

**Management Guidelines
Pilot Program
Pre-Exposure Prophylaxis
(PrEP) for High-Risk Persons
HIV infection in Indonesia**

Ministry of Health of the Republic of Indonesia
2021

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WELCOME WORDS

FOREWORD

All praise and thanks go to God Almighty because of His mercy and grace, we were able to complete **the Pilot Program Management Guidelines.**

Pre-Exposure Prophylaxis (PrEP) for People at High Risk of HIV Infection in Indonesia

This.

The purpose of preparing this guideline is to serve as a reference for administering the PrEP pilot program during the PrEP pilot period in Indonesia. With future adjustments, it is hoped that this guideline will become a reference for PrEP services that are integrated with HIV&STI services. The main aim of giving PrEP is to give ARVs to reduce the risk of HIV infection in someone who has a higher risk of being infected. In this way, it is hoped that it will be able to break the chain of HIV transmission, and can have an impact on reducing the incidence of morbidity and death due to HIV which can cause harm to individuals and society.

This guideline is intended for stakeholders related to HIV prevention and control in Indonesia, especially in PrEP services, namely: Management of health facilities/health facilities, health workers/health workers (including doctors, nurses, lab staff, pharmacists and other clinical staff) , peer educators, counselors, as well as policy makers and program managers as well as monitoring and evaluation.

In this guideline, people who use PrEP are referred to as PrEP Users, to show that people who use PrEP are empowered and can make decisions regarding their PrEP use.

The PrEP Pilot Program Governance Guidelines consist of five (5) chapters, which address the following matters:

CHAPTER 1 Introduction

This chapter discusses the background to the implementation of the PrEP Pilot Program in Indonesia and the creation of guidelines, objectives of the guidelines, scope of the guidelines, policies regarding the PrEP program, as well as health facilities providing the PrEP program.

CHAPTER 2 Pre-exposure Prophylaxis (PrEP)

Chapter 2 contains information about PrEP, namely the definition of PrEP, the purpose of giving PrEP, the goals of PrEP, the effectiveness of PrEP, PrEP regimens, the enabling environment for implementing the PrEP program, and the differences between PrEP and PPP.

CHAPTER 3 Implementation of the PrEP

Program The implementation of the PrEP Pilot Program is discussed in this chapter, namely regarding the model for implementing the PrEP Pilot Program in Indonesia, service packages and referrals, as well as PrEP implementation at the service level such as flow of services, procedures for restarting PrEP, and program management PrEP in special situations.

CHAPTER 4 Pharmacy Governance and

Logistics Pharmacy Governance and Logistics of the PrEP Pilot Program explains information related to the use of PrEP drugs, managing PrEP logistics, monitoring effective use of PrEP, and the role of pharmacy staff in implementing the program.

CHAPTER 5 Monitoring and Evaluation

This chapter includes an explanation of the main indicators of the program as well as the flow of program recording and reporting to ensure the program can run according to its objectives.

This guideline is accompanied by an appendix to support the use and implementation of the PrEP pilot program in Indonesia.

Attachment 1 PrEP form, contains forms that need to be filled in by program implementers to monitor the journey of PrEP users and success program.

Appendix 2 of the PrEP KIE (Communication, Information and Education) Package, contains basic information about PrEP from relevant sources.

Appendix 3 Counseling Guide, to make it easier for counselors to guide in provide counseling to PrEP users in need.

Appendix 4 Frequently Asked Questions (FAQ) contains things about PrEP that PrEP users and potential users and service providers need to know.

Appendix 5 Roles and Duties of PrEP Program Stakeholders

Appendix 6 Laboratory Examination Table for PrEP. This table contains information on what laboratory tests are performed at each stage of the PrEP program.

It is very possible that there will be changes or improvements to these guidelines in the future following the evaluation results from the implementation of the pilot program, as well as developments in the situation, policies and regulations in the future. We hope that these guidelines are useful and easy to use.

October 2021.

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AHI	Acute HIV Infection/ acute HIV infection
ART	Antiretroviral therapy/terapi antiretroviral
NUMBER	Antiretroviral
HEALTH FACILITIES	Medical facility
FTC	Emtricitabine
HIV	Human Immunodeficiency Virus
IMS	Sexually Transmitted Infections
IO	Opportunistic Infections
IPV	Intimate Partner Violence
KBG	Gender Based Violence
WHERE	Communication, Information, and Education
KTD	Unwanted Pregnancy
KTS	Voluntary Counseling and Testing (VCT)
LASS	Sterile Syringe Service
LPSK	Witness and Victim Protection Agency
LSL	Men who have sex with men
LSM	Non-governmental organization
SEAM	HIV Nucleic Acid Amplification Testing
PLWHA	People with HIV and AIDS
ODHIV	People with HIV
OFTEN	Oral Fluid Test
P2TP2A	Integrated Service Center for Empowerment of Women and Children
PBMC	Peripheral Blood Mononuclear Cells (blood cells that have a round nucleus, consisting of lymphocytes and monocytes)
PDP	Service, Support, and Treatment
IDU	Injecting drug users
PPP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis (Pre-exposure prophylaxis)
PTM	Non-Communicable Diseases
PUSPAGA	Family Learning Center
RAN	National Action Plan
ED	Regimen Event-Driven
RPJMN	National Medium Term Development Plan
STBP	Integrated Biological and Behavioral Survey
TDF	Tenofovir Disoproxil Fumarate
TFC-DP	Tenofovir-diphosphate / Tenofovir Difosfat
UPTD PPA	Regional Technical Implementation Unit for the Protection of Women and Children
WHO	World Health Organization / World Health Organization
WPS	Female Sex Workers

	Creatinine Clearance	Creatinine clearance/kidney clearance rate (aims to determine kidney function condition)
	Pharmacokinetics	The science that studies the effect/reaction of the body to a drug
	Immunosuppression	Related to the suppression of the body's immune system
	Opportunistic infection	Infections due to viruses, bacteria, fungi, or parasites that occur in people with weakened immune systems due to other causes.
	Insertif	Individuals who penetrate the sexual relationship
	HIV Risk Groups	Groups of people who engage in behaviors that put themselves at risk of infection with HIV, such as having unprotected sex with more than one partner or sharing use of unsterile needles in drug use.
	Counselee/PrEP user	Someone who is getting counseling about PrEP
	PrEP counselor	A person who has been trained and has expertise in counseling/counseling regarding PrEP
	Serodiscordant partners	Partners with different HIV statuses or someone whose partner is HIV positive and who himself is HIV negative.
	People-centered	Approach that focuses on program goals
	Prevalence	The proportion of the population that has certain characteristics in a certain period of time.
	PrEP Pilot Program	PrEP implementation pilot program to see the potential and challenges of the PrEP program in Indonesia before it is officially established on a national scale
1517	Regiment	Composition, type, amount, and frequency of drug administration as a therapy for the treatment or prevention of disease.
	Rectum	The lower part of the large intestine, where feces are stored before being expelled through the anus.
	Receptive	Individuals who receive penetration in sexual relations
	Substantial risk	Conditions or circumstances where individuals have a higher risk of being infected with HIV
	cervix	Also called the cervix, which is the part of the uterus that is connected to the vagina.
	Three Zero	The HIV AIDS prevention target that is expected to be achieved by 2030 is Zero New Infection (no new HIV infection), Zero AIDS Related Deaths (no AIDS deaths), and Zero Discriminations (no stigma and discrimination for HIV AIDS sufferers)
	Viral load	A measure (in numbers) of the amount of virus detected in a person's blood

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Appendix 3: Counseling Guide for the PrEP Program

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Appendix 6: Laboratory Tests for PrEP

Introduction

01

1. INTRODUCTION

1.1 Background

Control of *Human Immunodeficiency* (HIV) infection *Virus* is one of development targets in Indonesia. The 2020-2024 National Medium-Term Development Plan (RPJMN) states that the target for the incidence of new HIV infections in 2024 is 0.18 per 1,000 population, far lower than 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.

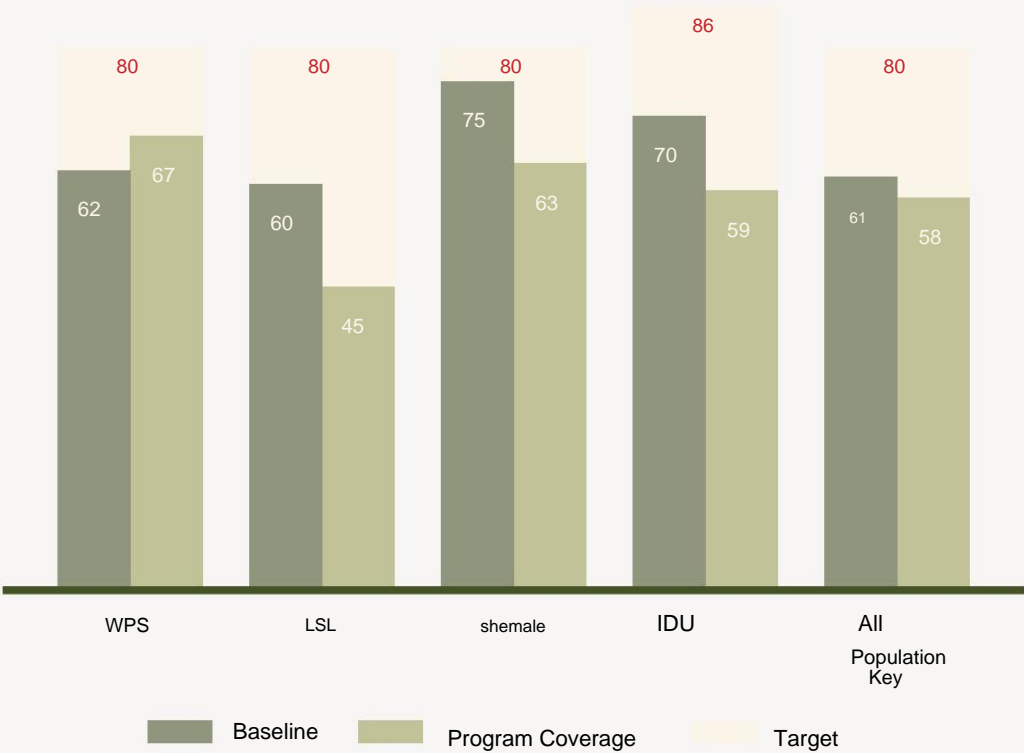
Prevention of new HIV infections in Indonesia has been carried out in various ways. Creating conditions that are conducive to increasing knowledge and awareness of the general public is carried out in a structured manner through various media.

For populations at high risk of contracting HIV, outreach is carried out accompanied by the provision of Information and Education Communication (IEC) materials. The provision of the material is also accompanied

with risk reduction efforts such as providing methadone substitution therapy and sterile syringes to groups of injecting drug users or condoms for risky sexual relations.

