonesian Ministry of Health
Directorate General of Disease Prevention and Control
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Jakarta, 2023

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FOREWORD

We would like to express our gratitude to the presence of God Almighty, for His mercy and grace, the Technical Instructions for the Management of the Oral Pre-Exposure Prophylaxis (PrEP) Program for people at high risk of HIV infection in Indonesia have been completed. This technical guidance is a guide for the Provincial Health Service, District/City Health Service, PrEP provider services, communities and other parties who need it in providing pre-exposure prophylaxis (PrEP) therapy.

Pre-exposure prophylaxis (PrEP) has an important role in preventing HIV transmission, because it can reduce the risk of HIV transmission by more than 90% (WHO, 2017). Implementation of PrEP in Indonesia began at the end of 2021 in 7 Provinces and in 2023 was expanded to 10 Provinces which includes Community Health Centers, Clinics and Hospitals. PrEP service providers will be expanded in stages, hopefully making it easier for key populations to access PrEP provider services. Currently, the flow of PrEP management has been simplified with the hope that the coverage of PrEP users will increase. The implementation of PrEP is carried out in an integrated manner with the management of HIV and STIs and in its implementation cooperation between service providers and the community is very necessary.

We hope that this technical guidance can provide great benefits in efforts to prevent and control HIV/AIDS and become the basis for guidelines for implementing Pre-Exposure Prophylaxis (PrEP) therapy in health services in Indonesia.

Jakarta, October 2023

Director of Infectious Disease Prevention and Control,

Dr. dr. Maxi Rein Rondonuwu, DHSM., MARS

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LIST OF ABBREVIATIONS AND ACRONYMS

ART *Antiretroviral therapy*

ARV *Antiretroviral*

ATLM Medical Laboratory Technologist

Health **Facilities** Health Service Facilities

HIV *Human Immunodeficiency Virus*

IHA Acute HIV Infection

STIs Sexually Transmitted Infections

IO Opportunistic Infections

KIE Communication, Information and Education

KTS Counseling and Voluntary Tests

LASS Sterile Syringe Services

LSL Men who have sex with men

NGO Non-Governmental Organization

ODHIV People with HIV

OFT *Oral Fluid Test*

PDP Care, Support and Treatment

NCDs Non-Communicable Diseases

NAP National Action Plan

RPJMN National Medium Term Development Plan

SOP *Standard Operating Procedure*

STBP Integrated Biological and Behavioral Survey

TDF *Tenofovir Disoproxil Fumarate*

WHO *World Health Organization*

WPS Female Sex Workers

LIST TERM

3TC *Lamivudine*

Creatinine Clearance Creatinine clearance/kidney clearance rate (aim to determine the condition of kidney function)

Event-Driven ED, one method of using PrEP

FTC *Emtricitabine*

Immunosuppression Related to suppression of the body's immune system

Opportunistic infections Infections due to viruses, bacteria, fungi, or parasites that occur in people whose immune systems are weakened due to other causes.

HIV Risk Group: A group of people who engage in risky behavior for HIV infection, such as having unprotected sexual intercourse with more than one partner or sharing unsterile needles for drug use.

MSM men who have sexual relations with other men, with anal sexual behavior (receptive/diagonal or penetrative/anal), or behave bisexually (having sex with both men and women).

Partners of PLHIV Partners of People with HIV. Both married partners and/or sexual partners of PLHIV (Technical instructions for filling out the HIV AIDS and STI Control Program Recording and Reporting Form 2015).

Risky Partner (Risk High) Someone who has a high risk of being infected with HIV because having a partner who comes from a high risk group, such as:

- Female Partners of Sex Workers •
- Male Partners are at high risk
- Male Partners of Sex Workers
- MSM couples
- Transgender Couples
- Couples of IDUs

(Technical instructions for filling out the 2015 HIV AIDS and STI Control Program Recording and Reporting Form).

PWID who use injecting drugs.

PrEP users Individuals who are registered in the Indonesian PrEP program and are currently taking PrEP medication.

People-centered An approach that focuses on program goals

PPP Post-Exposure Prophylaxis (in English it is called *Post-exposure Prophylaxis*)

PrEP Pre-Exposure Prophylaxis (in English called *Pre-exposure Prophylaxis*)

Prevalence The proportion of a population that has a certain characteristic in a certain time period.

Regimen Composition of the type, amount and frequency of drug administration as treatment therapy or disease prevention.

TDF *Tenovofir*

Three Zero Targets for preventing HIV AIDS which are expected to be achieved by 2030 are *Zero New Infections* (no new HIV infections), *Zero AIDS Related Deaths* (no deaths due to AIDS), and *Zero Discriminations* (no stigma and discrimination for HIV AIDS sufferers)

Viral load The measure (in numbers) of the amount of virus detected in a person's blood

Waria/Transgender Individuals with a *gender* identity different from that stated at birth. In the PrEP program, transgender people who are advised to use PrEP are waria/transgender. Waria/transgender are individuals who were declared male at birth, but identify themselves as female (Permenkes no. 23 of 2022).

WPS Female Sex Workers

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INTRODUCTION



CHAPTER 1: INTRODUCTION

BACKGROUND

Efforts to control disease must be aligned with strategic prevention efforts so that maximum control can be achieved, including in treating HIV. In the 2020-2024 National Medium Term Development Plan (RPJMN), it is stated that the target for the incidence of new HIV infections in 2024 is 0.18 per 1,000 population, this figure has decreased from the 2018 target of 0.24 per 1,000 population. This is in line with the global target to end the HIV epidemic by 2030, known as *Three Zero*, which includes *Zero New Infections* as one of its main pillars.

Prevention of new HIV infections in Indonesia has been carried out in various ways. For groups at high risk of contracting HIV, outreach is carried out accompanied by the provision of IEC materials. The provision of this material is also followed by risk reduction efforts such as providing methadone maintenance therapy and sterile syringes to groups of injecting drug users (IDUs) or condoms for risky sexual relations.

Data from the 2018 Integrated Biological and Behavioral Survey (STBP) shows an increase in condom use among female sex workers (FSW) up to 67% from 31% in 2009. IDUs have also obtained sterile syringes from drug/health equipment stores by 37.6% and another 45.3% had obtained needles from the Service

Sterile Syringe (LASS) in health facilities. However, the achievements of this prevention program still have not met the specified targets. In addition, the behavior of using condoms in the last commercial sexual relationship among men who have sex with men (MSM) and waria/transgender tends to decrease.

In 2016, the *World Health Organization* (WHO) released the *Global Health Strategy on HIV 2016-2021* guidelines which asked all countries to accelerate their HIV control response followed by sustainable action until they reach the desired targets by 2030. This strategy also calls for implementing a consistent approach. focuses on program targets or *people-centered* (people-centered) based on human rights and health equality (*WHO: PrEP module for leaders, 2017*)

WHO also recommends preventative/prophylactic therapy using ARV drugs known as *Pre-Exposure Prophylaxis* (PrEP) or Pre-Exposure Prophylaxis as an addition to the comprehensive prevention efforts that have been underway to date. The results of PrEP implementation in several countries have shown a reduction in HIV rates. PrEP containing Tenofovir (TDF) or a combination of TDF and Emtricitabine (FTC) can prevent new HIV infections by up to 90% if taken consistently.

INTRODUCTION

TDF-based PrEP has also been proven to provide only mild side effects and usually disappears within the first few weeks of use and is safe for pregnant and breastfeeding women.

ARV resistance in PrEP users is not common. The risk of developing resistance occurs in approximately 1/1000 PrEP users who have undetected acute HIV infection when starting PrEP. Therefore, it is very important to carry out optimal HIV testing before starting PrEP (*WHO: PrEP module for leaders, 2017*).

Clinical testing that has been carried out shows that there has been no decrease in condom use or increase in the number of sexual partners among PrEP users (*WHO: PrEP module for leaders, 2017*). Therefore, the integration of PrEP and STI services needs to be strengthened.

PrEP does not aim to replace other methods of preventing HIV transmission. PrEP targets groups at high risk of HIV infection and therefore requires additional prevention. PrEP, which is provided in the form of a comprehensive HIV prevention package, also functions as a gateway to integrated sexual reproductive health services. PrEP can fill the gap in targeted services for routine HIV testing in high-risk groups, screening and treatment of STIs as well as HIV prevention services including condoms.

Community involvement *plays* an important role in HIV control programs, including the PrEP program. Having community involvement will really help the PrEP program in reaching high-risk groups who still have obstacles in accessing health services and vice versa can also convey the needs of this population to stakeholders or services (Castro,

2019). Communities can also address barriers that occur in services, for example acting as counselors and making referrals for PrEP.

The ARV drugs used in PrEP are relatively cheap, are given to high risk groups without HIV only during high risk or emergency periods (the time period for taking the drugs is shorter) and can prevent HIV events that would require care and treatment for Opportunistic Infections (IO) which is more expensive (WHO: *PrEP module for leaders*, 2017). It is therefore important for the government to invest in prevention programs such as PrEP which are more cost-effective compared to lifelong ARV treatment.

Prophylactic antiretroviral administration, including pre-exposure prophylaxis (PrEP), has been regulated in Minister of Health Regulation Number 23 of 2022.

In the tenth part, article 18 paragraph 1 explains that antiretroviral prophylaxis is given to people who are at risk of HIV, both to people who have been exposed to HIV (PPP) and those who have not been exposed to HIV (PrEP).

To support program implementation, technical instructions are needed that can be used as a reference in administering PrEP services. It is hoped that this Technical Manual for the Management of the Oral Pre-Exposure Prophylaxis (PrEP) Program for People at High Risk of HIV Infection in Indonesia can become a standard guideline for program implementation and be utilized by various parties and all stakeholders to support program implementation in both the community and health service areas.

OBJECTIVE

This technical guidance is intended for stakeholders related to the prevention and control of HIV, AIDS and STIs in Indonesia, especially in PrEP services. These parties include:

1 **Health worker**. Power health consists of doctors, nurses, lab officers, pharmacists and other clinical officers. The scope of work carried out includes providing and carrying out necessary tests before starting or while using PrEP, providing return visit services, and providing counseling services if needed such as adherence counseling. Services by health workers in the PrEP program are carried out in health facilities, such as hospitals, community health centers and private clinics that provide HIV services.

2 **NGOs**. Established institutions with HIV preventive purposes and focused control. Within NGOs, there are two group components involved in implementing the PrEP program in Indonesia:

- **Peer educators**. Peer educators can reach communities in an effective way and hopefully increase demand for and access to PrEP programs. Peer educators can use this technical guidance as a reference in providing relevant and accurate information to increase the knowledge and awareness of community members

INTRODUCTION

regarding services or the use of PrEP.

- **Counselor.** Counseling also helps PrEP users overcome problems related to side effects, compliance, behavior changes in risk and other issues such as drug use or gender-based violence, which can influence decisions and adherence to PrEP use.

Health, which consists of two components:

3Dinas

- **Policy makers and program managers.** The implementation of the PrEP program must of course be supported by policies both at the planning level and at the health facility level which is directly related to PrEP users. This technical guidance can provide information regarding the benefits and limitations that occur in the implementation of PrEP in relation to HIV prevention and control.

- **Monitoring and evaluation.**

This technical guidance can be used by parties who have an interest in monitoring and evaluating the implementation of HIV services in both prevention and treatment aspects. This technical guide provides information relating to recording and reporting systems, indicators and report formats that can be used at the health facility, district/district level.

city, provincial, national and global.

SCOPE

The PrEP Program Technical Instructions include:

PrEP services in Indonesia.

Base discusses the background to the implementation of the PrEP Program in Indonesia and the creation of technical instructions, the objectives of the technical instructions, the scope of the technical instructions, and policies regarding the PrEP program.

information about PrEP.

Discuss information you need to know about PrEP, namely the definition of PrEP, the purpose of providing PrEP, the effectiveness of PrEP, the goals of PrEP, the criteria for individuals who can be offered PrEP, the requirements for getting PrEP, the location of PrEP services, the drugs used in the PrEP Program in Indonesia, the rules for taking PrEP, the implementation model PrEP in Indonesia, as well as the differences between PrEP and PPP and ARV.