This prevention program has shown progress. Data from the 2019 Integrated Biological and Behavioral Survey (STBP) shows an increase in condom use among female sex workers (WPS) up to 67% from the original 31% in 2009. Injecting drug users (IDU) have also obtained sterile syringes from drugstores 37.6% for medical devices and another 45.3% have obtained needles from the Sterile Syringe Service (LASS) at health facilities. However, the achievements of this prevention program still do not meet the specified targets. In addition, the behavior of using condoms in the last commercial sexual intercourse among men who have sex with men (MSM) and waria tends to decrease.

Figure 1.1 Percentage of *Baseline*, *Target*, and Coverage of 2015-2019 NAP Prevention Behavior



The prevalence of sexually transmitted infections (STIs), which is also considered an indicator of condom use in high-risk populations, shows something similar. The 2015 and 2018-2019 IBBS show that the prevalence of STIs in the FSW and MSM population tends to remain the same, although it has decreased among high-risk men and FSW customers. The highest prevalence of syphilis was found in the MSM population, in line with the trend of the spread of new HIV infections which are also found to be high in this population. The data presented from the National Action Plan (RAN) above also show that there are gaps in HIV prevention in Indonesia, such as the low proportion of high-risk populations utilizing HIV testing, new case detection that is still not optimal and STI services and their networks that are still limited. (RAN, 2020).

In 2016, the World Health Organization (WHO) released the guidelines for the *Global Health Strategy on HIV 2016-2021* which asked all countries to accelerate their HIV control response followed by continuous action to achieve the desired target by 2030. This accelerated response requires a fundamental change in thinking, and the commitment of all parties to seek innovation and new resources as needed.

This strategy also calls for the adoption of a program or client-focused (people-centered) approach that is based on human rights and health equity (WHO: *PrEP module for leader*, 2017)

Treatment Antiretroviral (ARV) already is widely recommended for administration in all people living with HIV (PLHIV) regardless of level of immunosuppression. In addition, WHO also recommends preventive therapy prophylaxis using ARV drugs known as *Pre-Exposure Prophylaxis* (PrEP) or Pre-Exposure Prophylaxis as part and addition to comprehensive prevention efforts that have been and are ongoing to date.

PrEP has been implemented in several countries and has shown a reduction in HIV incidence rates. Research on PrEP has been carried out around the world. The results of more than 10 clinical trials involving 18 countries show that PrEP drugs containing Tenofovir (TDF) or a combination of TDF and Emtricitabine (FTC) can prevent new HIV infections by up to 90% if taken consistently. 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.

Although it is often feared that PrEP will lead to high resistance to ARVs, the fact is that this risk is uncommon (*uncommon*). The risk of developing ARV resistance occurs in approximately 1/1000 PrEP users who have an acute HIV infection that was not detected at the time of starting PrEP. Therefore it is very important to carry out an optimal HIV test before starting PrEP (WHO: *PrEP module for leader*, 2017).

Regarding STIs, PrEP cannot prevent STI transmission as can the use of condoms. Many clinical testing studies have been carried out to look at this, and the results show that there was no decrease in condom use or increase in the number of sexual partners among PrEP users (WHO: *PrEP module for leaders*, 2017).

However, 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 high-risk populations who have a substantial risk of contracting HIV and thus require 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.

Compared with ARVs used as a lifelong treatment, PrEP is also more cost-effective, because the ARV drugs used in PrEP are relatively inexpensive, given to high-risk populations without HIV only during high-risk or emergency periods (the treatment time is shortened). and can prevent HIV events that will require more expensive Opportunistic Infection (OI) care and treatment (WHO: *PrEP module for leader*, 2017).

Community engagement

in the prevention and control of HIV and AIDS is important, as well as in the PrEP program. The existence of community involvement will greatly support and assist the PrEP program in reaching populations with substantial risks that are difficult to reach by health workers and vice versa can convey the needs of these populations to stakeholders or services (Castro, 2019). Barriers to services, such as a lack of human resources to provide counseling services, can also be overcome with the help of community members who have been trained as counselors.

With these various considerations, it is time for the PrEP program to be implemented in Indonesia. To support this implementation, guidelines for the PrEP Pilot Program need to be developed and socialized to all stakeholders implementing the HIV program in Indonesia.

1.2 Purpose

This guideline was developed as a reference in the management of PrEP pilot programs during the pilot period that can be used by the Ministry of Health or government-managed and community-based health facilities, both at the central and regional levels that provide HIV AIDS and STI services. The management of the PrEP program can be carried out by adjusting to the situation, conditions, context, policies and resources of each institution in order to provide a comprehensive PrEP program.

This guideline is also intended for stakeholders related to HIV prevention and control in Indonesia, especially in PrEP services. These parties include:

1 Health facilities (faskes), such as hospitals, health centers, and private clinics that provide HIV services.

2 Health workers (Nakes), including doctors, nurses, lab staff, pharmacists and other clinicians. The scope of work includes screening for substantial risk of HIV transmission, providing and carrying out necessary tests before starting or while using PrEP, providing return visit services, and providing counseling services if necessary such as adherence counseling.

3 Peer educators are people who are a part of or work with HIV key population groups. Peer educators can reach out to the community in an effective way and hopefully increase demand for and access to PrEP programs. Peer educators can use this guide as a reference in providing relevant and accurate information to increase community members' knowledge and awareness regarding PrEP services or use.

4 Counselor is a trained individual who can help provide counselling to people who have a high risk of being infected with HIV to consider or decide to start using PrEP. Counseling also assists PrEP users in overcoming problems related to handling side effects, adherence, changes in risky behavior and other issues such as drug use or gender-based violence, which can affect decisions and adherence to PrEP use.

5 Policy makers and managers program, implementation of the PrEP program of course. Of course, it must be supported by policies both at the planning level and at the health facility level that deal directly with PrEP users. This guide can provide information about the benefits and limitations of implementing PrEP in relation to HIV prevention and response.

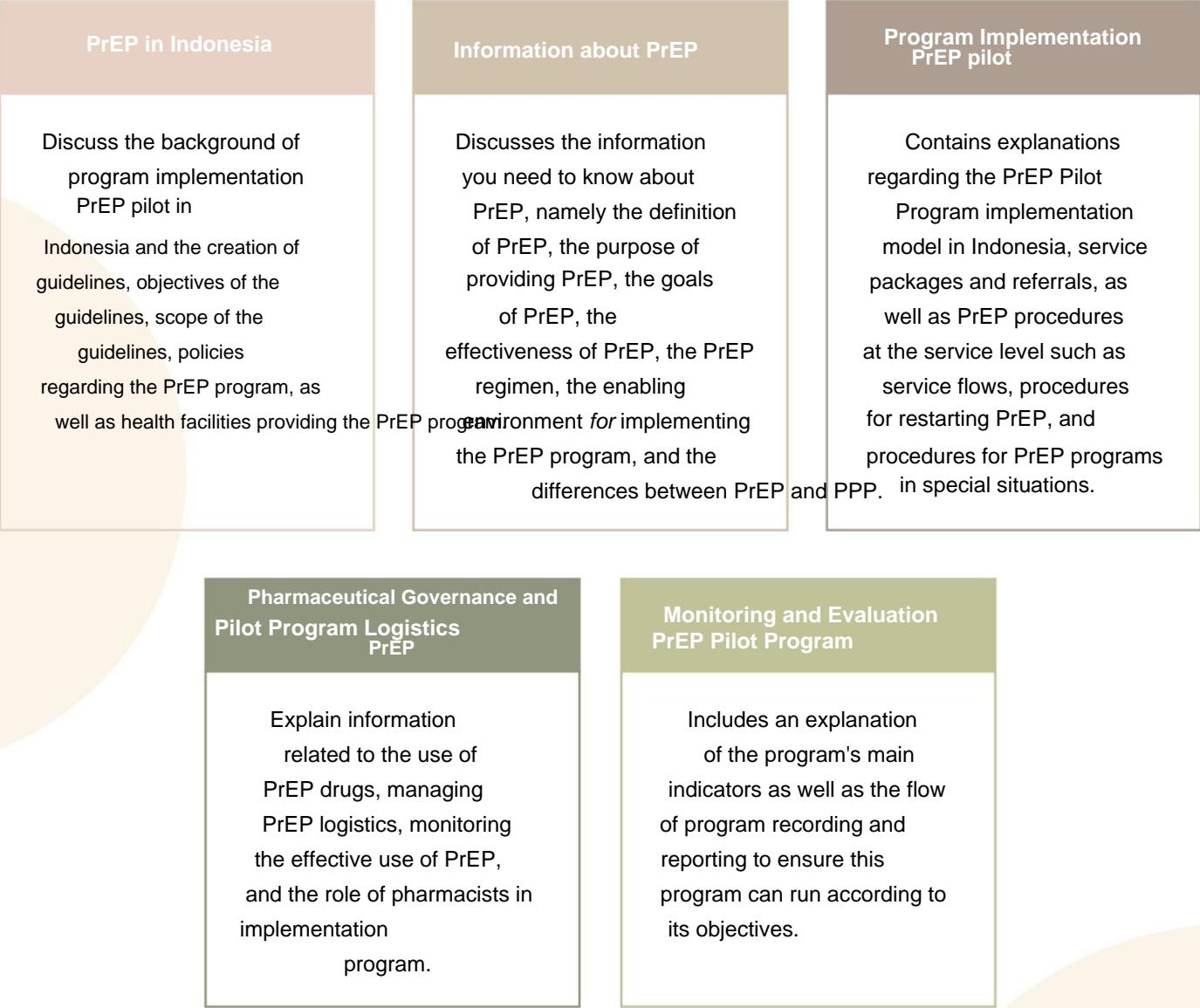
6 Monitoring and evaluation, this guideline can be used by parties who have an interest in monitoring and evaluating the implementation of HIV services in both prevention and treatment aspects. This guideline provides information relating to recording and reporting systems, indicators and report formats that can be used at the health facility, district/district level, city, province, national, and global.

7 Pharmacists This guideline can be used by pharmacists in health facilities as a reference in the types of drugs, prescribing, how to store them, and record them.

8 PrEP users complete and accurate information is available regarding PrEP to be able to assist in decision making regarding PrEP and support in ensuring compliance with PrEP use.

1.3 Scope

Guidelines for administering the PrEP Pilot Program include:



1.4 Policy

These guidelines are prepared based on:

- RI Law Number 36 of 2009 concerning Health.
- Policy “Global AIDS Strategy 2021-2026 – End Inequalities. End AIDS.” regarding countermeasures HIV AIDS.
- Presidential Regulation of the Republic of Indonesia Number 76 of 2012 concerning the implementation of patents by government on antiviral and antiretroviral drugs.
- Pedoman Global Health Strategy on HIV 2016-2021.
- National Action Plan for HIV and AIDS Control 2020-2024.
- National Medium Term Development Plan (RPJMN) 2020-2024.
- Permenkes Number 21 of 2020 concerning the Strategic Plan of the Ministry of Health for 2020-2024.
- 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.
- Program Action Plan for the Directorate General of Disease Prevention and Control, Ministry of Health, Year 2020-2024.
- WHO recommendations regarding PrEP (Pre-Exposure Prophylaxis) as an additional prevention effort HIV AIDS in September 2015.
- Strengthening Local Government in Health Development from the Ministry of Home Affairs.

1.5 Provider Health Facilities Program PrEP

In this PrEP pilot program, health facilities included as providers of the PrEP program are facilities that have the following criteria:

1. Have PDP (Service, Support and Treatment) services at government or private health facilities.
2. Having STI treatment services.
3. Have a network with population groups at risk of HIV or are facilities that are referred by the community.

Facilities that meet the criteria are selected based on the following:

- Is a health facility located in the City/Regency as determined by Ministry of Health to enter in PrEP pilot program.
- It is a health facility recommended by the Health Office Province and City Health Service/ local district. Recommendations are given based on an assessment that the health facility is friendly to population groups at risk of HIV, is frequently accessed or has a high number of coverage of population groups at risk of HIV.
- Willing to be involved in the full implementation of the pilot program.
- Health workers as implementers of the PrEP pilot program receive training on PrEP management in accordance with the guidelines.

The selected health facilities will receive support in the form of: •

Training of health workers (doctors, nurses and lab staff)

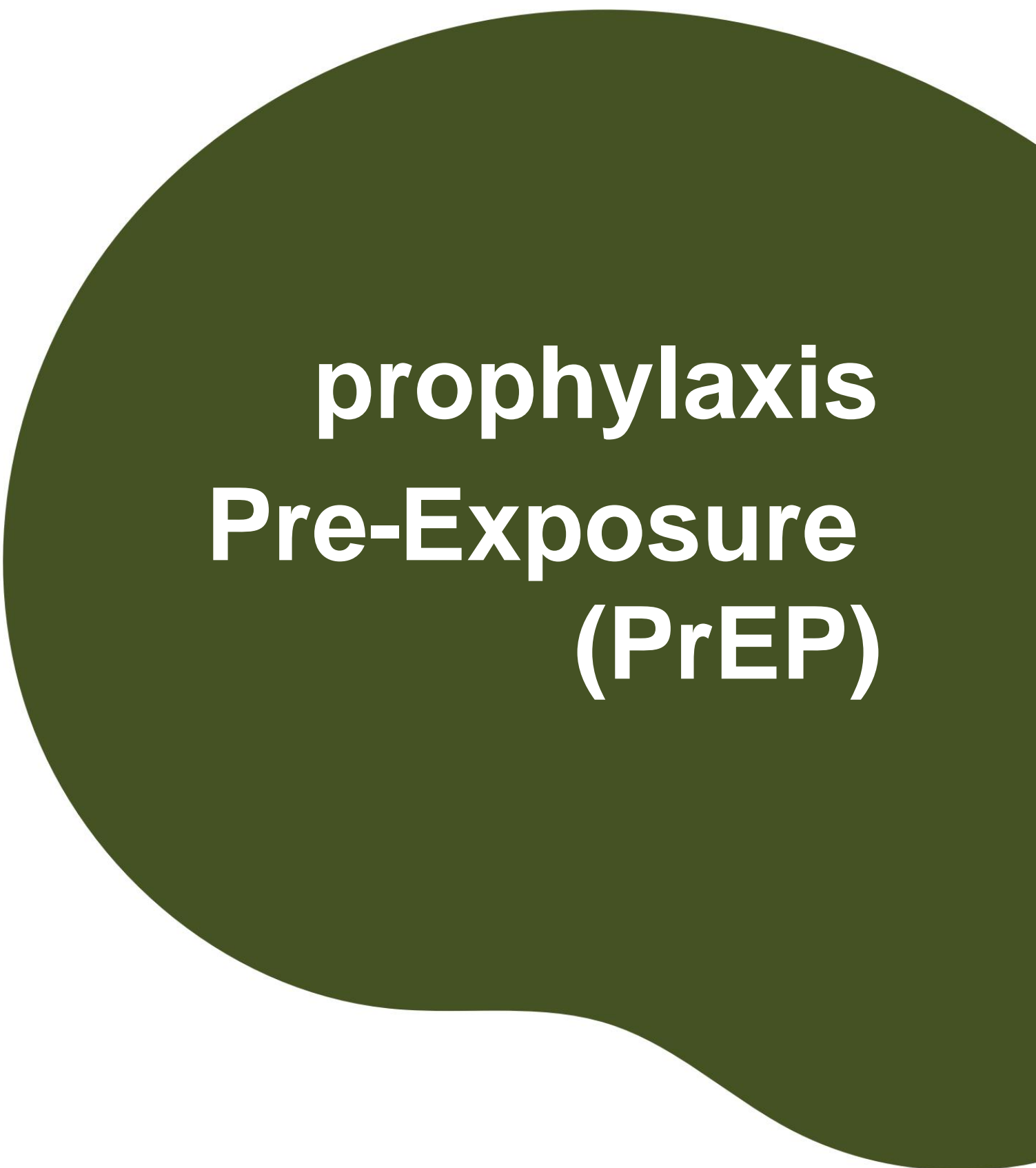
- PrEP drug logistics

- Operational support for PrEP

implementation • Laboratory tests required during the program (HIV tests, STI tests and HBsAg tests)

- Regular assistance and monitoring from the Ministry of Health, Provincial Health Office and local City/Regency Health Office, as well as the Ministry of Health's HIV Expert Panel.

As a continuation of the PrEP program after the pilot program ends, it is hoped that this health facility can continue to provide superior PrEP services in Indonesia.



prophylaxis Pre-Exposure (PrEP)

02

02

2. PRE-EXPOSED PROPHILAXIS (PrEP)

2.1 Definitions

Pre-Exposure Prophylaxis (abbreviated as PrEP in this guide) is the use of antiretroviral drugs (ARVs) by someone who is not infected with HIV, before being exposed to or exposed to HIV, and with the aim that he is not infected with HIV. PrEP is taken as long as a person is at high risk of becoming infected with HIV. If taken in the right dosage, PrEP can reduce the risk of contracting HIV through sexual intercourse by more than 90%. The level of protection of PrEP is highly correlated with adherence and needs to be used according to the rules of use. High adherence to PrEP is capable of producing a high level of protection from HIV infection, whereas adherence that is less than optimal will not provide the expected protective benefits.

2.2 Purpose of giving PrEP

The main goal of administering PrEP is to reduce the risk of HIV infection in someone who is at higher risk of becoming infected. In this way, it is hoped that it will be able to 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.

2.3 PrEP Administration Goals

Based on WHO recommendations in September 2015, PrEP should be offered as an additional prevention option for people at higher risk of HIV infection (substantial risk) as part of a combination HIV prevention approach (WHO: PrEP module for PrEP Users, 2017).

The goals of PrEP are:

- Men who have sex with men (MSM)
- Female Sex Workers (WPS)
- Waria/Transgender
- Injecting Drug Users (IDUs)
- Someone who has a sexual partner with HIV positive status (Serodiscordan Pair)

Criteria for people who have a higher risk of being infected with HIV, namely:

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 or PPP
6. Having an HIV positive partner with the following conditions (at least one):
 - have not used ARVs, - used ARVs irregularly in the last 6 months,
 - viral load count is unknown,
 - HIV is not suppressed (viral load >1000 copies/ml) after 6 days of treatment moon,
 - planning to have children, with a partner who has not had HIV to put down

If one of the criteria above has been met, then the prospective PrEP user is eligible to access the PrEP program and can carry out a PrEP screening to see the feasibility of using PrEP.

The eligibility criteria for using PrEP, namely:

- Have a negative HIV status
- There is no indication of having acute HIV infection
- Have a substantial risk/high risk of being infected with HIV
- There are no contraindications to the PrEP regimen (TDF/FTC)


2.4 Effectiveness of PrEP

PrEP can reduce the risk of HIV through sexual transmission by more than 90% when used properly and with good adherence. PrEP can be more effective when combined with other HIV prevention mechanisms such as the use of condoms and lubricants, harm reduction of drug use, and treatment for people living with HIV. It should be understood that PrEP cannot prevent the transmission of STIs such as syphilis, gonorrhea and chlamydia, therefore additional protection such as condoms still really needs to be done by someone who uses PrEP.

Proper use of PrEP, correct dosage, and good adherence are important factors for optimal PrEP effectiveness. If the PrEP drug is not used according to the rules, then the amount of drug in the blood will not be sufficient to prevent the virus from surviving and spreading in the body. PrEP will optimally prevent HIV transmission after being used for 7 days in someone who has receptive anal sex and 21 days in someone who has receptive vaginal sex. However, in this guideline, the PrEP regimen has been adapted to the latest management, which is 2 days for MSM risk groups and 7 days for non-MSM risk groups.

2.5 PrEP regimen

The World Health Organization (WHO) has recommended that medicines containing *Tenofovir Disoproxil Fumarate* (TDF) be used to prevent HIV infection in people who are at high risk of being infected with HIV. The ARV drug used in the PrEP pilot program in Indonesia is TDF/FTC.

Table 2.1 ARV drugs for PrEP		
Medicine name	Dose	Picture
Tenofovir disoproxil fumarate (TDF) / Emtricitabine (FTC)	300 mg TDF and 200 mg FTC	

There are 2 types of regimens in PrEP, namely the daily regimen *and* the *Event Driven* regimen (PrEP-ED). The provisions for giving PrEP regimens can be seen in the following table:

Table 2.2 Drug Regimen			
Scheme	Key Population Groups		
	LSL		Apart from MSM
	PrEP -ED	Daily	Daily
Dose First	2 pills in 2 – 24 hours before sexual intercourse	2 pills in 2 – 24 hours before sexual intercourse	1 pill a day for 7 days before sexual intercourse
Dose Advanced	1 pill 24 hours after the first dose followed by 1 pill 24 hours after the second dose	1 pill a day at the same time as the first dose	
Dose Stop	There isn't any	1 pill a day for at least 2 days after last sexual intercourse	1 pill a day until 7 days after last sexual intercourse

Change of Regime

The frequency of sexual intercourse is different for each person, depending on several factors, such as lifestyle, habits, relationship status with other people, sexual dynamics, as well as age. The risk of HIV infection is also affected by HIV prevalence in the population group. A daily regimen of PrEP is recommended for all persons at high risk of HIV infection with unpredictable/spontaneous patterns of sexual intercourse and potential exposure to HIV more than once a week. For the MSM group, in addition to the daily PrEP regimen, PrEP-ED can also be offered taking into account the situation and preferences of the PrEP user.