Implement the PrEP Program

Almost Indonesia. Contains explanations regarding the PrEP program flow, stopping PrEP, medical examinations and laboratory tests, handling PrEP in special situations, and the use of PrEP with conditions certain.

and PrEP Program

Monitoring and Evaluation. Includes an explanation of the indicators for achieving program implementation as well as the flow of program recording and reporting to ensure this program can run according to its objectives.

Manage PrEP Pharmacy and

Almost Logistics. Explains information related to pharmacy education for PrEP users such as prescribing medication when starting and returning PrEP visits (drug dispensing), storing PrEP medication, and compliance with PrEP users. Distribution and logistics requests for PrEP drugs will also be explained in this section.

POLICY

This Technical Instructions is prepared based on:

- Republic of Indonesia Law Number 17 of 2023 concerning Health.
- Kebijakan “*Global AIDS Strategy 2021-2026 – End Inequalities. End AIDS.*” Regarding the Prevention of HIV AIDS.
- Presidential Regulation of the Republic of Indonesia Number 76 of 2012 concerning the implementation of patents by the government for antiviral and antiretroviral drugs.
- Pedoman *Global Health Strategy on HIV 2016-2021.*
- *Technical Brief WHO, “Differentiated and Simplified Pre-exposure Prophylaxis for HIV Prevention”* tahun 2022.
- National Action Plan for Control of HIV and AIDS for 2020-2024.
- National Medium Term Development Plan (RPJMN) 2020-2024.
- Minister of Health Regulation Number 21 of 2020 concerning the Ministry's Strategic Plan Health 2020-2024.
- Minister of Health Regulation Number 23 of 2022 concerning *Human Management Immunodeficiency Virus, Acquired Immuno-Deficiency Syndrome, and Sexually Transmitted Incubation.*
- Minister of Health Regulation Number 64 of 2015 concerning Organization and Work Procedures of the Ministry of Health, Chapter V Directorate General of Disease Prevention and Control.
- Action Plan for the Directorate General of Disease Prevention and Control Program Ministry of Health 2020-2024.
- WHO recommendation regarding PrEP (*Pre-Exposure Prophylaxis*) as an additional HIV AIDS prevention effort in September 2015.
- Strengthening Regional Government in Health Development from the Ministry Domestic.



02

PROPHYLAXIS PRE-EXPOSURE (PrEP)



CHAPTER 2: PROPHYLAXIS

PRE-EXPOSURE (PREP)

ABOUT PREP

PrEP is the administration of antiretroviral drugs (ARV) which aims to prevent someone from becoming infected with HIV. PrEP should be offered as an additional prevention option for people at higher risk of HIV infection as part of a combination HIV prevention regimen (*WHO: PrEP module for PrEP Users, 2017*).

WHY PREP IS USED

If taken at the right dose, PrEP can reduce the risk of contracting HIV through sexual intercourse by more than 90%. It is hoped that the use of PrEP can break the chain of HIV transmission. In the long term, PrEP administration can also have an impact on reducing the incidence of morbidity and death due to HIV which can cause harm to individuals and society.

PREP GOALS

PrEP is provided by trained health workers through health facilities to the PrEP target group, which consists of:

a. Men who have sexual relations with other men
(LSL)*

b. Female Sex Workers (FSW)*

c. Waria/Transgender*

d. Injecting Drug Users (IDUs)*

e. PLHIV couples f.

High Risk Pairs (Risti)

*Is the risk target population prioritized in the PrEP program until 2026.

INDIVIDUAL CRITERIA THAT MAY BE OFFERED PREP

Individuals in the PrEP target group may be offered or advised to use PrEP if they have **one of the** following conditions:

a. Having more than one sexual partner

b. Not using condoms consistently

c. Having sexual intercourse through the anus (*anal sex*) without condom

PRE-EXPOSITION PROPHYLAXIS (PREP)

- d. There is a history of STIs in the last 3 months
- e. Have ever used PrEP
- f. Having an HIV positive partner with the following conditions (at least one):
 1. Have not undergone ARV treatment therapy,
 2. Irregular use of ARVs in the last 6 months,
 3. The amount of *viral load* is not yet known,
 4. *Viral load* is not suppressed (>1000 copies/mL) after ARV treatment for at least 6 months
 5. Plan to have children with an PLHIV partner whose *viral load* is detectable.

REQUIREMENTS FOR GETTING

PREP To obtain PrEP, target groups who meet the criteria must meet the following requirements:

1. Have HIV negative status based on test results with the applicable SOP in Indonesia
2. Indonesian citizen
3. Has no clinical signs of HIV infection acute

CRITERIA AND LOCATIONS FOR ACCESSING PREP

PrEP can be obtained at health facilities that provide PrEP that have been appointed based on the following criteria:

1. Has testing, PDP and STI services and prioritizes community health centers, private clinics and community-based clinics.
2. Have a network with NGOs that work in treating and controlling HIV and STIs.
3. Have a network for supporting laboratory examinations.
4. Have received capacity building (training, workshops,

orientation, OJT) regarding PrEP management.

5. Able to record and report.

A list of health facilities providing PrEP can be accessed at the following link:

<https://bit.ly/FasyankesPrEPIndonesia>

Or you can scan the QR code below:



TIME TO USE PREP

PrEP can be taken when someone has a high risk of HIV infection and can be stopped if the risk is low or non-existent, so PrEP does not need to be taken continuously like ARVs for treatment. However, the level of protection of PrEP to prevent HIV infection is highly correlated with adherence and needs to be used according to the instructions for use.

The more compliant a person is, the higher the level of protection they get from PrEP. Suboptimal compliance will provide less of the expected protective benefits.

REGIMENT PREP

The ARV drugs used in the PrEP program in Indonesia are TDF/FTC and TDF/3TC.

Table 2.1 ARV drugs for PrEP

Medicine name	Dose
<i>Tenofovir disoproxil fumarate (TDF) / Emtricitabine (FTC)</i>	300 mg TDF and 200 mg FTC
<i>Tenofovir disoproxil fumarate (TDF) / Lamivudine (3TC)</i>	300mg TDF and 300mg 3TC

METHOD OF USE

There are two methods of using PrEP, namely daily and event-driven (ED). The drinking regimen for using PrEP is differentiated based on population group, which will be explained in tables 2.2 and 2.3:

Table 2.2 Rules for Taking PrEP for Men and Waria/Transgender

Population	Method Usage	Starting Oral PrEP	Use Oral PrEP	Stop Oral PrEP
All individuals assigned male sex at birth, who: <ul style="list-style-type: none"> • Having risky sexual relations • Not in exogenous estradiol based hormone therapy 	Daily	Take 2 pills 2-24 hours before risky sexual relations (the closer to 24 hours before, the more ideal)	Take 1 pill every day	Take 1 pill daily until 2 days after risky sexual relations final
	Event-Driven (ED)		Take 1 pill daily until 2 days after the last risky sexual intercourse	

All individuals who were declared male at birth can use PrEP with two choices of use methods, namely daily PrEP and **Event-Driven (ED) PrEP**, including MSM, **male sex workers**, and **waria/transgender**.

The medication regimen for ED PrEP users is the same as for daily PrEP users for all male clients. The difference in these two methods of use lies in the length of time you take the medication. Clients with a high frequency of risky sexual intercourse are advised to use daily PrEP, while clients with a low frequency of risky sexual intercourse can use ED PrEP. As a general guideline, PrEP ED can be offered to individuals who engage in risky sexual intercourse on average once a week. This is intended so that individuals with a low frequency of sexual intercourse do not need to take medication every day like individuals who have more frequent risky sexual relations.

Meanwhile, all people who are at high risk of HIV infection with unpredictable sexual intercourse patterns/spontaneous and potential exposure to HIV more than once a week would recommend a daily PrEP method of use. PrEP consumption needs to continue when risky sexual behavior continues. The more frequently risky sexual behavior is performed, the longer the duration of PrEP use.

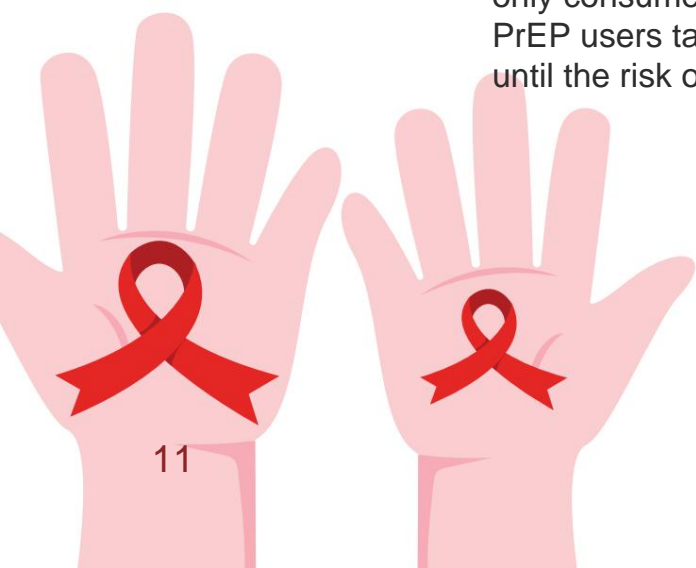
PRE-EXPOSITION PROPHYLAXIS (PREP)

A person using PrEP ED can change it to daily dose PrEP if sexual intercourse occurs more frequently (having sexual intercourse more than once a week), so the pills must continue to be taken every day to protect against HIV exposure. On the other hand, users of daily dose PrEP can change the dose to PrEP ED if the frequency of sexual intercourse decreases (having sexual intercourse a maximum of once a week), so that the risk of HIV exposure becomes lower. The decision to change the dose must be consulted with a health professional first, accompanied by a more objective assessment of risk factors.

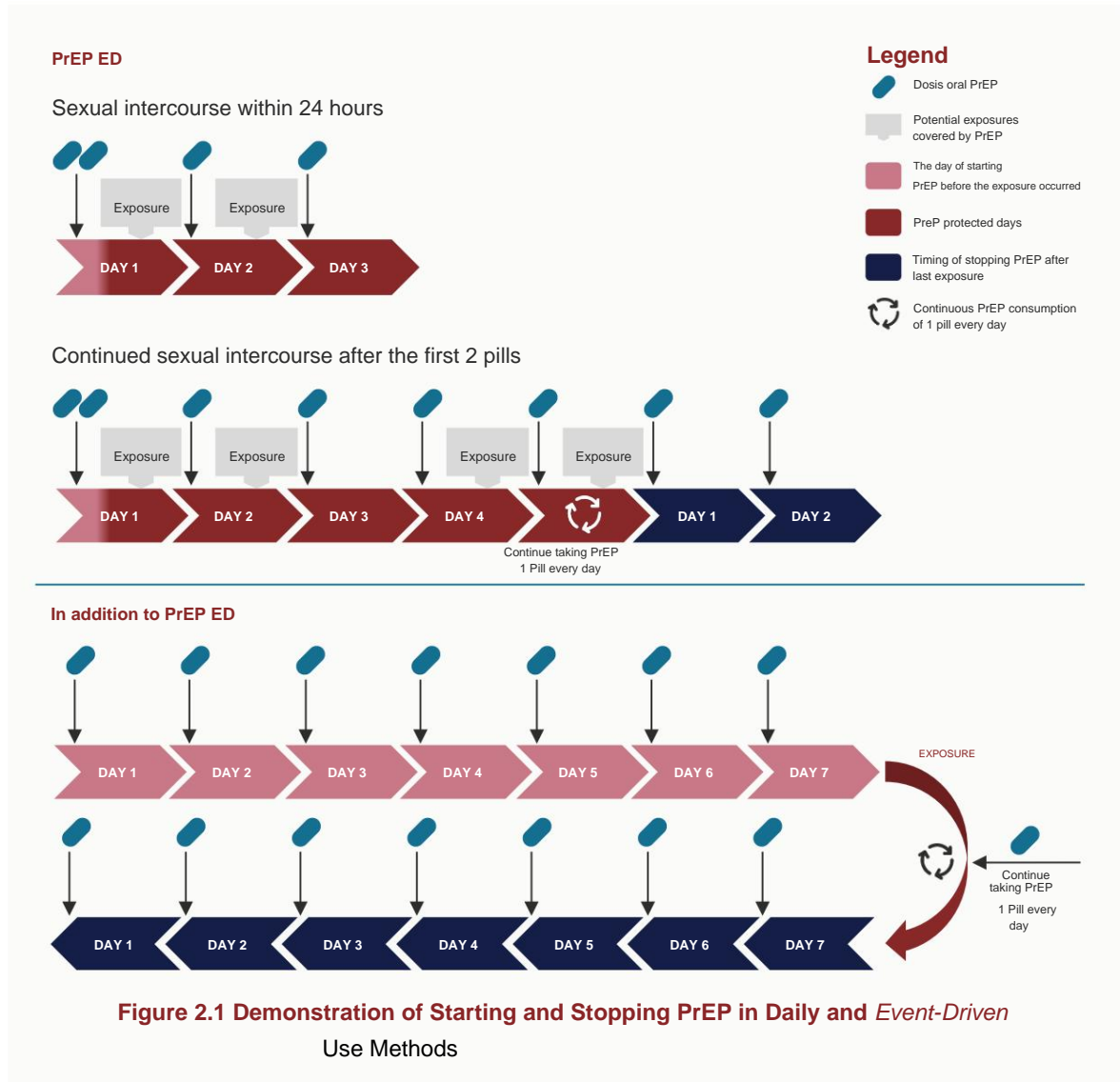
Table 2.3 Rules for Taking PrEP for Women, Men in Hormone Therapy and IDUs

Population	Method Usage	Starting Oral PrEP	Use Oral PrEP	Stop Oral PrEP
<ul style="list-style-type: none"> All individuals assigned female sex at birth All individuals assigned male sex at birth who are undergoing exogenous estradiol-based hormone therapy IDU 	Daily	Take 1 pill every day up to 7 days before risky sexual intercourse	Take 1 pill every day	Take 1 pill daily for up to 7 days after the last risky sexual intercourse

Table 2.3 explains the rules for taking PrEP for population groups consisting of individuals who were assigned female at birth, men who are undergoing hormone therapy, and IDUs. In contrast to the male population group as listed in table 2.2, the population group mentioned in table 2.3 can only consume PrEP using the **daily use method**. Daily PrEP users take the drug continuously without interruption until the risk of HIV exposure ends.



To differentiate the rules for taking daily and *Event-Driven* (ED) PrEP medication more easily, UNAIDS has created a demonstration of how to take PrEP medication in two different methods of use. Figure 2.1 will provide a demonstration of starting and stopping PrEP in both daily and ED use methods.



PREP IMPLEMENTATION MODEL IN INDONESIA

In its implementation, PrEP services are carried out by following the available technical instructions. The Indonesian PrEP program is focused on providing services in health facilities, but still with support and collaboration with the community. The process, stages and matters related to the process and stages are explained in the following model table for implementing PrEP in Indonesia:

PRE-EXPOSITION PROPHYLAXIS (PREP)

Table 2.4 PrEP Implementation Model in Indonesia

	Before Starting PrEP		Starting PrEP		PrEP continuation
	Promotion and Education	Testing & Counselling HIV	Visit First	Visit First Repeat	Visit Repeat
When (Frequency)	On HIV prevention promotion & education	Day 0	Day 1	1st month	3rd month and routinely every 3 months thereafter or incidentally
Where (Location)	Community, in the building (Fasyankes/PDP services), outside the building (<i>mobile</i>), web/applications/social media	Community, in the building (Fasyankes/PDP service), outside the building (<i>mobile</i>)	In the building (Fasyankes/PDP Services), outside the building (<i>mobile</i>)		
Who (Executor Service)	Community outreach workers/peer educators or HIV counselors	Outreach officer/peer educators in the community, health workers (doctors, nurses, lab workers, RR officers)	Health workers (doctors, nurses, lab staff, pharmacists, RR staff)	Health workers (doctors, nurses, lab workers, pharmacists, RR officers, HIV counselors/peer educator)	
What (Package Service)	Packet KIE regarding PrEP integrated with HIV prevention packages	Your HIV*	Willingness to start PrEP, counseling & education form usage PrEP, medication PrEP, test referral (optional)	Administering PrEP medication, checking for side effects, monitoring compliance, counseling usage PrEP, test referrals (STIs, Hep B, Hep C, Creatinine by criteria)	Your HIV, your IMS, tes Creatinine (with criteria), administering PrEP medication, checking for side effects, monitoring compliance with counseling use of PrEP.
How (Giving Service)	Campaigns on social media, through communities	Available at designated health facilities and included in the government program			

*This includes IHA examination and conclusion of HIV test results as well as counseling for PrEP education and exploring risk factors/risk behavior screening

From table 2.4 above, it can be explained that PrEP services can be provided both inside the building (at health facilities or PDP services) and outside the building (on a mobile basis). Mobile PrEP services can be integrated with the mobile KTS (Voluntary HIV Counseling and Testing) program while still following the procedures as carried out in health facilities or PDP services.

THE DIFFERENCE BETWEEN PrEP AND PPH (POST EXPOSURE PROPHYLAXIS) AND ARV

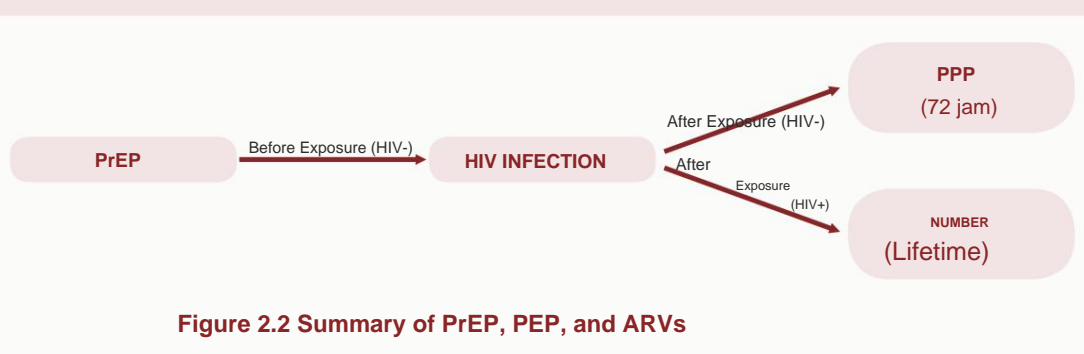
If PrEP is started to be used **before** someone has sexual intercourse at risk of HIV infection, then PPP (or PEP - *Post-Exposure Prophylaxis*) is given to someone who is indicated **to have been exposed/ exposed to HIV or has a condition that puts them at risk of HIV infection**. However, as with PrEP, individuals receiving PEP need to be confirmed to have negative HIV status

The following are several conditions that cause a person to be at risk or exposed to HIV and need to be advised or referred to PPP services, namely:

- After experiencing sexual violence, for example rape.
- Medical accidents that usually occur in health workers are when the blood, semen, vaginal fluid or breast milk of someone infected with HIV enters the health worker's bloodstream. For example, being accidentally pricked by a used syringe during an examination of someone infected with HIV.

PPP should be given as soon as possible within 72 hours or less, with the ideal time being 4 hours after exposure. PPP administration is given within 28-30 days to reduce the possibility of HIV infection after exposure.

Meanwhile, ARVs are used by someone who **has been diagnosed as HIV positive** through standard testing as treatment. ARVs need to be taken for life, in contrast to PPP and PrEP which are used based on certain conditions and can be stopped.



03

GOVERNANCE PROGRAM PREP IN INDONESIA



CHAPTER 3: PROCEDURE PROGRAM PREP INDONESIA

The services and implementation of the PrEP program in health facilities have certain pathways and procedures that need to be carried out in order to be standardized. PrEP services have been integrated with existing HIV and AIDS prevention programs. In this section we will discuss the flow of the PrEP program, how to use it and the rules for stopping using PrEP. During PrEP use, some people with certain conditions may experience situations that will impact their use of PrEP. Therefore, in this section

There will also be discussions regarding handling the use of PrEP in special situations, such as people who experience seroconversion (change in serological test results from HIV negative to HIV positive) when using PrEP, handling side effects, and handling creatinine clearance. The use of PrEP in pregnant women, someone undergoing methadone maintenance therapy, someone using hormone therapy, and information regarding changing PrEP services will also be discussed in the sub-topic of using PrEP with certain conditions.

PREP PROGRAM FLOW

Briefly, the flow of the PrEP program can be seen in Figure 3.1.

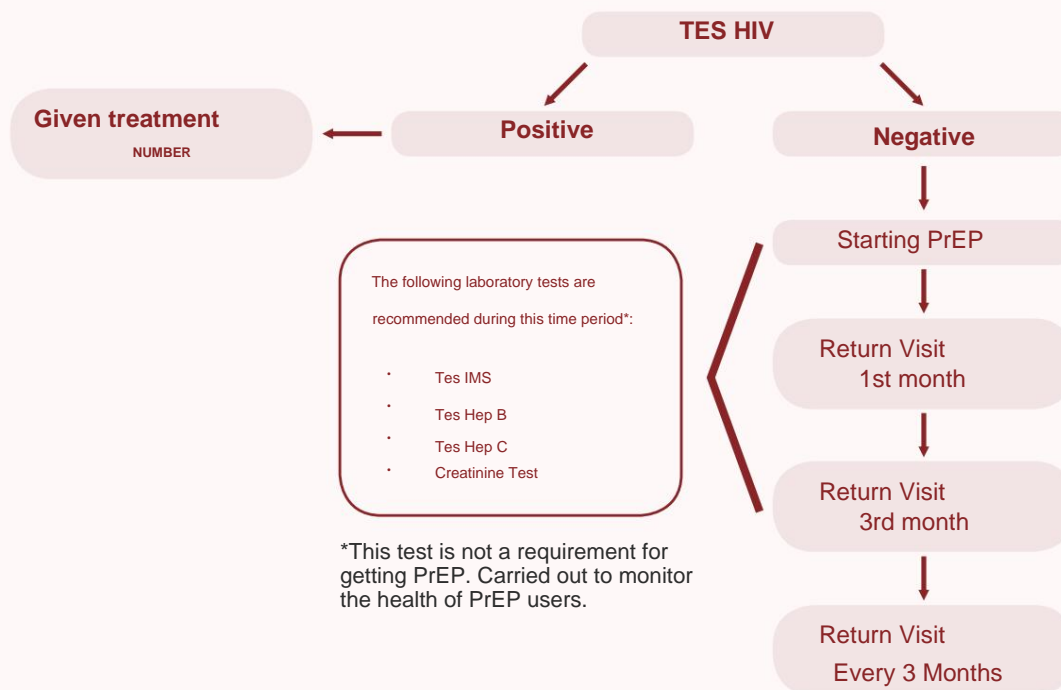


Figure 3.1 PrEP Program Flow

The following is an explanation of the PrEP program flow.

HIV testing

PrEP is intended for someone who is HIV negative but has a high risk of infection as an additional form of prevention effort.

Therefore, optimal HIV testing needs to be carried out to confirm the status concerned. This is also to ensure that resistance to ARVs does not occur if it turns out that PrEP users start using PrEP while having HIV positive status, and use a method of using PrEP that can be started and stopped.

PrEP is offered to high-risk groups who undergo HIV testing at health facilities with negative results. Therefore, health workers/counselors need to start discussing PrEP before an HIV test is carried out. Health workers need to screen for risk behavior, possible exposure to HIV, and the presence of physical symptoms that have appeared in the last 3 days that could lead to acute HIV infection (IHA). Then, carry out an HIV test according to current national procedures. If the test result is positive, refer to PDP services to start ARV use.

The conditions for HIV test results to be accepted for starting PrEP are as follows:

1 HIV test is carried out at a health facility PrEP provider

- a. HIV testing needs to be done at a health facility if it has a *sameday* HIV testing service (results come out on the same day), and
- b. Recording of test results is carried out directly (*real time*) on the day the test results come out.

2 HIV testing is done outside health facilities providing PrEP

- a. Acceptable HIV testing locations must be clinical laboratories or public health laboratories.
- b. HIV test results are given in physical/printed form.
- c. The test results are valid within 14 days from the time of sampling, prospective PrEP users have no risk behavior, and there is no indication of IHA based on the doctor's assessment.
- d. Test results from outside PrEP provider health facilities can be accepted without retesting if the health facility does not have same-day HIV testing services or it is not possible to issue HIV test results on the same day. If an HIV test can be carried out at the health facility with same day results, then the HIV test results from outside the health facility are not valid.