Someone taking PrEP-ED can change it to daily doses of PrEP if sexual intercourse occurs more frequently (having sexual intercourse more than 1 time per week), so the pill must be continued to be taken every day as protection from HIV exposure. Conversely, users of daily doses of PrEP can change the dose to PrEP-ED if the frequency of sexual intercourse decreases (having sexual intercourse a maximum of 1 time per week), so that the risk of HIV exposure becomes lower. The decision to change this dose must be consulted with a health professional first, accompanied by a more objective assessment of risk factors.

Drug Interactions

Food. One of the things that potential PrEP users and users often ask is whether PrEP medication should be taken after or before meals.

FTC can be consumed before or after meals.

hormonal. TDF/FTC has no interactions with hormonal contraceptive drugs or other hormone drugs. For example, a woman who uses hormonal contraception regularly will not interact with the drugs used in PrEP. The use of PrEP in transgender women who regularly take hormone drugs for feminization or in transgender men who regularly take hormone drugs for masculinization, both of which will not interact with PrEP drugs.

Other drugs. TDF/FTC don't have interactions with other drugs and can be consumed together safely. PrEP drugs can be taken together with antidepressant drugs, tuberculosis drugs and malaria drugs. However, TDF has interactions with adefovir, which is a drug used to treat hepatitis B, so TDF and adefovir should not be used together.

there is an interaction between PrEP drugs and alcohol or other drugs. However, adherence to PrEP users may be greatly affected while using alcohol or other drugs.

2.6 An enabling environment for PrEP

Based on the health system framework of the World Health Organization (WHO), every health facility system needs to facilitate an enabling environment so that health facilities can run effectively. Likewise with the PrEP program, a supportive environment is needed so that this program can run well. An enabling environment for the PrEP program can be created under the following conditions:

- The attitudes and behavior of health workers are inclusive, non-stigmatizing and non-judgmental, and promote the safety and equality of service users. Service delivery is carried out centered on the service recipient (in this case the PrEP user) thereby enabling PrEP users to make decisions independently after being well informed regarding the PrEP program.
- Availability of the necessary medical products and technology to enable health workers to administer PrEP effectively optimally according to program management.
- Availability of information regarding health programs (in this case the PrEP program) so that they can be disseminated and used for program activities such as promotion, education and counseling activities. Information must be reliable, accurate and trustworthy so that it can help service beneficiaries understand the benefits and impacts they may receive from the program.
- Health interventions accessible by easily by PrEP targets.
- Budget allocation and financing strategies that support achieving good health *outcomes*, universal health coverage and cost effectiveness program.
- Policies, regulations and operational incentives that consider and support an enabling environment for beneficiaries of the PrEP program. Creating an enabling environment requires coalition building in various sectors – including collaboration and involvement from the target community

PrEP users, for example communities/NGOs of key HIV AIDS populations.

To support the achievement of a supportive environment, health workers provide

PrEP should:

- Prescribe treatment regimens that are proven to be safe and effective for people who are not infected with HIV and meet the criteria recommended to reduce the risk of HIV transmission.
- Educating PrEP users about medication and regimens to maximize safety.
- Provide medication adherence support to help PrEP users achieve and maintain their level of medication protection.
- Provide HIV risk reduction support and prevention services or referral services to help PrEP users minimize their exposure to HIV.
- Provide effective contraception for women using PrEP.
- As a strategy to support the long-term health of PrEP users, it is necessary to monitor the presence of HIV infection, drug toxicity, and the level of risky behavior so that it can indicate changes in these users.

2.7 The difference between PrEP and PEP

PPP stands for Post Exposure Prophylaxis. In English, PPP is also known as PEP, namely *Post-Exposure Prophylaxis*. If PrEP was used before HIV exposure, PPP is used after a person has been exposed to HIV. PPP is an effort to prevent HIV infection by taking prescribed drugs after a person is exposed/exposed to HIV or experiences conditions that put him at risk of HIV infection within 72 hours.

The following are a number of conditions that put a person at risk or exposed to HIV and need to be advised or referred for PPP services, namely:

- Having unsafe sex with PLWHA (people living with HIV AIDS), for example having sex without using a condom or breaking the condom during sex.
- Using the same syringe or used by PLHIV.
- Experiencing rape.
- Medical accidents that usually occur to health workers are when the blood, semen, vaginal fluids or breast milk of someone infected with HIV enters the bloodstream of the health worker. For example, being accidentally stabbed with a used syringe while examining someone who is infected with HIV.

PPP is carried out by using antiretroviral drugs (ARV) and drug prescriptions are carried out by health workers. PPP should be continued for 4 weeks, but may be discontinued if there are severe side effects.

PPP is for emergency situations only. Therefore:

- PPP is only given if someone is exposed/ exposed to HIV.
- PEP is not a substitute for other HIV prevention routinely used.
- PEP is not an appropriate HIV prevention option for people who may be frequently exposed/exposed to HIV.
- If someone is at ongoing risk of being exposed/ exposed to HIV it is better to use

PrEP.

Implementation Program PrEP

03

3. IMPLEMENTATION OF THE PrEP PROGRAM

3.1 Model for implementing the PrEP Program

The implementation of the PrEP program in Indonesia is focused on providing services in health facilities, but still with the support and cooperation of 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:

Table 3.1 PrEP Implementation Model in Indonesia

	Before Starting PrEP		Start PrEP	PrEP continuation	
	Promotion and Education	Filtering / Screening	Visit First	Visit Repeat First	Visit Repeat
When (Frequency)	During the development of the PrEP program	Day 0	1st day	1st month	3rd month and routine every 3 months thereafter or incidental
Where (Location)	Communities, health facilities, web/applications PrEP	Community, health facility/ PDP, web/app services PrEP	PDP health facilities/services		
Who (Executor Service)	Outreach workers/peer educators in the community or HIV counselors in PDP services	Outreach workers/peer educators in the community, health workers (doctors, nurses, lab workers, RR officers)	Health workers (doctors, nurses, lab workers, pharmacists, RR officers)	Health workers (doctors, nurses, lab workers, pharmacists, RR officers, counselors HIV/peer educators)	
What (Package Service)	Package K.I.E. about PrEP (PrEP promotion & education)	Screening form/ screening, test HIV, tes IMS, tes HBsAg & Hep C, tes creatinine	Willingness to start form PrEP, PrEP medication, counseling & education usage PrEP	Administration of PrEP medication, side effect check, adherence assessment, counseling risk reduction).	Your HIV, your IMS, tes Creatinine (by criteria, every 6 months), PrEP drug administration, side effect checking, compliance assessment, couns risk reduction).
How (Gift Service)	Campaign on social media, through the community	On site meetings, App/Website for recording and Reporting			

3.2 PrEP Program Service Packages and Referrals

The PrEP program in Indonesia consists of a package of services provided by health facilities. It is best if all packages can be provided from the same health facility, but if it is not available but based on the assessment of the health worker it is needed, then it must be referred to the health facility that provides it. Services that can be referred are for example laboratory services, medication, care, assistance, counseling or provision of certain drugs.

3.2.1 PrEP Promotion and Education Activities

PrEP promotion and education activities are activities to introduce and provide information about the PrEP program to key HIV population groups and individuals at risk of HIV infection such as serodiscordant couples. Promotion and education regarding the PrEP program for those who are at high risk of being infected with HIV is expected to encourage these people to access and use PrEP as an effort to prevent HIV. This activity can be carried out based on recruitment sources for potential PrEP users, namely community-based and health facility-based as follows:

Community	Medical facility
<p>Communities can assist initial recruitment to the PrEP program by carrying out promotional and educational activities for key HIV populations that they reach, especially key populations who are at substantial risk. In this promotional and educational activity, the community can provide communication, information and education (IEC) packages regarding PrEP in written form as well as educational meeting activities held by the community. If anyone is interested in using PrEP from the promotional and educational activities carried out, the community can direct that person to start accessing PrEP through an application or come directly to a service that provides PrEP programs.</p>	<p>Health workers in health facilities, especially in health facilities that have PDP services, can carry out promotion and education about PrEP to clients in health facilities who meet the target criteria for PrEP. VCT clients and serodiscordant couples who access HIV services at health facilities can also be targets for PrEP promotion. In carrying out promotional and educational activities, health workers can use the IEC package regarding PrEP. If a potential user is interested in PrEP, health workers can direct the person to carry out the PrEP screening stage.</p>

Points related to material for promotional and educational activities can be seen in table 3.2 and a more complete explanation of these points (IEC packages) can be seen in Appendix 2 of this guideline.

Table 3.2 Points of Promotional and Educational Materials	
Points that can be included in PrEP promotional and educational materials include:	
A. Basic PrEP Information	B. Points to Emphasize on PrEP Users
<ul style="list-style-type: none">• Understanding PrEP• PrEP goals & criteria for PrEP users<ul style="list-style-type: none">• PrEP effectiveness• PrEP and its relationship to STIs<ul style="list-style-type: none">• Locations to access PrEP• Risks or side effects of PrEP• Differences between PrEP, PPP and ART• The importance of continuing to do HIV prevention other than using PrEP• Starting and stopping PrEP	<ul style="list-style-type: none">• Rules for PrEP use and the importance of compliance• Medical conditions that need to be considered in the use of PrEP• PrEP does not provide protection from other STIs other than HIV• PrEP is not birth control• How to store PrEP medication

3.2.2 Risk Behavior Screening

Risk behavior screening is carried out by prospective PrEP users to thoroughly check the eligibility of the person concerned in using PrEP by providing an assessment of his behavior and risk for contracting HIV. This risk behavior screening uses a questionnaire consisting of questions related to risky sexual behavior, number of sexual partners, history of STIs and HIV status and HIV treatment conditions of sexual partners (see table 3.3). To facilitate filling out the questionnaire, a digital-based questionnaire will be used. However, if there are problems in the field, a paper-based questionnaire can be used (see form 1 in the attachment) which then still needs to be transferred to a digital format. This screening can be carried out independently by prospective PrEP users or guided by peer educators or accompanying health workers. The stages of filling out this questionnaire are also the beginning of the process of recording data on prospective users

PrEP.

Table 3.3 Risk Behavior Screening Questionnaire

In the last 3 months:				
1	How many people have you had vaginal or anal sex with?	Male Partner: a. 0 b. 1 c. 2 d. 3 e. If more than 3, please specify:___	Female Pair: a. 0 b. 1 c. 2 d. 3 e. If more than 3, please specify:___	
2	Do you use a condom every time you have sex?	Can	No	Don't know
3	Do you have a sexually transmitted infection?	Can	No	Don't know
4	Do you have a sexual partner who has HIV and are planning to become pregnant OR do you not consistently use a condom when having sexual intercourse with that partner?	Can	No	Don't know
			Continue to question no. 5	
	a. If "Yes", has he been on antiretroviral therapy?	Can	No	Don't know
	b. If "Yes", has he used ARVs regularly in the last 6 months?	Can	No	Don't know
	c. If "Yes", is the viral load count known?	Can	No	Don't know
	d. If "Yes", has the HIV been suppressed (viral load < 1000 copies / ml) after 6 months of treatment?	Can	No	Don't know
5	Have you used PrEP or PPP before?	Ever been		Never
6	Did you use a condom the last time you had sex?	Of		No
7	On average in 1 week how many times do you have sex?	1 time		If more than 1 time, state the amount: ___

The answers to the risk behavior screening questionnaire have a weight value of 0 and 1. The total value of each answer will be added up so that the result of this questionnaire is a score between 0 and 8. However, for questions number 4, 6 and 7 there is no weighted value. For number 4, there is an indication of substantial risk in the next question, namely numbers 4a to 4d, so the weighted scores are on numbers 4a to 4d. Numbers 6 and 7 are additional data that will be used to monitor risky behavior.