HIV tests performed at health facilities providing PrEP are reported in the HIV test report (SIHA) as the HIV testing coverage of that health facility. For tests carried out outside the PrEP provider health facility, it will be reported as HIV test coverage at the health facility where the test was carried out and the PrEP provider health facility being accessed. To overcome differences in recording and reporting related to test logistics and test results at health facilities providing PrEP, health workers need to make adjustments at the end of the month or the end of the recording period.

In the current technical instructions for the PrEP program, there is a simplification or streamlining of the PrEP program flow at the screening stage. Previously on

The PrEP Pilot Program carried out two screening activities, namely risk behavior screening and medical screening, both of which were carried out separately.

In the current technical guidelines, risk behavior screening activities are integrated into HIV testing counseling and are no longer a separate activity.

Starting PrEP

After the HIV test results are declared negative, prospective PrEP users can proceed to the stage of starting PrEP.

Stages of starting PrEP include:

- Filling in initial data for prospective PrEP users by health workers at health facilities providing PrEP
- PrEP education and counseling
- Screening for indications of acute HIV infection (IHA)
- Ask about willingness and use of PrEP agreement
- Data collection on risk factors
- Determining the method of use of PrEP
- Referral for supporting laboratory tests

The initial data that health workers will ask potential users for is name, telephone number, NIK, date of birth, gender according to KTP, risk group, HIV test results, and PrEP offered by health workers at health facilities.

Information points for education about PrEP that will be delivered to prospective PrEP users can be seen in table 3.1. A more complete explanation of these points can be seen in attachment 2 "KIE package" in this technical guide.

Table 3.1 Information Points for Counseling and Education regarding PrEP

Basic PrEP Information
<ul style="list-style-type: none"> • Understanding PrEP • PrEP goals and criteria for PrEP users • Effectiveness of PrEP • Rules for taking PrEP • PrEP and its relationship to STIs • The importance of continuing to use condoms to prevent transmission of HIV and STIs • Risk of PrEP side effects • Follow-up procedures in the PrEP program (repeat visits), routine HIV and STI testing.

PREP PROGRAM ADMINISTRATION IN INDONESIA

Before starting PrEP, the doctor will ask about possible indications of acute HIV infection (IHA). IHA is the initial stage of HIV infection, when the virus has just entered a person's body. Signs of IHA usually appear not long after someone engages in risky behavior with other people infected with HIV. This can last up to 14 days after exposure to HIV. The presence of IHA can be seen from the symptoms below:

- a. Demam
- b. Feeling easily and constantly tired
- c. Swollen lymph nodes
- d. Swelling of the tonsils or tonsils
- e. Sore throat
- f. Muscle and joint pain
- g. Diarrhea
- h. The appearance of a rash

Doctors can ask the following 2 questions to see indications for IHA in prospective PrEP users.

1. In the last 3 days, have you had unprotected sexual intercourse with an HIV-infected person who is not on treatment?
2. In the last 3 days, have you had a fever, felt easily and constantly tired, swollen glands, swollen tonsils, sore throat, muscle and joint pain, diarrhea, or a rash?

If you answer "No" to 2 questions, the prospective user does not have an indication of IHA and can be given PrEP.

If you answer "Yes" and "Don't know" to one or both of these questions, the prospective user is classified as having an indication of IHA.

If a prospective PrEP user has an indication for IHA, advise the person to undergo another HIV test after 14 days. The person will be able to use PrEP if the most recent HIV test result remains negative and there is no IHA.

For prospective PrEP users who do not have an indication for IHA, doctors can continue offering PrEP by asking about their willingness to use PrEP. If willing and agreeing, prospective PrEP users can give verbal consent. For prospective users who are under 18 years of age, consent can be given by the introducer. This is in line with procedures



granting consent to HIV testing for individuals from at-risk population groups aged under 18 years. After the prospective user agrees to use PrEP, the doctor will conduct a consultation to determine the method of use that will be used by the PrEP user.

Doctors will collect data regarding risk factors for PrEP users. This data will be used to monitor risk factors for PrEP users in subsequent counseling sessions. The data that will be asked for is:

- Type of sexual intercourse performed (through the anus, vagina, or both)
- Number of sexual partners (both male and female)
- Frequency of sexual intercourse in 1 week
- Consistent or regular use of condoms
- Use of condoms during last sexual intercourse
- Having a sexual partner with HIV positive status, and not using condoms consistently when having sexual relations with that partner or (in women) planning to become pregnant

At this meeting, the doctor can give a referral to the PrEP user to carry out other laboratory tests such as STI, hepatitis B, hepatitis C and creatinine examinations according to the provisions or conditions of the PrEP user. If these laboratory tests were not performed at the start of PrEP, recommend that PrEP users have them performed at the next return visit, between the 1st month and 3rd month return visits.

Furthermore, PrEP users can ask for medication from the pharmacy according to the drug prescription based on the method of using PrEP that has been agreed with the doctor.

Notes on STI screening when starting PrEP:

STI testing can be done directly when someone starts PrEP at a health facility that provides PrEP. The type of STI examination depends on the STI examination resources available at the health facility. However, to start PrEP there is no need to wait for the STI test results to come back.

The results of STI examinations carried out outside the PrEP provider health facility can be accepted on condition that:

- STI test results that came out within the last 1 month,
- Acceptable test locations must be clinical laboratories or public health laboratories, and examination results are provided in physical/
- printed form.

Return Visit

The follow-up procedure that PrEP users need to do after starting to use PrEP is a repeat visit. At the return visit, PrEP users should undergo:

- Screen for PrEP side effects
- Medical and laboratory examinations
- Compliance monitoring
- Counseling in the PrEP program

There are 2 types of return visits, namely routine return visits and incidental return visits. Routine re-visits consist of routine re-visits in the 1st month, 3rd month and every 3 months thereafter. PrEP users will be scheduled for regular follow-up visits by a health professional. Incidental return visits are visits outside the routine return visit schedule. If a PrEP user experiences problems such as side effects or a PrEP user using the ED method runs out of medication, he or she can make an incidental visit to a health facility providing PrEP.

In detail, what is done during a return visit is as follows.

Monitoring drug side effects.

- 1 PrEP users may experience side effects in the first month of PrEP use. Side effects need to be managed properly because they can affect compliance, effectiveness and continuity of PrEP use, so they need to be identified as soon as possible and the symptoms treated. The following are examples of side effects that PrEP users may experience along with codes for filling in the recording and reporting form.

Table 3.2 PrEP Side Effect Codes

PrEP Side Effect Codes
GI (nausea, diarrhea, stomach pain, vomiting)
Skin (rashes, <i>allergic/oversensitive reactions</i>) <i>Peripheral neuropathy</i> (burning/numbness/tingling)
CNS (dizziness, anxiety, nightmares, depression, seizures) <i>Hepatic dysfunction</i> (jaundice) <i>Haematological</i> (anemia, neutropenia) <i>Fatigue</i> (weakness) <i>Headache</i> _
<i>Bone dysfunction</i> (fraktur, osteopenia)
<i>Metabolic</i> (changes in body fat, hyperglycemia, dyslipidemia)
<i>Kidney dysfunction</i> (nephrolithiasis, renal system incompatibility)

2 Medical Examination and

Laboratory.

Inspection medical and laboratory tests carried out during PrEP return visits are HIV tests, STI tests, and other laboratory tests.

- **HIV testing.** HIV testing must be carried out at the 3rd month return visit and every 3 months thereafter using standard tests available at health facilities. If the ^{Which} test results are negative, the PrEP user can continue using PrEP.

If the HIV test result is positive, PrEP should be stopped and referred immediately for ARV treatment.

- **STI testing.** STI screening and treatment is important during PrEP use, although the results do not determine a person's participation in using PrEP. STI testing should be done every 3 months for

routine health monitoring in PrEP users as a key population group vulnerable to STIs. PrEP users who are detected as having an STI can continue to use PrEP simultaneously with STI treatment.

STI testing can be done based on a syndrome approach and simple laboratory tests, such as syphilis and gonorrhea. The type of STI test carried out is adjusted to the resources or availability of STI examinations at the health facility. If the test result is positive, provide treatment in accordance with the IMS technical instructions, or refer to a health facility that has IMS services. The number of STI tests carried out for the PrEP program can be recorded as the number of tests achieved by the health facility.

- **Other laboratory tests.** Other laboratory tests performed in the PrEP program are Hepatitis B, Hepatitis C, and Creatinine tests. This test is carried out according to the condition of the PrEP user. These tests can be performed between the start of PrEP and the 3rd month visit. A more complete explanation of the provisions of this test will be explained in the "Laboratory Tests" section.

obedience.

Monitoring
3Monitoring Compliance with PrEP users who use daily doses or *Event-Driven* (ED), is done by asking how they usually take PrEP medication.

PrEP users. Health workers can provide an adherence assessment based on the PrEP user's honest answers with a rating of "Compliant" or "Not Adherent".

Adherent PrEP users are PrEP users who take PrEP medication with the right number of pills and the right time to take them according to the instructions for use. Non-adherent PrEP users are PrEP users who take PrEP medication incorrectly and do not comply with the rules for use, in terms of the number of pills and when to take them.

The policy regarding remaining medication brought by PrEP users during return visits is left to the policy of each PrEP provider's health facility working area. Further explanation regarding drug logistics can be seen in the chapter "Pharmacy Governance and PrEP Logistics"

PrEP. PrEP in
4Counseling in the program program counseling aims to evaluate the use of PrEP that has been carried out, and plan future use of PrEP.

The counseling provided in this program can take the form of risk counseling, behavior reduction of compliance counseling. or Counseling is very useful in providing support for PrEP users to continue using PrEP, reduce risk behavior, and maintain or improve compliance.

The counseling process can be directed to determine whether the user The PrEP will continue stopping or using

using PrEP.. If after counseling it is decided to continue PrEP, the PrEP user will be prescribed medication by a doctor according to the provisions taking into account the frequency of sexual relations of the PrEP user.

For daily regimen PrEP users, at the 1st month return visit they will be prescribed 2 bottles of medication to be consumed until the 3rd month return visit. Furthermore, at the 3rd month and every three months follow-up visit you will get 3 bottles for use for 3 months until the next visit.

For users of the PrEP ED regimen, 1 bottle of medication will be prescribed at each repeat visit.

Data obtained during repeat visits are recorded and reported using the Revisit Form according to the instructions. Filling out the form is carried out by the health worker responsible for the health facility.

STOP PREP

PrEP is an additional HIV prevention effort for individuals who are at high risk of becoming infected with HIV due to their risky behavior. A person can stop using PrEP if the person no longer engages in risky behavior. Apart from these reasons, PrEP users may stop for the following reasons

This.

Table 3.3 Reason Code for Stopping PrEP

Reason Code for Stopping PrEP	
1 =	Intractable and bothersome side effects of the PrEP regimen
2 =	Positive HIV test result (seroconversion)
3 =	Severe illness, hospital treatment
4 =	Out of stock of medicine
5 =	PrEP users experience financial problems
6 =	Feeling no longer at risk of infection HIV
7 =	Switching PrEP services/programs
8 =	Other: _____



Please remember, to stop using PrEP a person needs to implement a stop dose regimen. The stopping dose can be seen in the rules for taking PrEP in Chapter 2 in the "Method of Use" section. A person who has stopped using PrEP can restart according to applicable procedures. Taking PrEP again after stopping will not cause the body to become resistant to PrEP drugs or cause the effectiveness of PrEP drugs to decrease when returning to using PrEP.

For consideration: The WHO guidelines do not make recommendations about when PrEP users should consider stopping PrEP or what procedures PrEP users who have considered stopping should need to restart.

In the PrEP program in Indonesia, a PrEP user can start using PrEP again by repeating the process and ensuring that the conditions for using PrEP are met.

LABORATORY TEST

PrEP users will carry out several supporting laboratory tests which aim to provide data for monitoring the PrEP user's health condition while using PrEP. The only laboratory test that is mandatory and a prerequisite for accessing PrEP is an HIV test. STI testing is recommended to be carried out at the same time as HIV testing which is carried out every 3 months. Supporting laboratory tests, such as Hepatitis B, Hepatitis C and creatinine tests, are not a requirement for accessing PrEP. If the test has not been carried out or the results have not come back, potential users can still access PrEP. Supporting laboratory tests can be performed at the time of starting PrEP until the 3rd month routine follow-up visit.

Table 3.4 Provisions for Medical Examination and Supporting Laboratory Tests

No	Inspection Medical	Nature of Current Tests Starting PrEP	Information
1	Your HIV	Must. Prerequisites for obtaining PrEP	All PrEP users must be HIV negative. Done every 3 months.
2	Tes IMS	Recommended. It is not a requirement to get PrEP	STI testing is done at the same time as HIV testing. The type of STI test is adjusted to the STI examination resources available at the health facility. Done every 3 months.
3	Hepatitis B	Not a requirement to get PrEP	Hepatitis B is not a contraindication for PrEP. All individuals can get PrEP.
4	Hepatitis C	Not a requirement to get PrEP	Hepatitis C is not a contraindication for PrEP. All individuals can get PrEP.
5	Creatinine Tests	According to the criteria. Not a requirement to get PrEP	There are several specific criteria for when a creatinine test needs to be done, but all clients can start PrEP without waiting for the creatinine test results to come back.

Table 3.5 Explanation of Hepatitis B & Hepatitis C Tests

Population	Tes Hepatitis B	
	When starting	During a return visit
All candidates users PrEP	<ul style="list-style-type: none"> • Recommendations. Can be done at a follow-up visit 1 – 3 months after starting PrEP. • Not a prerequisite in starting PrEP (both daily and <i>Event-Driven regimens</i>). • If the results show positive for Hepatitis B, treatment can still be given at the same time as PrEP. • If the results show negative, it is recommended to get the HBV vaccine. 	<ul style="list-style-type: none"> • If it hasn't been done by now starting PrEP, then the test can be carried out according to the health facility's capabilities. • If it has been done, <i>follow-up</i> on subsequent visits is optional/choice.
	Hepatitis C test	
	When starting	During a return visit
	<ul style="list-style-type: none"> • Recommendations. Can be done at a follow-up visit 1 – 3 months after starting PrEP. • Not a prerequisite in starting PrEP (both daily and <i>Event-Driven regimens</i>). • If the results show positive for Hepatitis C, treatment can still be given at the same time as PrEP. 	<ul style="list-style-type: none"> • If it hasn't been done by now starting PrEP, then the test can be carried out according to the health facility's capabilities. • If done, <i>follow-up</i> is carried out every 12 months after the last test.

Table 3.6 Explanation of the Creatinine Test

Population	Creatinine Test	
	When starting	During a return visit
Individuals aged < 30 years and do not have kidney-related comorbidities	Optional.	<ul style="list-style-type: none"> • Do so if not already done when starting PrEP; If it has been done and the results are normal, follow-up at subsequent visits is optional. • If initial test results show a slight decrease in kidney function, it is recommended to have a check every 6-12 months.
Individuals aged 30-49 years and have no kidney-related comorbidities	Only do it once, at the follow-up visit 1 – 3 months after starting PrEP.	<ul style="list-style-type: none"> • If the initial test results are normal, <i>follow-up</i> at subsequent visits is optional. • If initial test results show a slight decrease in kidney function, it is recommended to have a check every 6-12 months.

Population	Creatinine Test	
	When starting	During a return visit
<ul style="list-style-type: none"> Individuals aged 50+ years and has no kidney-related comorbidities Individuals of any age with kidney-related comorbidities Individuals with initial kidney function test results that show a slight decrease in kidney function 	<p>Only do it once, at the return visit 1 – 3 months after starting PrEP.</p>	<p>Creatinine tests are performed every 6-12 months.</p>

PREP MANAGEMENT IN SPECIAL SITUATIONS

This section will explain PrEP management in certain situations, namely changes in HIV status (seroconversion), handling side effects, and managing creatinine clearance.

Change in HIV Status (Seroconversion)

This section will explain PrEP management in certain situations, namely changes in HIV status (seroconversion), management of side effects, and management of creatinine clearance:

- Confirm HIV test results in accordance with the nationally applicable HIV testing algorithm.
- Refer immediately for HIV drug resistance testing.
- Immediately direct PrEP users to start ARV therapy (according to national ARV guidelines).
- Document seroconversion and possible causes of seroconversion (non-adherence, stopping PrEP, or PrEP failure, i.e. presence of HIV infection while adhering to PrEP).

Handling Side Effects

- Side effects should be grouped based on the degree of side effect, namely mild, moderate or severe. Handling actions can refer to Minister of Health Regulation No. 23 of 2022 which has been published by the Indonesian Ministry of Health.
- In general, side effects with mild symptoms are relatively common and self-limiting and often do not require discontinuation of PrEP. Mild side effects that may occur include nausea and/or vomiting, diarrhea and/or flatulence, dizziness, headaches, and weight loss. Side effects must be treated by providing counseling and providing treatment based on symptoms.

- Severe side effects such as major toxicities, including renal toxicity and metabolic complications, associated with TDF/FTC have been rare in PrEP users to date. Stop taking PrEP and consult the PrEP user with a specialist in internal medicine if serious side effects occur. • Every side effect must be recorded in the medical record regardless of severity.
- After completion of the assessment, it can be decided whether the PrEP user will continue or discontinue PrEP.

Treatment of Creatinine Clearance

Very few individuals experience a decrease in creatinine clearance following PrEP use. Approximately 80 percent of increases in serum creatinine are *self-limiting* caused by dehydration, exercise, diet, diabetes mellitus, hypertension, liver failure, hepatitis C virus, or possibly false positive test results. Treatment for increased creatinine can be managed without stopping PrEP use.

Impaired renal function, as indicated by eGFR <60 mL/min per 1.73 m² or estimated creatinine clearance <60 mL/minutes, is a contraindication to the use of TDF-based oral PrEP.

Health workers should pay attention to kidney function in PrEP users who are over 30 years old or who have kidney-related comorbidities by measuring kidney function when starting and while taking PrEP (see table 3.6).

Before stopping PrEP due to decreased kidney function, the creatinine test should be repeated on another day, for example 1 – 2 days later with a different sample. Kidney function usually returns to normal after stopping PrEP. Other HIV prevention options should be discussed with the client when stopping PrEP. PrEP can be restarted if eGFR is confirmed ≥ 60 mL/min per 1.73 m² (or creatinine clearance ≥ 60 mL/min) and HIV testing is negative within one to three months after stopping PrEP.

If kidney function does not return to normal after stopping PrEP, other possible causes of kidney disorders should be evaluated and immediate referral to a specialist in internal medicine.

USE OF PREP UNDER CERTAIN CONDITIONS

PrEP can still be used by someone with certain conditions, such as women who are pregnant and breastfeeding, someone who is undergoing methadone therapy, or if the PrEP user wants to move PrEP access to a health facility providing PrEP in another area.

The following is an explanation of these conditions.

Pregnancy and Breastfeeding

Based on research conducted on women regarding their pregnancy and breastfeeding status, it is known that the use of PrEP for pregnant women is considered convincing in reducing the risk of HIV infection, and the benefits obtained from consuming PrEP are greater than the risks that must be accepted (WHO, 2017) . According to WHO, use

PrEP does not need to be stopped if a woman is identified as pregnant or should breastfeed after giving birth. PrEP can be considered as part of a safe pregnancy planning package for women who are at high risk of HIV infection, for example for women whose partners are HIV positive.

The choice to start, continue, or stop PrEP when a woman is pregnant should be made by the woman herself, followed by a discussion with a health professional about the risks and benefits.

Methadone Maintenance Therapy

The use of PrEP drugs in combination with FTC/TDF has no contraindications with methadone drugs. Methadone is contraindicated with ARV drugs containing nevirapine or efavirenz. Therefore, it can be said that the PrEP drug with the FTC/TDF combination used in the Indonesian PrEP program currently will not cause side effects and is safe to use for someone who is undergoing methadone therapy.

Hormone Therapy in Transgenders

PrEP does not affect or interact with hormone therapy that is being carried out, usually in transgender people, whether transwomen or transmen. PrEP guidelines in the UK and America state that there are no known interactions between PrEP and drugs for hormone therapy in transgender people. This is also reinforced by studies regarding the interaction of hormonal drugs for transgender people (estradiol or testosterone) with PrEP

showed that daily use of oral PrEP (FTC/TDF) did not affect estradiol concentrations in transwomen or testosterone concentrations (free or total) in transmen (Grant et al., 2021).

Switching Services

PrEP users are allowed to change PrEP access to another health facility that also provides PrEP services.

When switching services, PrEP users need to include the NIK or temporary NIK obtained when starting PrEP at the previous health facility. There is no process of transferring data from previously accessed health facilities to the health facilities that will be accessed because the data is recorded digitally and can be seen by all health facilities providing PrEP.



04

MONITORING AND EVALUATION PROGRAM PREP



CHAPTER 4: MONITORING AND EVALUATION PROGRAM PREP

Regular monitoring (*monitoring*) of the PrEP program needs to be carried out to assess program uptake, effective use and safety, as well as to estimate demand and to ensure the necessary logistical supplies are sufficient and uninterrupted. As health services offering PrEP develop, surveillance, monitoring and reporting systems need to be implemented alongside PrEP services, and progress evaluated regularly. Monitoring and evaluation will ensure that the PrEP program is delivered safely and effectively, focuses on those who need it most, and achieves maximum impact through strategies to empower available resources.

PrEP programs can be integrated into existing HIV services and reporting systems. This is useful for connecting and integrating services to make it easier for people to benefit from the PrEP program. To improve program performance, data must be analyzed and the results used to provide information and direction on program strategy. Monitoring and reporting strategies should also maximize data quality and minimize the burden on health workers in collecting and reporting data.

Indonesia has currently implemented a reporting system for HIV, namely SIHA (HIV and AIDS Information System), and PrEP recording will be integrated into it. Recording of the PrEP program will start from HIV test results from health facilities and recording of starting PrEP to regular return visits over several months of PrEP use.

PREP PROGRAM EVALUATION INDICATORS

The goals of monitoring and evaluating a PrEP program will include increasing PrEP coverage among target populations, setting program targets, identifying clinical or structural areas for service improvement, and evaluating the program and its impact. PrEP program evaluation indicators can be seen in table 4.1.

Table 4.1 PrEP Program Evaluation Indicators among Service Providers

No	Indicator	Operational definition	Level	Data source
1	The number of people in the risk group who have a negative HIV test result	Number of people in the target risk group PrEP does the test HIV negative results and eligible to use PrEP within a certain period*	health facilities, District/City, Province, National	SIHA report (test report HIV at the level of services provided PrEP)
2	Number of people offered PrEP	Number of people in the target risk group PrEP who received a PrEP offer at a health facility within a certain period*	health facilities, District/City, Province, National	SIHA report, Recording report PrEP
3	Number of people using PrEP	Number of people in the target PrEP risk group who used PrEP in a given period*	health facilities, District/City, Province, National	SIHA report, Recording report PrEP

* The reporting period can be determined per month, per 3 months, per 6 months or per year.



Monitoring and Evaluation of PrEP Programs at the Community Level

PrEP program evaluation indicators are also created at the community level so that they can complete the picture of PrEP program data that can be used in the monitoring and evaluation process of the PrEP program.

Table 4.2 Indicators for Evaluation of PrEP Programs at the Community Level

No Indicator	Operational definition	Level	Data source	
1	Amount people reached and given PrEP information	Number of key PrEP target populations reached and provided with information PrEP (according to IEC in technical guidelines) personally	IU, SSR, SR, PR NGO implementing outreach/assistance	<i>Outreach report</i> (information system of each community)
2	The number of people given the information PrEP and offered PrEP	Number of key PrEP target populations offered Verbal PrEP in community outreach areas	IU, SSR, SR, PR NGO implementing outreach/assistance	<i>Outreach report</i> (information system of each community)
3	Number of people referred to come to health facilities	Number of key PrEP target populations who are referred and come to health facilities	IU, SSR, SR, PR NGO implementing outreach/assistance	Referral card/ letter verified by health personnel

PREP PROGRAM RECORDING AND REPORTING

Recording and reporting of the PrEP program will be carried out using the PrEP online form integrated into SIHA.

There are 2 different types of data recording and reporting, namely recording and reporting at the health facility level; as well as recording and reporting at district/city, provincial and national levels.