Based on the score of this questionnaire, it will be known whether prospective PrEP users have a greater risk of contracting HIV so that it is considered appropriate to use PrEP as an effort to prevent HIV or vice versa. The following is a table of weight values/scores for the risk behavior screening questionnaire.

Table 3.4 Risk Behavior Screening Questionnaire Response Score

Number Question	Score	Answer	Score	Answer
Number 1	Will get a score of 0, if answered:	0 & 1 male and/ or 0 & 1 women	Will get a score of 1, if answered:	2, 3 & over 3 male and/or 2, 3 & over 3 women
Number 2		Can		No & Don't know
Number 3		No		Yes & Don't know
Number 4	There is no value weight. Indications of substantial risk are in questions 4a through 4d.			
Number 4a	Will get a score of 0, if answered:	Can	Will get a score of 1, if answered:	No & Don't know
Number 4b		Can		No & Don't know
Number 4c		Can		No & Don't know
Number 4d		Can		No & Don't know
Number 5		Never		Ever been
Number 6	There is no value weighting. Additional data for risk behavior monitoring. Does not indicate substantial risk.			
Number 7				

For individuals who get a score of 0, it means that the person does not have a higher risk of being infected with HIV or does not have a substantial risk that they do not meet the criteria for using PrEP. However, individuals who get a score of 0 will still be advised to use other prevention methods such as using condoms consistently, being faithful to one sex partner, and others.

Whereas for individuals who get a score of 1 to 8, it means that the person has 1 or more conditions that put him at higher risk of being infected with HIV (has a substantial risk) so he meets the criteria for using PrEP.

Table 3.5 Recommended Terms of Risk Behavior Screening

Total Score 0	"You don't meet the criteria for taking PrEP. You can use other HIV prevention methods (use condoms consistently, stick to 1 sex partner, etc.). Please visit the health service in your area to get information about these HIV prevention methods and find out your HIV status."
Total Shoes 1 - 8	"It is recommended that you use PrEP and please visit a service that provides PrEP programs in your area."

The results of this assessment are not the only consideration in deciding whether a potential user should start using PrEP. These risk factors need to be explored further when conducting pre- and post-HIV testing counseling in health services to help potential users and health workers make the decision to start using PrEP.

The risk behavior screening questionnaire will be repeated every 3 months after starting PrEP to monitor any changes in behavior at risk of contracting HIV in the PrEP users concerned. The results of filling out this questionnaire can be used as a consideration in deciding whether to stop using PrEP or make changes to regimen choices, for example from daily regimens to PrEP-ED or vice versa. In addition, these results can also be used to determine whether the user concerned needs to receive HIV transmission risk reduction counseling services or switch to a more appropriate HIV prevention strategy.

3.2.3 Laboratory Tests for PrEP

Prospective PrEP users will need to carry out several laboratory tests to see medical eligibility related to HIV status and PrEP contraindications before starting to use PrEP. This laboratory examination helps health workers determine when prospective PrEP users should start PrEP. In addition, the results of this examination can also determine other treatments that potential users must take before starting or concurrently using PrEP.

The lab tests that will be carried out are an HIV test, an STI test, a Hepatitis B test, a Hepatitis C test, and a Creatinine test. Some of these tests are a requirement for starting PrEP, need to be retested within a certain time, and some need to be done but are not a requirement for starting PrEP. In the PrEP service flow, this laboratory examination is at the medical eligibility screening stage.

Table 3.6 Laboratory Tests for PrEP

Tes Lab	Test Description	Test Result Description
HIV	service standards	Be a prerequisite for PrEP
IMS	Syndromic examination and simple laboratory tests	Not a prerequisite for PrEP but should be done
Hepatitis B (HBsAg)	service standards (paid by the program)	Prerequisite for PrEP for potential MSM users choosing a PrEP-ED regimen
Hepatitis C Service	service standards (not covered by the program)	Not a prerequisite for PrEP but should be done
Creatinine	service standards (paid by the program) If the service has facilities for checking serum creatinine, the results of the creatinine examination are converted to a renal clearance rate/ <i>Creatinine clearance</i> using the <i>Cockcroft-Gault formula</i> .	Not a prerequisite for PrEP but needs to be done for prospective users according to indications*

* Indications for creatinine testing: over 30 years of age or under 30 years of age who have hypertension and/or diabetes.

The following describes each test in the laboratory testing package for PrEP.

HIV test. As a form of prevention, PrEP can only be given to someone who is HIV negative but is in a situation that puts him at a higher risk of contracting HIV. Therefore, it is very important to have an HIV test done before someone can start taking PrEP.

PrEP users will undergo HIV counseling and testing at the medical eligibility screening stage and return visits every 3 months to confirm their HIV status. At the medical eligibility screening stage, if the HIV test results show a negative result then the potential user can start taking PrEP. However, if the test shows a positive result, the potential user will be referred to an ARV therapy service. Likewise, during the return visit, the user can continue PrEP if the HIV test shows a negative result.

In the PrEP program, the negative HIV status of prospective PrEP users must be confirmed from the results of an HIV test conducted during the candidate's period.

users access the PrEP program. If before accessing the PrEP program the prospective user has taken an HIV test, the prospective user must still undergo the HIV test procedure in the PrEP program.

2 STI test. Examination and treatment of STI is an important thing to do when starting or while taking PrEP. If a potential PrEP user is detected to have an STI, the potential user can start PrEP simultaneously with STI treatment according to existing guidelines. An STI test also needs to be done at a return visit every 3 months. STI screening can be done based on a syndromic approach and simple laboratory tests, including syphilis, which are available at health facilities.

If the results come out positive, then appropriate treatment is given, or referred to a health facility that has STI services. The components of STI management include anamnesis history of infection/disease, physical examination and collection of specimens, diagnosis, ending with appropriate treatment.

Hepatitis B (HBsAg) and Hepatitis C are necessary
3 Tests for Hepatitis B and Hepatitis C Tests

and if the result is positive is not a contraindication to starting PrEP. Hepatitis B (HBsAg) testing is preferred for prospective users from the MSM risk group who choose the PrEP-ED regimen. This is because a person with Hepatitis B should not use this regimen. The drug used for PrEP (*Tenofovir Emtricitabine*) is also active in suppressing the Hepatitis B virus, so if it is not taken regularly every day it can cause relapse. HBsAg examination can be carried out using a rapid test at the service with a fee borne by the program. While the Hepatitis C test is carried out to find Hepatitis C cases in order to increase the coverage of the Hepatitis C (*Direct Acting Antiviral*) treatment program .

DAA) which has also been provided by the government. Because these two tests are not prerequisites, the absence of Hepatitis B and C screening does not prevent starting PrEP.

and **Creatinine Monitoring.** The results of the creatinine examination
4**Tests** at the screening stage do not determine whether a person can take PrEP or not, but is needed to monitor the condition of kidney function before and after starting the PrEP program. Decreased kidney function as indicated by a renal clearance rate (*creatinine clearance*) <60 ml/minute is a contraindication to the use of PrEP containing TDF. Creatinine screening can be done before starting PrEP or it can also be done no later than 1 month after starting PrEP for PrEP users with the following criteria:

1. A 30 year old prospective PrEP user or older
2. Prospective PrEP users under 30 years of age, with comorbid diseases related to kidney function, such as diabetes and/or hypertension

Creatinine monitoring after taking PrEP is carried out every 6 months (routine visits at 6 and 12 months after starting PrEP), with the following conditions:

1. PrEP users with a renal clearance rate of <60 ml/minute, need to repeat the creatinine test 1-2 days later. If the creatinine retest still shows a renal clearance rate of <60 ml/d minutes then can not continue PrEP.
2. PrEP can be restarted if it is confirmed that the renal clearance rate is >60 ml/min at 1 to 3 months after stopping PrEP. The rate of renal clearance usually returns to normal after stopping PrEP, but if it does not return to normal after stopping PrEP it is necessary to consider other causes, such as diabetes and hypertension. In this condition it is necessary to be referred to an Internal Medicine Specialist.

Individuals over 50 years of age with a renal clearance rate of <90 ml/minute and with comorbid diseases such as diabetes and hypertension are more likely to experience a decrease in kidney function.

However, systematic reviews and meta-analyses of patients from programs that have been implemented globally show that only 1% of individuals who receive creatinine screening have renal clearance rates that are below normal (WHO, 2021). In other words, it is likely that the number of PrEP users who experience impaired kidney function will be small, however this monitoring still needs to be done.

The results of serum creatinine (mg/dL) can be converted into renal clearance rate/ *creatinine clearance* (ml/ minutes) using the following *Cockcroft-Gault* formula:

$$\text{Creatinine clearance} = \frac{[(140 - \text{age (years)}] \times \text{body weight (kg)}]}{[72 \times \text{serum Cr (mg/dL)}]}$$

(multiply by 0.85 for women)

3.2.4 Counseling

The use of PrEP is related to behavior, therefore to help ensure that the use of PrEP can be carried out optimally, counseling is necessary under certain conditions. Counseling on the PrEP program will be provided at the return visit stage. The following is counseling related to the use of PrEP:

Table 3.7 Indications for Counseling on Return Visits		
Condition	Indication	Follow-up
Inappropriate remaining amount of PrEP medication. PrEP adherence is poor		Compliance Counseling
STI test results indicate the presence IMS	Inconsistent condom use/ behavior increases the risk of HIV transmission	Risk Reduction Counseling
The Risk Behavior Screening indicates (one or more of the following): <ul style="list-style-type: none">• More than one sexual partner• Number of sexual partners increased compared to 3 months ago• Did not use a condom in the last sexual intercourse (through the anus/vagina).• In one week on average risky sexual intercourse performed more than once	HIV risk behavior increased or there was no change when compared to risk behavior reported in the previous 3 months	Risk Reduction Counseling
PrEP users request counseling. There are complaints or problem using PrEP		Risk Reduction Counseling or Compliance Counseling (according to the needs of PrEP users)

A. Risk Reduction Counseling

The use of PrEP is a way to complement and strengthen other HIV prevention methods that are already present in HIV prevention programs such as using condoms and reducing risks. Therefore, the understanding and efforts of PrEP users to continue to carry out behaviors that will reduce their risk of contracting HIV must be continuously encouraged and maintained. For this reason, risk reduction counseling needs to be carried out during the period of PrEP use. This needs to be done so as not to create differences in perceptions that by using PrEP, risky sexual behavior can be carried out more freely by PrEP users.