Health Facility Level In accordance with the explanation of the PrEP program management flow in the previous chapter, PrEP registration in health facilities will begin when risk groups with negative HIV test results access PrEP at the service. Recording begins by filling in the requested data on the PrEP start form which will be available online in the SIHA application.

Table 4.3 Health Facility Level Report

No	Indicator	Program Stages PrEP	Form PrEP used	Registrar Officer
1	Indicator 1: The number of people in the risk group who have a negative HIV test result	Your HIV	Test Form HIV/SIHA	Peer Counselor/ HIV Counselor/ Doctor/ Nurse/Officer Pharmacy/RR Officer
2	Indicator 2: Number of people offered PrEP	PrEP Offers	PrEP form/ FITNESS	Peer Counselor/ HIV Counselor/ Doctor/ Nurse/Officer Pharmacy/RR Officer
3	Indicator 3: Number of people using PrEP	Starting PrEP	PrEP form/ FITNESS	Peer Counselor/ HIV Counselor/ Doctor/ Nurse/Officer Pharmacy/RR Officer

Regency/City, Provincial and National levels

PrEP program recording and reporting at district/ city, provincial and national levels will be taken from the PrEP program recording and reporting database carried out by health facilities in regions according to the level of need (district/city, provincial or national).

Table 4.4 Health Facility Level Report

No	Report Program	Kurun Time	Data source	Indicator
1	Report Quarterly	3 months	HIV Test Report & PrEP (DRY)	<ul style="list-style-type: none"> Number of people in the risk group who tested negative for HIV Number of people offered PrEP Number using PrEP
2	Report Yearly	12 months	HIV Test Report & PrEP (DRY)	

Calculation of the Number of PrEP Users

The number of PrEP users will be calculated per year per name and not based on the number of visits to health facilities.

If a PrEP user continues their access to PrEP at a service that provides PrEP in the following year, then the person concerned will be counted again in that year.

PrEP users will be recorded and declared to have stopped PrEP under the following conditions:

- Tell health workers at the health facility to stop PrEP, or
- For PrEP users with the daily use method: do not arrive more than 1 month after the scheduled return visit determined by the health worker.

PrEP FORM

The PrEP form is used as a recording and reporting tool for the PrEP program. The data recorded in this form can be used and utilized at any level (health facility level as well as district/city, provincial and national levels) as monitoring and evaluation material.

The PrEP form can be seen in attachment 1 or the following link https://bit.ly/PrEP_Formulir



05

GOVERNANCE PHARMACY AND LOGISTICS PREP



CHAPTER 5: GOVERNANCE PHARMACY AND LOGISTICS PREP

PHARMACY EDUCATION FOR PREP USERS

Drug Dispensing

Prescribing PrEP medication is very dependent on the PrEP client's arrival schedule. For example, a service may prescribe a one-month supply at the first visit and then a two-month supply at subsequent visits. If visits to the PrEP provider are planned every three months, then health workers can advise PrEP users to come to the service a few days earlier than the regularly scheduled follow-up visit to avoid the user running out of medication.

Table 5.1 Drug Supply for PrEP Users

Method Usage	Start PrEP (Month 0)	Dispensing Medication on a Schedule				
		Regular Revisit after starting PrEP				
		1st month	3rd month	6th month	9th month	12th month
Daily	1 Bottle	2 Bottles	3 Bottles	3 Bottles	3 Bottles	3 Bottles
PrEP ED	1 Bottle	<p>The amount of medicine stock given at each visit is 1 bottle. ED PrEP users can return to the service to dispense PrEP medication on routine return visits or on visits outside the routine schedule (incidental)</p> <p style="text-align: center;">when the medicine runs out.</p>				

The optimal amount of medication that should be given to PrEP users depends on the method of PrEP use used and the schedule of regular return visits to the service for routine HIV and STI testing. It should be noted that PrEP medication is given in bottles and is not retailed.

When prescribing medications to be used for PrEP, pharmacists have the responsibility to explain the effective and safe use of these medications to PrEP users. Pharmacy personnel are also responsible for maintaining optimal storage conditions, such as temperature and humidity control.

Pharmacists need to ensure that the appropriate medication is administered in the correct dose to the right person. Pharmacy personnel have many roles in providing PrEP, including:

- Manage drug supply and demand chains
- Ensure the accuracy of prescribing PrEP medications
- Provide information about PrEP, including counseling to support adherence
- Provide information regarding the storage of PrEP drugs which is carried out in its own group and is different from ARV drugs
- Provide information about possible side effects and their management
- Provides information about potential drug interactions
- Ensure that there are no dietary restrictions while using PrEP
- Monitor PrEP user compliance when returning for prescription refills/ drug *dispensing*
- Recording and reporting related to receipt, use and requests in the PrEP application

PrEP Medication Storage

Storage of PrEP drugs (TDF/FTC) is the same as storage of other HIV program drugs, namely stored at room temperature ranging from 15–30°C, in a dry place, and not exposed to direct sunlight. The same medication storage guidelines apply to storage of medications outside of the service as at home.

PrEP User Compliance

The effectiveness of PrEP in HIV prevention depends on PrEP users' compliance in taking their medication every day. Pharmacy staff play a big role in supporting PrEP users to take medication regularly. It is important for pharmacy staff to be open and non-judgmental when asking PrEP users about medication use. If PrEP users think that health care providers will offer criticism, then PrEP users may overreport PrEP consumption and hide adherence problems.

Carrying out monitoring at the time of return visits to the service to collect PrEP medication can be a useful way to assess whether PrEP users are taking their medication regularly. One way to estimate the consistency of drug refills is to calculate the drug ownership ratio, namely the number of tablets given divided by the number of days between refills. Another way is to ask PrEP users about the frequency of risky behavior.

This will be done during PrEP counseling.

PrEP users who had return visits before their medication ran out tended to show better adherence.

However, the remaining medication that PrEP users bring with them during return visits also needs to be considered. Large amounts of remaining medication and/or inconsistency with the risk behavior patterns of PrEP users may indicate low adherence.

As part of compliance monitoring, PrEP users are advised to bring remaining PrEP medication with them to routine visits.

PrEP users who carry large amounts of medication residue need to receive adherence counseling. The results of counseling can determine whether the PrEP user will continue PrEP or stop. In this regard, accuracy and assessment of health workers in health facilities is needed.

Compliance can be seen from the remaining amount of medication and risky sexual behavior. This can affect the number of bottles of medicine given, taking into account the time when the medicine will run out. However, the medication taken to the health facility will be asked to be brought back by the PrEP user to be finished.

DISTRIBUTION AND DEMAND LOGISTICS OF PREP MEDICINES

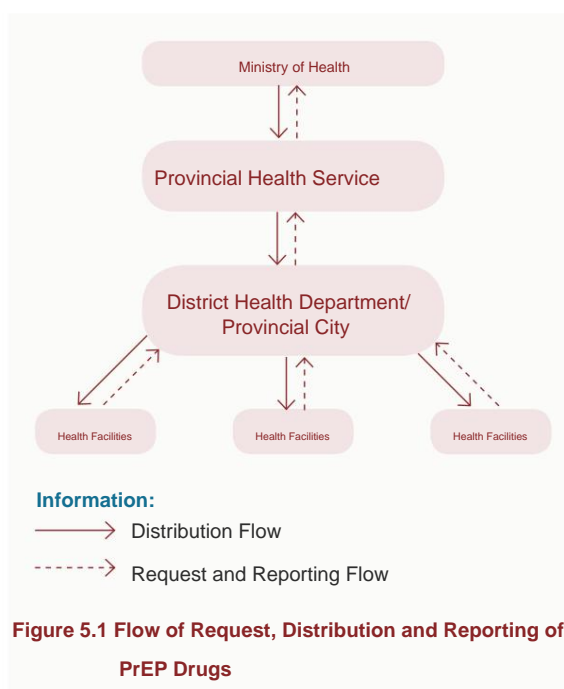
Procurement of PrEP drug logistics is entirely the responsibility of the central government, in this case the Ministry of Health. The Provincial and City/Regency Health Services play a role in planning and requesting drugs, distribution to health services and monitoring/supervision of services implementing the PrEP program.

Total supply of PrEP medication available

will likely vary by situation and population, so numbers cannot be determined with certainty.

From a logistical perspective, the supply of PrEP drugs is carried out separately from ARVs intended for HIV treatment. In other words, drugs that can be given and used by users who need PrEP are drugs that are logistically intended for the PrEP program.

The drug distribution mechanism and logistics of PrEP drugs follow the following flow:



In the PrEP Program in Indonesia, reporting of logistics and distribution of PrEP drugs follows the regulations for reporting logistics and distribution of ARVs that apply nationally, but uses separate recording and reporting forms.

The logistics and distribution rules for PrEP drugs fully refer to the Technical Instructions for Logistics Management of the HIV AIDS & PIMS Program (These technical instructions can be accessed at the following link: <https://bit.ly/JuknisLogistikHIVPIMS>).

LIST REFERENCES

- CDC. (2018). Preexposure Prophylaxis for the Prevention of HIV Infection in the United States.
- CDC. (2021). About PEP. <https://www.cdc.gov/hiv/basics/pep/about-pep.html>. Accessed on 26 July 2023.
- Centers for Disease Control and Prevention: CDC/ ATSDR Committee on Community Engagement. (1997). "Principles of Community Engagement: First Edition."
- Grant , RM , Pellegrini , M . , Defechereux , PA , Anderson , PL , Yu , M . , Glidden , DV , O'Neal , J . , Yager , J . , Bhasin , S . , Sevelius , J . , & Deutsch , M. B. (2021). Sex Hormone Therapy and Tenofovir Diphosphate Concentration in Dried Blood Spots: Primary Results of the Interactions Between Antiretrovirals And Transgender Hormones Study. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*, 73(7), e2117–e2123. <https://doi.org/10.1093/cid/ciaa1160>
- Indonesian Ministry of Health. (2011). National Guidelines for Clinical Management of HIV Infection and Antiretroviral Therapy in Adults. Jakarta: Ministry of Health of the Republic of Indonesia.
- Indonesian Ministry of Health. (2022). Regulation of the Minister of Health of the Republic of Indonesia Number 23 of 2022 concerning Management of *Human Immunodeficiency Virus, Acquired Immunodeficiency Syndrome* and Sexually Transmitted Infections.
- MHAHS. (2018). PrEP (Pre-Exposure Prophylaxis). <https://mhahs.org.au/index.php/en/hiv/prep-pre-exposure-prophylaxis>. Accessed July 26, 2023.
- National Action Plan for Control of HIV and AIDS for 2020-2024.
- Spiritia. (2021). Postexposure Prophylaxis. <http://spiritia.or.id/article/detail/19>. Accessed July 22, 2021.
- UNAIDS. UNAIDS Data Book 2022. Accessed at unaids.org on 25th of July, 2023.
- WHO. (2017). WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection, Module 1: Clinical. Geneva: World Health Organization.
- WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 3: Counsellors. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.
- WHO. (2017). WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection, Module 4: Leaders. Geneva: World Health Organization.
- WHO. (2017). WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection, Module 5: Monitoring dan Evaluation. Geneva: World Health Organization. Licence: CC BY-NC-SA 3.0 IGO.
- WHO. (2017). WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection, Module 11: PrEP Users. Geneva: World Health Organization.
- WHO. (2018). WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection, Module 5: Monitoring and Evaluation. Geneva: World Health Organization.
- WHO. (2019). Technical Brief: What's the 2+1+1? Event-driven Pre-Exposure Oral Prophylaxis to prevent HIV in men who have sex with men: Update to WHO's recommendation on oral PrEP. Geneva: World Health Organization.
- WHO. (2021). Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach. Geneva: World Health Organization.
- WHO. (2022). Differentiated and Simplified Pre-Exposure Prophylaxis for HIV Prevention: Update to WHO Implementation Guidance. Technical Brief.