Things that need to be considered regarding the implementation of risk reduction counseling include:

- Performed at every return visit (once every 3 months) along with HIV and STI tests.
- The results of both tests can be used to evaluate risky behavior by PrEP users and to inform risk reduction counseling. Encourage PrEP users to continue maintaining behaviors that can reduce their risk of contracting HIV.
- If the results of the STI test performed show positive results, then encourage immediate treatment and provide counseling that leads to things that can be done by PrEP users so as not to be re-infected.
- If the HIV test results show positive results, then refer and direct them to start ARV therapy immediately.

B. Compliance Assessment and Compliance Counseling

Compliance plays a very important role in achieving optimal results in using PrEP. Adherence counseling aims to help ensure users can comply in using PrEP by taking medication according to the rules every day, identify if there are obstacles encountered, and assist in overcoming these obstacles.

To assist in assessing adherence to PrEP users, the daily regimen can be calculated as follows:

Compliance =

Number of pills given at last visit - Amount remaining

The number of pills given at the last visit

x 100%

Table 3.8 Conditions for Compliance Assessment Results		
Result conditions	< 95%	Poor Compliance
	≥ 95%	Good Compliance

Compliance counseling services are carried out under the following conditions:

- When PrEP users openly ask for this counseling because they face obstacles in carrying out the program PrEP
- Has an indication of poor compliance
- PrEP users who get the results calculated low compliance.

The key components of PrEP adherence counseling are:

- Creates a sense of trust and two-way communication
- Provide simple explanations and education to PrEP users regarding:
 - Schedule and dosage of medication to be taken
 - Management of possible side effects
 - Information regarding the relationship between adherence and PrEP success
 - Symptoms and signs of IHA (Acute HIV Infection) and what to do
- Support PrEP user compliance by:
 - Observe patient compliance without prompting judgmental attitude.
 - Identify factors that hinder adherence, and work with PrEP users to develop a plan to overcome these barriers.
 - 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 they are taking each day's medication at the correct dose is important for maximum protection.
 - Help make a schedule and or ways that can help PrEP users prevent forgetting to take their medication schedule.
 - Discuss side effects and how How to fix it.
 - Support users' success in maintaining compliance with taking their medication.

3.2.5 References

Referrals are given to PrEP users only under certain conditions, namely when PrEP users need/require them. To make it easier for PrEP users, networks and access to these referrals need to be built and maintained properly.

A. Circumcision Reference

Circumcision is a procedure for removing the foreskin of the penis. One of the benefits of male circumcision is that it can reduce the risk of sexually transmitted infections (STIs), including HIV. Since 2007, the World Health Organization (WHO) has recommended circumcision as a preventive measure against HIV for men. Research conducted by WHO shows that circumcision can reduce the risk of transmitting STIs from women to men by up to 60% (WHO, 2012). To get circumcision services, male clients can visit health clinics or hospitals that provide circumcision services. Several puskesmas also provide circumcision services.

B. Reference to Gender Based Violence (KBG)

Violence experienced by potential users or those who are already using PrEP can influence their decision to start, continue or affect their adherence to using PrEP. HIV key groups, especially female sex workers (WPS), transgender, and men who have sex with men (MSM) are vulnerable to experiencing gender-based violence (KBG) from partners (referred to as “*intimate partner violence*”), family, living environment, work environment or even from the information and health services they access. BEC is a term used to describe various forms of acts of violence that endanger or result in suffering to a person, which are carried out based on social differences including male and female gender, which can result in physical, sexual, psychological suffering, and/or neglect including in the form of threats, coercion and various other forms that deprive a person of freedom, both in public/public spaces and in private life” (IASC, 2015). The impact on each victim/survivor of violence varies, depending on the characteristics of the traumatic event and the appreciation of the victim/survivor himself, which also depends on personality, age, gender and background (upbringing style, previous traumatic experience, socioeconomic level, culture), as well as presence/absence of family/social support.

In the context of HIV prevention and control, the existence of stigma and discrimination felt by key groups of HIV survivors of BECs can prevent them from accessing HIV services, such as carrying out HIV tests, starting treatment or maintaining ARV adherence for those living with HIV (ODHIV). Likewise in the PrEP program, the impact of BEC on potential users and PrEP users from key groups will affect the user's success in accessing information services, initiating, and adhering to PrEP treatment.

Therefore, health workers need to recognize the forms of birth control that potential candidates and PrEP users may experience. Forms of BCG that health workers may encounter in potential PrEP users and/or PrEP users include:

- a. **Sexual Violence**, such as rape, slavery and/or sexual trafficking, sexual harassment, sexual exploitation and/or abuse and forced pregnancy or abortion.

In addition to having physical, psychological and social impacts, forms of sexual violence have an impact on reproductive health such as unwanted pregnancies (KTD), pregnancy complications and miscarriages, STIs, HIV and AIDS.

- b. **Physical Violence**, namely actions that hurt the body and can result in injury, pain and physical disability or even death.

- c. **Psychological Violence**, is an act that causes mental or emotional suffering, such as trauma, depression, anxiety, fear or excessive anger, shame or self-loathing, to suicidal intentions and behavior.

- d. **Economic Violence**, can be either not economic neglect, such as providing proper financial support, preventing someone from earning an income, and preventing someone from using the property they are entitled to.

- e. **“Harmful practices”** which are forms of gender inequality and discriminatory social, cultural and religious norms, as well as traditions, which relate to a person's position in the family, community and society to control his freedom, including his sexuality.

If peer counselors or health workers find potential users or have used PrEP who are suspected of or admit to experiencing gender-based violence, they can refer the victim/survivor to the necessary services with the consent of the person concerned for further assistance.

Either peer counselors or health workers can contact the services needed by victims/survivors of violence to the following institutions

This:

1. Local police
2. Family Learning Center (PUSPAGA) at city/regency level
3. Integrated Service Center for the Empowerment of Women and Children (P2TP2A) at the City/District level
4. Regional Technical Implementation Unit for the Protection of Women and Children (UPTD PPA) at the Provincial level
5. Witness and Victim Protection Agency (LPSK)
6. Community Social Institutions (NGOs) that network with government agencies in providing assistance services for victims of violence.

It should be noted that in assisting potential users or already using PrEP as victims/survivors of BECs, the following principles must be observed: 1. Pay attention to the confidentiality of victims/survivors

2. Giving trust to the victim/survivor
3. State that the violence they face is not their fault
4. Ensure security
5. Respect the rights of victims/survivors to make decisions that are considered the best for them when they are able to think clearly

C. Referrals to Drug Abuse and Mental Health Issues

Injecting drug users (IDU) are not specifically discussed in this guide, because the main prevention strategies for IDU are Sterile Injecting Equipment Services (LASS), Methadone Maintenance Therapy (PTRM) and Educational Information Communication (IEC) as well as outreach to key groups. To complement HIV prevention strategies, PrEP is recommended to be part of a more comprehensive prevention package for IDU.

If during counseling practice or screening before starting PrEP it is known that potential users or those who use PrEP have drug abuse problems or other mental health problems that can affect adherence to PrEP use, then health workers can refer PrEP users to behavioral counseling service programs or mental health services/

psychotherapy or social services and services to help reduce the risk of injecting drug use or other mental health problems.

Some of the services available and accessible specifically for drug abuse problems are as follows:

1. The LASS program at the nearest health center or hospital
2. PTRM services at the nearest puskesmas or hospital
3. Pratama clinic BNN (National Narcotics Agency)
4. Referral services for other mental health problems (Psychiatry clinic, Psychologist practice, or the nearest Mental Hospital)

D. Reference for Reproductive Health

Referrals related to reproductive health consist of referrals for contraception needs, pregnancy tests, and STI tests. A pregnancy test is done for women every three months. Even though pregnant and breastfeeding women are not contraindicated with PrEP, a pregnancy test will still be carried out to make decisions related to pregnancy and the fetus if the woman continues to use PrEP during pregnancy until breastfeeding.

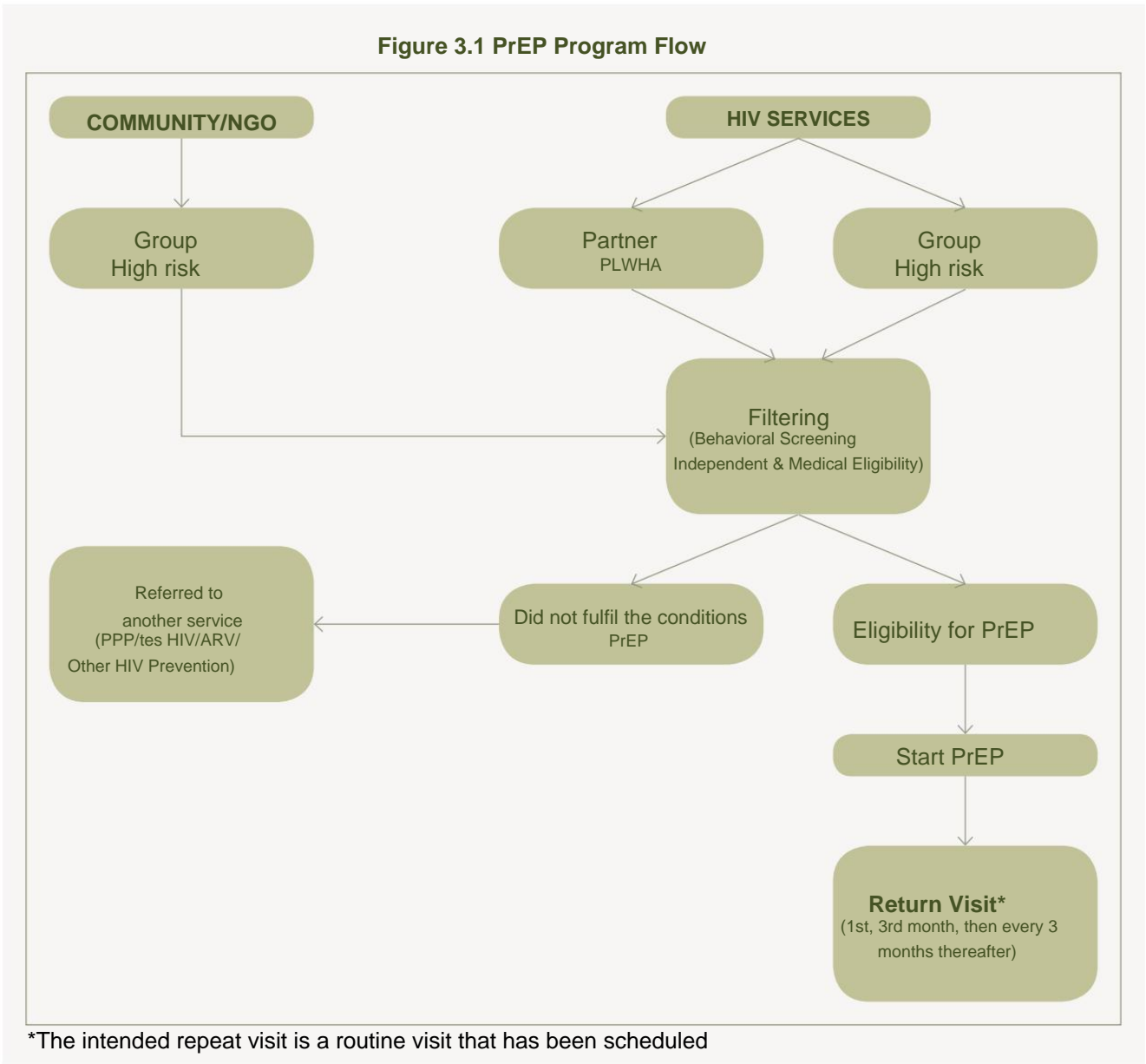
For women who are on PrEP and are sexually active but do not wish to become pregnant, effective birth control can be provided to be used alongside the PrEP regimen they are currently using (CDC, 2018). In addition to contraception options for women who are sexually active, the PrEP package also consists of providing condoms and lubricants, which are primarily intended for users who are MSM.