APPENDIX

Appendix 1: PrEP Form


If you need a printed PrEP form, please access and download the form at the following link:
https://bit.ly/PrEP_Formulir _____

or scan the following QR code:



Appendix 2: Information and Education
Package Basic PrEP Information

Question	Explanation
What is PrEP?	<ul style="list-style-type: none"> • PrEP is an abbreviation for Pre-Exposure Prophylaxis or in Indonesian it is called Pre-Exposure Prophylaxis. • PrEP is an effort to prevent HIV infection by taking ARV drugs according to the instructions for use. • PrEP is used by someone at high risk before and during their actions/behaviors at risk of HIV infection.
Who can access PrEP?	<p>PrEP's target groups are:</p> <ol style="list-style-type: none"> 1. Men who have sexual relations with men (MSM) 2. Female Sex Workers (WPS) 3. Waria/Transgender 4. Injecting Drug Users (IDUs) 5. PLHIV Couples 6. High Risk Couples (Risti) <p>This group may be offered or advised to use PrEP if they have one of the following conditions:</p> <ol style="list-style-type: none"> 1. Having more than one sexual partner 2. Not using condoms consistently 3. Having sexual intercourse through the anus (anal sex) without a condom 4. There is a history of STIs in the last 3 months 5. Have ever used PrEP 6. Having an HIV positive partner with the following conditions (at least one One): <ol style="list-style-type: none"> a. Not yet undergoing ARV treatment, b. Irregular use of ARVs in the last 6 months, c. The amount of <i>viral load</i> is not yet known, d. <i>Viral load</i> is not suppressed (VL \geq1000 copies/ml) after ARV treatment for at least 6 months, e. Planning to have children with an PLHIV partner who <i>has viral load</i>- it is still detected <p>To receive PrEP, target groups who meet the criteria must meet the following requirements:</p> <ol style="list-style-type: none"> 1. Have HIV negative status based on test results with the applicable SOP Indonesia 2. Indonesian citizen 3. Has no clinical signs of acute HIV infection <p>Individuals aged < 18 years need to be accompanied by a guardian or companion to access PrEP at health facilities.</p>
Who can't use PrEP?	People who have positive HIV status
Is PrEP effective in protecting someone from HIV?	PrEP does not provide 100% protection from HIV, but PrEP has been shown to reduce the risk of HIV infection by up to 90% if taken according to the recommendations for use given by health workers.

Question	Explanation
Can using PrEP prevent STIs?	PrEP cannot prevent transmission of STIs, so consistent use of condoms must still be done.
When does PrEP start to be effective in risky sex?	<ul style="list-style-type: none"> • All individuals assigned male sex at birth, having risky sexual intercourse and not being on exogenous estradiol-based hormone therapy, PrEP is taken as 2 pills 2-24 hours before risky sexual intercourse. • All individuals who were assigned female sex at birth, all individuals who were assigned male sex at birth who are undergoing exogenous estradiol-based hormone therapy and IDU, PrEP can work effectively after taking 1 pill every day in the 7 days before risky sexual intercourse .
Where can I access PrEP services?	<p>PrEP can be obtained at health facilities that provide PrEP that have been appointed based on several criteria, namely as follows:</p> <ol style="list-style-type: none"> 1. Has testing, PDP and STI services and prioritizes community health centers, private clinics, and community-based clinics. 2. Have a network with NGOs that work in handling and controlling HIV and PIMS. 3. Have a network for supporting laboratory examinations. 4. Has received capacity building (training, workshops, orientation, OJT) regarding PrEP management. 5. Able to record and report. <p>The list of health facilities providing PrEP can be accessed at the following link: https://bit.ly/FasyankesPrEPIndonesia ,</p> <p>or scan the following QR code</p> 
Is it a risk? use of PrEP?	The use of PrEP can cause relatively mild side effects. Possible side effects include: nausea, dizziness, headaches, fatigue, stomach cramps and diarrhea. However, this side effect is not always experienced by everyone. Usually these side effects will stop after a few weeks. If the pain persists and cannot be tolerated, immediately contact a doctor or health professional.
Is PrEP the same as ARV therapy?	PrEP is not the same as ARV medication therapy. PrEP is intended for people who have negative HIV status as a prevention effort. Meanwhile, ARVs are intended for people who have HIV positive status as a treatment effort. What PrEP and ARV medication therapy have in common is the use of ARV drugs.

Question	Explanation
Are there other ways to protect against HIV besides PrEP?	<ul style="list-style-type: none"> • Condom use is effective in preventing HIV if used regularly consistent with all sexual partners. Condoms also protect against STIs and prevent pregnancy. • ARV treatment aims to reduce the amount of virus (viral load) until HIV is undetectable in the blood, so as to reduce the risk of transmission to PLHIV's sexual partners. • Post-exposure prophylaxis (PEP), namely giving ARVs after someone has been exposed to HIV. If used properly, PEP can protect against HIV. • Do not change sexual partners. For IDUs, use sterile syringes and do not share them with other people.
When can I start using PrEP and when can I stop?	<p>Oral PrEP users can immediately start taking prescribed PrEP before engaging in risky sexual intercourse. PrEP use can be stopped for the following reasons:</p> <ul style="list-style-type: none"> • No longer need PrEP because the risk of HIV infection decreases, for example, you have used condoms consistently or you have not engaged in risky behavior. • Does not want to take medication as prescribed or often misses taking medication. This indicates that the prevention method with oral PrEP is not suitable for this individual • Experiencing side effects that are detrimental to health. • Blood tests carried out in the laboratory show that the body reacts negatively to the use of PrEP. <p>Stopping PrEP requires following the PrEP discontinuation rules in accordance.</p>

B. Information for PrEP users

This information can be provided by:

- Doctors who prescribe PrEP, • HIV counselors, and
- Pharmacy Officer
- Outreach Officer/Peer Educator
- Environmental WHERE

Purpose of providing information:

To provide correct information to PrEP users so that it can be used appropriately and provide optimal impact to prevent HIV infection.

Attention to information givers:

Use simple language when providing information about the drug and use of PrEP.

The basic information for PrEP users that needs to be emphasized is:

- This medicine needs to be consumed according to the dosage and rules. For users using the daily method, the medication needs to be taken every day with the consistency of taking the medication at the same time. Determining the time to take medication can be done at any time

days according to user needs and conditions.

- In general, PrEP is easy to use because it can be taken with or without food. PrEP also does not interact with alcohol.
- PrEP provides up to 90% protection in people who take it appropriately rule.
- When a person starts PrEP, it takes time to build protective levels in the blood and other tissues. Compliance with taking medication according to the prescribed dose and time is very important so that the medication has enough time to protect optimally.

The following important points can be conveyed during interactions with PrEP users:

a. Take PrEP medication according to the rules and dosage based on the method of using PrEP.

b. Rules for taking PrEP medication

1. Rules for Taking PrEP for Men and Waria/Transgender

Population	Method Usage	Starting Oral PrEP	Use Oral PrEP	Stop Oral PrEP
All individuals assigned male sex at birth, who: <ul style="list-style-type: none"> • Having risky sexual relations • Not in exogenous estradiol based hormone therapy 	Daily	Take 2 pills 2-24 hours before risky sexual intercourse (the closer to 24 hours before, the more ideal)	Take 1 pill every day	Take 1 pill daily until 2 days after the last risky sexual intercourse
	Event-Driven (ED)		Take 1 pill daily until 2 days after the last risky sexual intercourse	

b. Rules for Taking PrEP for Women, Men on Hormone Therapy and IDU

Population	Method Usage	Starting Oral PrEP	Use Oral PrEP	Stop Oral PrEP
<ul style="list-style-type: none"> • All individuals assigned female sex at birth • All individuals assigned male sex at birth who are undergoing exogenous estradiol-based hormone therapy • IDU 	Daily	Take 1 pill every day up to 7 days before risky sexual intercourse	Take 1 pill every day	Take 1 pill daily for up to 7 days after the last risky sexual intercourse

c. PrEP is very effective in preventing HIV infection, but it does not protect against other sexually transmitted infections or prevent pregnancy. Therefore, consistent use of condoms is still necessary.

d. PrEP provides a high level of protection in people who take the medication regularly. Over time it takes to build up a level of protection

drugs in the blood and other tissues, other HIV prevention efforts must be carried out within the time specified according to the method of use and risk group in using PrEP.

- e. If you miss a dose of PrEP on a particular day and realize it the same day, you should take the medication as soon as you remember. If you don't remember until the next day, just take one pill each day as usual
- f. In general, store pills in a bottle with a drying agent (silica gel). However, you can take some pills with you when traveling.
- g. Try to keep bottles and pills away from intense heat or cold and keep away from direct sunlight and damp atmosphere.

There are KIE tools regarding the PrEP program in the form of brochures, posters or videos that can be downloaded and viewed at the following link: <https://bit.ly/kie-prep>

or scan the following QR code:



Appendix 3: Counseling Guide for the PrEP Program

This Counseling Guide was adapted from *Supplementary Information from the WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 3: Counsellors*. Geneva: WHO; 2017.

The goals of counseling depend on the situation, whether the client has started PrEP or not, and the client's needs.

For those who do not have PrEP, counseling can be carried out at the same time as HIV testing counseling. The purpose of counseling is so that the individual can prepare the next steps based on the HIV test results they will obtain.

For those who choose PrEP, counseling then continues with preparing the individual to start PrEP, explaining the procedures for using it and making specific plans for using PrEP.

For PrEP users, follow-up counseling aims to check side effects if experienced, reproductive and sexual health and/or current drug use behavior; readiness to remain on PrEP; factors supporting and barriers to PrEP use. Follow-up counseling may also include problem solving, such as how to overcome compliance issues and challenges of disclosure to a partner.

Counselors in the PrEP program can be played by health workers, peer counselors, HIV counselors or outreach/support officers from HIV programs who are trained in the PrEP program. In addition, the preferences of the client/PrEP user should be considered, such as preferring to speak with peer or lay counselors who have experience or are from the same key population. Counselor/ Other PrEP users may prefer counseling with a medically trained counselor (eg, nurse, doctor or clinical officer).

For PrEP outreach counseling, counselors can convey the following important information:

- Dosage requirements or administration procedures to obtain optimal protection from PrEP drugs
- Actions to take if you miss a dose of PrEP medication
- General compliance strategy
- The importance of continuous monitoring of health conditions during the PrEP program, such as routine HIV and STI testing.
- Side effects and management of side effects
- How to safely stop and restart PrEP
- Reproductive and sexual health protection strategies beyond PrEP
- Reduction of adverse impacts for IDUs
- Comprehensive HIV prevention planning

For PrEP users who do not adhere to taking medication, a doctor or counselor can provide adherence counseling. Adherence counseling aims to help ensure users can adhere to using PrEP by taking PrEP medication according to the rules, identify if there are any obstacles they face, and assist in overcoming these obstacles.

Compliance counseling services are provided under the following conditions:

- When PrEP users openly request this counseling because they face obstacles in undergoing the PrEP program
- Non-adherent PrEP users in PrEP use.

Key components in PrEP adherence counseling are:

- Creates a sense of trust and two-way communication
- Provide simple explanations and education to PrEP users regarding:
 - ÿ Schedule and dose of medication that must be taken
 - ÿ Handling side effects that may arise
 - ÿ Information about the relationship between adherence and the success of PrEP
 - ÿ Symptoms and signs of IHA (Acute HIV Infection) and things that need to be done
- Support PrEP user compliance by:
 - ÿ Observe patient compliance without displaying a judgmental attitude
 - ÿ Identify factors that hinder adherence by discussing with PrEP users and creating a plan to overcome these barriers.
 - ÿ Understand that forgetting the daily dose/forgetting to take medication once in a while is normal. At the same time, ensuring PrEP users always know why to take the medication each day at the correct dose is important for maximum protection.
 - ÿ Help create a schedule and/or methods that can help PrEP users prevent forgetting their medication schedule.
 - ÿ Discuss side effects and how to overcome them.
 - ÿ Supports user success in maintaining compliance with taking their medication.

The following counseling guide uses the Integrated Next Step Counseling (INSC) method, which is a series of steps designed to help counselors achieve a more interactive, user-centered approach to PrEP focused specifically on PrEP adherence. This method was developed to address the challenges of informing PrEP choices, developing adherence plans, and developing broader plans for reproductive and sexual health.