3.3 Management of the PrEP Program

The management of the Indonesian PrEP Program will be explained in the following flow form.

3.3.1 PrEP Program Flow

In brief, the flow of the PrEP program can be seen in Figure 3.1. There are several stages that potential users must go through before getting PrEP and participating in the entire series of the Indonesian PrEP Pilot Program.



The following is an explanation of each stage in the PrEP program flow.

1. Initial Recruitment to Community and Services HIV

The recruitment phase aims to invite and involve individuals who are at substantial risk or individuals at higher risk of infection with HIV (PrEP targets) to use PrEP. The main activity at the recruitment stage is the promotion and education of PrEP by health workers in HIV services and peer educators in the community. After being given information about PrEP, it is hoped that the PrEP target will be interested and willing to use PrEP as an HIV prevention effort. If PrEP targets or potential PrEP users are interested and willing to use PrEP, health workers and peer educators can direct the person to carry out the screening stage.

2. Screening (Independent Risk Behavior Screening & Medical Eligibility Screening)

The screening stage aims to find out whether a person is eligible or not eligible for PrEP. In this stage, there are two core activities that prospective PrEP users go through, namely:

a. Risk Behavior Screening

Before starting PrEP, potential users who are interested in using PrEP will first be directed to screen through the PrEP application. This screening is done to see if someone has a greater risk/

substantial risk of being infected with HIV. Screening was carried out using a questionnaire regarding risky behavior online. Prospective PrEP users can carry out this screening independently, or be guided by a health worker (counselor

HIV) in health facilities, or Peer Educators in the Community. Individuals who are recommended to receive PrEP from the screening results will then be asked to come to the nearest PrEP provider health service to undergo medical eligibility screening. Risk behavior screening results will be recorded in the online PrEP application system.

Note: If the online questionnaire has not or cannot accessed, potential PrEP users will fill out a questionnaire in paper form. Fill in the questionnaire This paper will be transferred to the online questionnaire so that the results and data of potential PrEP users can be stored safely.

b. Medical Eligibility Screening

Medical eligibility screening is carried out on prospective PrEP users who are considered to have a greater risk (substantial risk) based on the results of the risk behavior screening that has been carried out. This stage consists of a series of tests that are performed to assess the individual's eligibility to receive PrEP medically. All tests in this phase are carried out at PDP services implementing the PrEP Pilot Program in Indonesia. The results of the medical eligibility screening will be recorded on the online PrEP application.

Some of the tests carried out are:

- HIV testing for all potential PrEP users. An NR (Non Reactive) test result is a prerequisite for starting PrEP. Someone who gets an R (Reactive) result cannot get PrEP and will be referred to an ARV service.
- STI screening for all potential PrEP users. The results of an STI examination are not a prerequisite for starting PrEP, but individuals who are known to have an STI will be referred for treatment.
- Hepatitis B screening for all potential PrEP users. The results of the NR (Non Reactive) Hepatitis B test are a prerequisite for starting PrEP for prospective PrEP-ED users. The results of R (Reactive) in this examination will be a reference for treatment.
- Hepatitis C screening for all prospective PrEP users. The results of these tests are not a prerequisite for starting PrEP and will only be part of the national data.

- Creatinine screening for all candidates
PrEP users aged 30 years and over, and prospective PrEP users under 30 years of age who have a history of comorbidities such as hypertension and diabetes. A creatinine examination is carried out to see creatinine clearance levels of potential PrEP users. Creatinine clearance <60 ml/ minutes means one cannot start/ continue PrEP and will be referred to an Internal Medicine Specialist. Creatinine clearance will also continue to be monitored while undergoing the PrEP program.

Apart from being examined/tested, in this screening prospective PrEP users will also be asked about possible indications of acute HIV infection (IHA). Acute HIV infection is the initial stage of HIV infection, when the virus has just entered a person's body. Signs of IHA usually appear soon after a person engages in risky behavior with another person who is infected with HIV.

This can last up to 14 days after HIV exposure.

The presence of IHA can be seen from the following symptoms:

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

An individual with IHA should not take PrEP. To see this, there are two assessment questions that are given during the medical eligibility screening, to ensure that potential PrEP users are not in the window period.

The questions asked were related to the potential PrEP user's last risky sexual behavior, as well as possible IHA symptoms in the last 3 days. If it is indicated that you have IHA, the process of starting PrEP will be postponed, after which the prospective user concerned will be referred to the PPP (Post-Exposure Prophylaxis) service.

3. Starting PrEP

Once declared medically fit, prospective PrEP users can immediately start PrEP at the service. This stage involves consent from the prospective PrEP user to start PrEP and counseling regarding the PrEP medication that will be given.

This stage consists of several activity points, namely:

- Explaining the registration number to PrEP users. The registration number is obtained automatically from the PrEP application. This number will become the identity of the PrEP User, and will be used as long as they are still part of the program. PrEP User registration numbers are recorded in the national systemexamples of side effects that may be experienced by PrEP users along with codes for filling in the recording and reporting forms.
- Ensure potential users are well informed about the Indonesian PrEP Pilot Program, and agree to start PrEP. Prospective users will sign an informed consent as a condition of starting PrEP.
- Determine the regimen to be used by PrEP users. All prospective PrEP users will be on a daily regimen, except PrEP users from the MSM group. PrEP users from the MSM group who do not have Hepatitis B and have sexual intercourse no more than once a day a week, can choose an Event-Driven (ED) regimen, and will go through specific stages for users of the ED regimen which will be explained further in this guideline.
- Administration of drugs to PrEP users by pharmacists in health facilities. Each PrEP user will receive one vial of 30 pills when starting PrEP. The next drug administration is scheduled for the first return visit one month later (for daily regimen users), or when the drug given is about to run out (for ED regimen users).
- Explanation of dosage and time to take medication by pharmacy staff at the service. The dosage for PrEP users will depend on the regimen used. For the daily regimen, PrEP users are required to take 1 pill of medication a day consistently, while the ED regimen is taken according to their risk behavior for HIV exposure.
- Ensure the user's readiness to comply with taking medication according to the dose given.
- An explanation of the risk of side effects and what PrEP users should do if they experience them. • Explanation of further procedures that must be followed and carried out by PrEP users consisting of:
 - a. Repeat visit, and
 - b. Periodic tests are carried out at every return visit

4. 1st Month Return Visit

Routine repeat visits to health facilities that provide the PrEP program are carried out in the first month after starting PrEP, with the aim of determining whether users will continue PrEP or stop it. The activities carried out in this activity are:

- Monitoring of drug side effects. PrEP users may experience side effects in the first months of taking PrEP. Side effects need to be handled properly because they can affect compliance, effectiveness and continuity of PrEP use, so they need to be identified as soon as possible and symptoms treated. The following are

Table 3.9 PrEP Side Effect Code

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

- Monitoring adherence to daily doses of PrEP users can be done by asking if there are missed PrEP doses and calculating the remaining PrEP drugs carried by PrEP users. Provisions for calculating drug residue can be seen in CHAPTER 3.2.2 HIV Counseling and Testing: Compliance Assessment and Compliance Counseling. • Counseling. If there are complaints or problems using PrEP, PrEP users can also receive counseling (risk reduction or compliance, as needed). Counseling will be very useful in providing support for PrEP users to be able to continue the PrEP program and maintain or improve adherence. • Drug taking. For daily dose PrEP users, at the 1st month return visit it is also to take the drug for the next dosing period (two bottles for two months) and schedule a return visit two months later (3 month repeat visit).

The following are some of the reasons that can cause a person to quit the PrEP program along with the quit reason code:

Table 3.10 Reason Codes for Stopping PrEP	
Reason Codes to Stop PrEP	
1 = PrEP regimen side effect	
2 = Severe illness, hospitalization	
3 = Out of stock of medicine	
4 = PrEP users experience financial problems	
5 = Feeling that you are no longer at risk of being infected with HIV	
6 = Switch to PrEP services/programs	

The results of the activities carried out during the return visit are recorded and reported using the Return Visit Form in digital or paper form. Filling out the form is carried out by the responsible health officer.

5. Repeat Visits Every 3 Months After Starting PrEP

Regular follow-up visits every 3 months are carried out to assess the process of undergoing the PrEP program and evaluate whether the recipient can continue or stop PrEP. Routine return visits to the health facility providing PrEP are recommended at the 3rd month, 6th month, 9th month and 12th month after starting PrEP. At this stage, PrEP use can be continued if there are no problems during PrEP use, stopped if there are reasons for stopping PrEP.

In routine repeat visits every 3 months, the activities that need to be carried out are:

- Monitoring of drug side effects, such as at Monthly Return Visits
the 1st.
- HIV test using standard tests available at health facilities.
If the test results are NR (negative), then daily dose PrEP users can continue using PrEP. If the HIV test results are reactive (positive), then PrEP must be stopped and immediately referred for ARV treatment.
- STI test. Periodic STI checks are carried out to monitor reproductive and sexual health conditions of PrEP users. The presence of an STI in PrEP users is not a reason to stop PrEP, but an evaluation of risky sexual behavior and inconsistent use of condoms in key HIV population groups, thus forming the basis for assessing the need for risk reduction counseling.
- Evaluation of Risky Behavior (within the last 3 months), using a risky behavior questionnaire. Completion of the risk behavior questionnaire (digital or paper form, as available) has previously been carried out at the PrEP Screening stage. Filling out the risk behavior questionnaire every 3 months after starting PrEP is an attempt to monitor any changes in risky behavior for HIV infection. Reduction in risky behavior may be the reason for discontinuing daily doses of PrEP or switching to PrEP-ED doses if the risk of transmission cannot be eliminated. An increase in risky behavior is an indication for counseling to reduce the risk of HIV transmission or the need to switch to a more appropriate HIV prevention strategy.
- Monitoring adherence to daily doses of PrEP users can be done by asking if there are missed PrEP doses and calculating the remaining PrEP drugs carried by PrEP users. Provisions for calculating drug residue can be seen in CHAPTER 3.2.2 HIV Counseling and Testing: Compliance Assessment and Compliance Counseling.