Example of a counseling guide using the INSC method:

Steps	Main Components	Sample Speech
Introduction to the counseling session that will be conducted	Explain what you will talk about and its purpose. Ask for approval to continue.	<p><i>Good afternoon, Now we will discuss your goals and how we will achieve these goals. What do you think?</i></p> <p>Goals can be: knowing about PrEP, wanting to start PrEP, being able to use PrEP according to the provisions, overcoming barriers to PrEP and so on.</p>

Steps	Main Components	Sample Speech
Review the counselee/ user experience PrEP	Ask what PrEP users already know about PrEP and how did they find out?; or experience using PrEP, if you have had it.	<i>Thank You. Can you tell us what you already know about PrEP? Or What was your experience while using PrEP?</i>
Exploration of the context of barriers and factors that support PrEP counselees/users.	Use open-ended questions to explore factors or situations that can help make the process of taking medication easier and those that make it more difficult.	<i>Can you tell us about your experience with PrEP since you were last here? What would make PrEP easy to do? What makes it difficult?</i>
Plan a discussion that focuses on things that make the process of taking medication easier.	Pause to consider the information gathered in the previous stage to design the next question.	<i>Let me think for a moment about what you said earlier.</i>
Identify compliance-related needs	Steer the conversation toward identifying PrEP users' perceptions of things that can help integrate PrEP use into daily life.	<i>Looking at the current situation, what would need to happen/be done so that you can get used to taking PrEP medication in your daily life?</i>
Create a strategy with the counselee/users, let PrEP users about the next step	Discussions with PrEP users, let PrEP users try and identify strategies to increase the effectiveness of PrEP use.	<i>How can that be achieved? What ideas could help you achieve it?</i>
Agree on which strategy to try next	Ask what strategies the PrEP user would like to try or continue.	<i>Of the things we've talked about, which ones will you try to do from now until the next time we meet?</i>
Closing	Provide a conclusion from the discussion that has been held, then thank the PrEP user.	<i>You realize that... would make this easier in your life and... is something that could help. You will try to do that from now until our next meeting. Thank you for our discussion time today, I look forward to discussing with you again in the next session.</i>

Appendix 4: Frequently Asked Questions (FAQ)

A. Frequently asked questions by PrEP candidates/users

Question	Explanation
How method storing PrEP medication?	<ul style="list-style-type: none"> • Each bottle of PrEP medication contains 30 pills for one month of use. Store the bottle at room temperature, and do not store it in a cold room such as a refrigerator or a hot room such as a car. • Keep the pills in the medicine bottle along with the small object that came with the medicine bottle (silica gel - to keep the medicine dry).
What information do you need to know about how to take PrEP medication?	<ul style="list-style-type: none"> • WHO recommends taking one pill every day. This daily dose is a safe dose and is able to provide the best protection from HIV infection. • PrEP can be taken every day with the consistency of taking the medication at the same time. Determining the time to take medication can be done at any time throughout the day according to the user's needs and condition. The duration of PrEP use is adjusted to the risk behavior undertaken and the method of PrEP use chosen. • PrEP can be taken at the same time as food. • PrEP can be taken while using medications or during consuming alcoholic beverages • PrEP can be taken while using hormonal contraception, sex hormones, or drugs that are not prescribed by a doctor. However, for males at birth who are undergoing exogenous estradiol-based hormone therapy, they can only use PrEP with the provision of a daily use method. • Before starting a PrEP program, each prospective user will carry out tests to ensure HIV negative status. If a positive HIV result is obtained, the prospective PrEP user will immediately be directed to receive HIV treatment. • While using PrEP, each user will do HIV testing every 3 months to ensure HIV status remains negative. • The risk of HIV infection changes according to the user's situation and condition. A person may decide to stop using PrEP if they feel the risk of infection is no longer great, such as if they have only one sexual partner.
How to remember to take PrEP medication	<ul style="list-style-type: none"> • Most people find it helpful to make patterns habit of taking medication, for example at the same time every day (such as after breakfast, after brushing your teeth, or when watching the same television show every day). • Make reminders, for example from your cell phone or write notes that can be seen every day. • Support from a partner, family, or friends can also help and encourage you to continue taking PrEP medication consistently. <ul style="list-style-type: none"> • If your medication schedule is disrupted (for example due to a change in routine, or forgetting to eat), always carry one or more pills just in case. • Running out of medication is a common case that makes a person skipping a dose of medication. Get into the habit of coming back to the health facility early to ask for a new dose before the old dose runs out.
What to do if you miss a dose of medication	<ul style="list-style-type: none"> • If you forget a dose, take the medicine as soon as you remember. Example: if your usual schedule for taking medication is every morning at 8 am after breakfast, and you just remember that you forgot to take it at 10 am, then immediately take one pill right away. Schedule taking the medicine again as usual the next day. • If you are not sure that you have taken the medicine in one day, you can take one more pill to make sure you don't forget to take the medicine. • Protection against HIV infection is still quite high in someone who takes daily PrEP even if they occasionally miss a daily dose. If you forget or miss your daily dose more than once a week, think about ways or methods that can help you to always take your medication every day.

Question	Explanation
Side effects PrEP	<ul style="list-style-type: none"> • Side effects do not always appear in every PrEP user, but are common. These side effects may include mild nausea, headaches, or stomach cramps. • The above side effects are usually not bothersome and will disappear in the first weeks of using PrEP. • Strategies that are commonly used to overcome the symptoms felt at stomach: take the medicine with food, or take the medicine just before bed. • For some people, the PrEP medication affects how their kidneys work. After starting PrEP, people who have certain problems with their kidneys will be monitored and have regular tests. If test results show problems, PrEP use will be temporarily stopped. If kidney function has improved, then PrEP use can be resumed.
Pregnancy plan while using PrEP	<ul style="list-style-type: none"> • It is recommended to convey pregnancy plans to a doctor or other health workers • Choose one of the following two ways to have children safely (if one of the partners is HIV positive): <ul style="list-style-type: none"> • Consistently take ARV pills for positive partners, and check if the viral load is still high • Use PrEP according to the dose given • Use the two methods above for a safer pregnancy. ARVs are used by positive partners, and PrEP is used by partners with negative HIV status.
Telling others about PrEP	<ul style="list-style-type: none"> • Tell people close to you who are trusted to help you carry out the PrEP program optimally, such as support for taking medication regularly. • There is no pressure to tell others if you are on PrEP. However, someone may need to create a scenario if someone else finds out suddenly. • Many people think well and positively about PrEP, because Using PrEP is a form of responsibility towards oneself and concern for others to be protected from HIV. • If others do not understand PrEP and ask about it this program, provide clear facts that PrEP is a recommendation from WHO and governments and health services
Can I stop PrEP?	<ul style="list-style-type: none"> • A person's sexual behavior and injection drug use can change over time, so the risk of HIV infection can also change. Starting PrEP does not mean a person will use it for life. If the risk of HIV infection becomes low, then a person can stop PrEP and use other prevention methods to protect themselves from HIV, such as condoms. • Convey your desire to stop PrEP to health workers who have been assisting in the PrEP program you are undertaking.

B. Frequently Asked Questions to Pharmacy Officers

How to take PrEP tablets every day

Take one pill every day. PrEP can be taken at any time of the day. PrEP does not have to be taken at the same time every day, but it will greatly help your compliance if it is taken at the same time every day.

While it is safe to use PrEP with many other medications, it is necessary to examine each one specifically. We can help you check if there might be a problem. Please tell me what other drugs you are taking.

Length of time on PrEP

Until you are no longer at risk of HIV infection, such as no longer having risky sexual relations.

Possible side effects

Most people have no side effects. About one in every 10 people may experience mild nausea, headaches, or stomach cramps that can last a few days to a week when they first start PrEP.

Effect of PrEP on body weight

PrEP medication does not affect body weight. Some people taking PrEP think that the drugs can cause weight gain or loss. Although PrEP medications do not affect a person's weight, there may be other problems associated with PrEP use, such as reduced feelings of anxiety, which can lead to weight gain or loss.

Effective time of PrEP

A degree of protection was achieved after two days of taking PrEP medication; However, for women or men who are on hormone therapy, maximum protection is obtained after seven days.

How does PrEP work?

Blocks HIV from spreading in the body.

What to do if you forget a dose

If you miss your pill on a particular day and realize it the same day, take your pill as soon as you remember. If you don't remember until the next day, there is no need to take two pills on the same day. Just take one pill every day as usual.

What to do if you vomit after taking one dose of PrEP If you see the pill being thrown up, wait an hour for the vomiting to pass and take another pill. If vomiting occurs an hour or more after taking the pill, or you do not notice that the pill has been vomited, take the next pill the next day as usual.

Appendix 5: Roles and Duties of PrEP Program Stakeholders

A. City/Regency Health Service

- Ensure the PrEP program is running at the selected service location
- Ensure active involvement of various stakeholders (health services, community and other relevant stakeholders)
- Receive monthly monitoring results from recording and reporting officers and summarize the results
- Analyze the results of the monthly recap for program purposes
- Provide feedback to services regarding the quality of the service's PrEP program
- Provide regular reports to the Provincial Health Service and Ministry of Health

B. Implementing doctor/Counselor

- Explain the procedures for using PrEP, procedures and requirements for eligibility and follow-up, risks and benefits, the importance of compliance, rules for starting and stopping, determining the method of use, explaining comprehensive prevention efforts by continuing to use condoms and related laboratory tests if any
- Conduct HIV and STI-related counseling, including risk reduction behaviors and the need for condom use when taking PrEP (including distribution of free condoms and lubricants to PrEP users), perform anamnesis, counseling and physical examination
- Evaluate PrEP users for STI status and decide to initiate PrEP
- Screen PrEP users for possible IHA
- Interpret laboratory test results
- Decide on compliance with criteria and continuation of PrEP
- Evaluate possible side effects of PrEP
- When necessary, can request additional specimen collection and testing laboratory
- Write a PrEP prescription for follow-up by pharmacy staff
- Record relevant information on the PrEP form • Conduct side effect evaluation and refer to specialist if necessary
- Ensure access to ARV treatment therapy for infected PrEP users HIV

C. Nurse/Phlebotomist/Counselor

- Explain the procedures for using PrEP, procedures and requirements for eligibility and follow-up, risks and benefits, the importance of compliance, rules for starting and stopping, determining the method of use, explaining comprehensive prevention efforts by continuing to use condoms and related laboratory tests if any
- Provide HIV and STI-related counseling, including risk reduction behaviors and the need for condom use when taking PrEP (including distribution of free condoms and lubricants to PrEP users)
- Perform blood draws and collect other specimens as indicated
- Ensure proper identification and transportation of samples to the clinical laboratory
- Inform PrEP users about the results of HIV testing and other tests done

- Ensure access to ARV treatment therapy for infected PrEP users
HIV
- Reevaluate HIV risk during follow-up
- Performs compliance counseling and pill counting
- Complete documents for review by the treating physician
- Record relevant information on data forms.

D. ATLM

- Receive blood samples and other specimens for processing and testing
- Responsible for managing relevant test kits, other laboratory materials, and specimen collection devices and associated clinical supplies
- Perform serological tests for HIV, HCV, syphilis and other STI examinations
- Prepare specimens for transportation and outbound referral tests if necessary • Receive and document lab test results from referrals
- Ensure good laboratory practices and safe collection and disposal of sharps and other hazardous materials and waste • Complete the prescribed forms to notify the treating physician and/
or counselor/nurse regarding the results of laboratory tests that have been carried out
- Enter laboratory result data in the recording and reporting application

AND. **Pharmacy Officer**

- Process prescriptions and record medications dispensed
- Explain and repeat the rules for using the drug to PrEP users
- Ensure continuous supply of medicines and prevent stock outs
- Complete relevant forms for data entry in recording and reporting applications for monitoring purposes

F. Recording and Reporting Officer

- Complete data record forms and supervise data entry
- Store data information for monthly reports between source and database
- Perform daily backups and data storage in the system application cloud recording and reporting
- Generate weekly and monthly monitoring reports to evaluate PrEP program performance.

Appendix 6: Community-based PrEP Monitoring

HIV community-based monitoring/monitoring (Community-Led Monitoring/CLM) is an accountability mechanism for HIV response at various levels that is led and implemented by communities of people living with HIV, key population networks, other affected groups or other HIV community entities.

CLM uses a structured platform and trained community workers to systematically and routinely collect and analyze qualitative and quantitative data on HIV service delivery. In this case CLM will be used for the PrEP program. CLM provides opportunities for networks and community groups to carry out their oversight functions. In short, CLM is carried out for and by the community so that it is hoped that it can contribute to improving services which can also be felt by the community as program beneficiaries.

Community-based PrEP monitoring within the CLM framework is shown in the following diagram.