- Risk Reduction Counseling and Compliance

Counseling can be carried out based on needs or problems complained of. Counseling will be very useful in providing support for PrEP users to continue the PrEP program and maintain or improve their adherence. • Taking medication. For daily dose PrEP users, the 3rd month return visit is

used to take the drug dose for the next dosing period (three bottles for three months) and schedule a return visit 3 months later.

- The creatinine test is repeated at the 6th and 12th Month Return Visits for PrEP users who had a creatinine test when starting PrEP, ie those aged 30 years and older, and younger than 30 years of age with a history of hypertension and/or diabetes. If the serum creatinine result is converted to a creatinine clearance/kidney clearance rate of ≥ 60 mL/minute, you can continue PrEP. Creatinine Clearance Result/
Kidney clearance rate < 60 mL/min so the creatinine test needs to be repeated 1-2 days later. PrEP can be continued if the Creatinine Clearance/Kidney Clearance Rate result from the repeat test is ≥ 60 mL/min. However, if the re-test results do not increase the Creatinine Clearance/Kidney Clearance Rate, stop the PrEP and immediately refer to an Internal Medicine Specialist.

PrEP is continued if there are no problems during PrEP use, or stopped if there are reasons for stopping PrEP. The results of activities carried out during return visits are recorded and reported using the Revisit Form in digital or paper form.

Filling out the form is carried out by the responsible health officer.

Table 3.11 PrEP Implementation Flow

Deep stages Program	Main Activities/ must be done	Activity Additional	Expected results	Follow-up	Location	Executor who Involved	Supporting facilities
Initial Recruitment in Community and Service	Promotion and Education		Key HIV population groups receive basic information about appropriate and relevant PrEP.	Individuals who are potential and interested in joining the PrEP program may be encouraged to take part in the Screening Stage.	Service PDP	HIV counselor	Information media
					Community	Educator Peers, Officer Outreach	Information media
Filtering (Behavior Screening At risk Independent & Screening Medical Eligibility)	Behavioral Screening At risk Independent		Identify individuals who are at greater risk (substantial risk) of being infected with HIV	Individuals at greater risk (<i>substantial risk</i>) are advised to use PrEP, by first conducting a medical eligibility screening. Individuals who are not at high risk of HIV infection are advised of other prevention methods.	Service PDP	Candidate or PrEP users. Filled in independent or assisted by HIV counselor	Questionnaire section Screening Form Risk Behavior Screening
					Community	Candidate or PrEP users. Filled in independently or assisted by peer educators	
	HIV testing		NR (Negative) HIV test results are a condition for starting PrEP.	Prospective PrEP users who test negative for HIV can start PrEP. Reactive results (R) were unable to start PrEP and were referred to ARV services.	Service PDP	HIV counselors, doctors, nurses, lab workers	Screening Form; standard HIV test kits available in health facilities.
		Inspection IMS	Test results do not determine whether to take PrEP	If based on the results of the examination there is an STI, then the treatment of the STI and the use of PrEP can be done simultaneously.			Simple laboratory for STI.

		Inspection Hepatitis B (HBsAg)	The examination results are not decisive to follow PrEP, except for MSM who want PrEP-ED	Start PrEP. For MSM with a positive test result suggest daily PrEP. A positive result is a contraindication to PrEP ED			Standard (rapid) test kits are available at health facilities or refer to collaborating labs.
		Inspection Hepatitis C	The test results do not determine whether to follow PrEP	Hep C can be tested while starting PrEP. There are no contraindications, so you can start while waiting for the test results to come back.			Standard test tools available, convert results using formulas Cockcroft-Gault
		Inspection Creatinine	Testing can be delayed up to 1 month after starting PrEP. Outcomes are not decisive following PrEP.	If it is known that the Creatinine Clearance/Kidney Clearance Rate result is <60 mL/min, it is necessary to carry out routine Creatinine checks at the 6th and 12th months after starting PrEP.			
Start PrEP	Informed consent, Counseling		PrEP users sign informed consent. PrEP users agree to follow all PrEP processes including HIV testing regularly.	Return visit agreement. PrEP user data is entered in the recording and reporting system to be monitored for 1 year.	Service PDP	PDP doctors, pharmacists, officers RR	PrEP Starting Form, PrEP medication, information media
Return Visit First (1 Month after Starting)	Monitoring Side effects, Monitoring obedience, Taking medication PrEP	Reduction Counseling Risk and Compliance Counseling.	PrEP users can continue or stop taking PrEP	PrEP is continued if there are no problems during the use of PrEP, discontinued if there are reasons for stopping PrEP.	Service PDP	PDP doctors, pharmacists, officers RR	Return visit form, PrEP medication, information media, Counseling Guide

Repeat visit 3rd month after starting PrEP	your HIV, Effects Monitoring In addition, compliance assessment, Evaluation of risky behavior, Drug Retrieval	Tes IMS, Counseling Reduction Risk and Counseling Obedience	PrEP users can continue or stop taking PrEP	PrEP is continued if there are no problems during the use of PrEP, discontinued if there are reasons for stopping PrEP.	Service PDP	PDP doctors, pharmacists, nurses, lab staff, RR officer	Return visit form, PrEP medication, information media, standard HIV test kits available at health facilities, Simple laboratory for STIs, Guide Counseling
Repeat visit 9th month after starting PrEP	your HIV, Securities Monitoring In addition, compliance assessment, Evaluation of risky behavior, Taking Medication	Tes IMS, Counseling Reduction Risk and Counseling Obedience	PrEP users can continue or stop taking PrEP	PrEP is continued if there are no problems during the use of PrEP, discontinued if there are reasons for stopping PrEP. Creatinine clearance <60 m L/ minutes: Unable to continue PrEP and immediately refer to a specialist in internal medicine.	Service PDP	PDP doctors, pharmacists, nurses, lab officers, RR officers	Return visit form, medication PrEP, information media, standard HIV testing kits available at health facilities, Simple laboratory for STIs; standard Hepatitis B test kits available and convert the results to Creatinine Clearance/Clearing Rate Kidney, calculated using the formula Cockcroft-Gault, Counseling Guide
Repeat visit 12 months after starting PrEP	your HIV, Monitoring Side effects, Monitoring Obedience, Evaluation of risky behavior, Drug Retrieval	Tes IMS, Inspection Creatinine (with criteria), Counseling Reduction Risk and Counseling Obedience	PrEP users can continue or stop taking PrEP.	PrEP is continued if there are no problems during the use of PrEP, discontinued if there are reasons for stopping PrEP. Creatinine clearance <60 m L/ minutes: Unable to continue PrEP and immediately refer to an Internal Medicine Specialist.	Service PDP	PDP doctors, pharmacists, nurses, lab staff, RR officers	Return visit forms, PrEP drugs, information media, standard HIV test kits available at health facilities, simple laboratory for STIs; test kit Available standard Hepatitis B and . results are converted into results Creatinine Clearance/Cleanup Rate Kidney, calculated using the formula Cockcroft-Gault, Counseling Guide

3.3.2 Stopping and Restarting PrEP

PrEP is an effort to prevent HIV transmission in individuals who are at greater risk of contracting HIV due to their behavior. People can change, and so can their behavior, so if someone feels they no longer need PrEP then they can stop. PrEP is not an ARV so it should not need to be used for life.

PrEP use may be discontinued for the following reasons:

- The risk of HIV transmission is reduced due to changes in behavior or changing situations in the user's life.
- Having trouble ensuring compliance or frequently skipping drug time.
- Experiencing side effects that can not be overcome and interfere with activities daily.
- Blood test results show that there are adverse drug effects on the body.

With these changes, it can happen that someone starts taking PrEP, stops and then starts again. This is not a problem, as long as all procedures and ways to start and stop can be done properly.

Starting to use PrEP and then stopping will not cause the body to become resistant or cause the effectiveness of PrEP to decrease when you return to using PrEP. Starting, stopping and restarting can be done safely by PrEP users.

In stopping PrEP, the user must make sure to take the stopping dose, namely:

- MSM using daily regimen : 1 pill daily for at least 2 days after last sexual intercourse
- Non MSM using daily regimen : 1 pill daily until 7 days after last sexual intercourse

For MSM using the PrEP-ED regimen, even though there is no stopping dose, it is necessary to make sure to use the first dose and follow-up doses with the appropriate number of pills and time.

PrEP users who have stopped and want to restart PrEP need to do another HIV test, and must be sure they are free from PrEP contraindications. The procedure for restarting PrEP is as follows:

1. HIV test and check if the PrEP user is not experiencing IHA (Infection Acute HIV).
2. STI testing as baseline data, results do not determine PrEP use.
If there is an STI then the treatment can be given together with the administration of PrEP.
3. The creatinine test needs to be done for users who are > 30 years old or <30 years old and have comorbid diseases such as hypertension and or diabetes. PrEP users who stop because the results of a retest of the renal clearance rate/creatinine clearance (creatinine clearance) are <60 ml/minute, can restart PrEP 1-3 months after stopping PrEP provided that the results of the renal clearance rate/creatinine clearance have reached ≥60 ml/minute .
4. Test for hepatitis B and C. If you have done the test in the last 3 months, then can use the data from the test.

For consideration: WHO guidelines do not make recommendations about when PrEP users should be considered stopping PrEP or what procedures a PrEP user who has considered paused should need to restart.

In the PrEP pilot program in Indonesia, a PrEP user can restart PrEP by repeating the procedure and making sure the conditions for taking PrEP are met.

3.3.3 *Event-Driven Pre-Exposure Prophylaxis (PrEP-ED)*

There are two regimens for using PrEP, namely the daily regimen and the Event-Driven regimen (PrEP-ED). PrEP-ED is the use of medication only when the risk of contracting HIV is higher than at other times. With a shorter dose and time of use, PrEP-ED is currently only recommended for this group

MSM risk. This relates to the amount and time the drug can reach the anal area to optimally prevent transmission. The use of PrEP-ED in MSM has been shown to have high effectiveness, namely reducing the risk of HIV infection by up to 86%.

However, there are considerations regarding when MSM can take event-driven (ED) doses of PrEP, as listed in the following table:

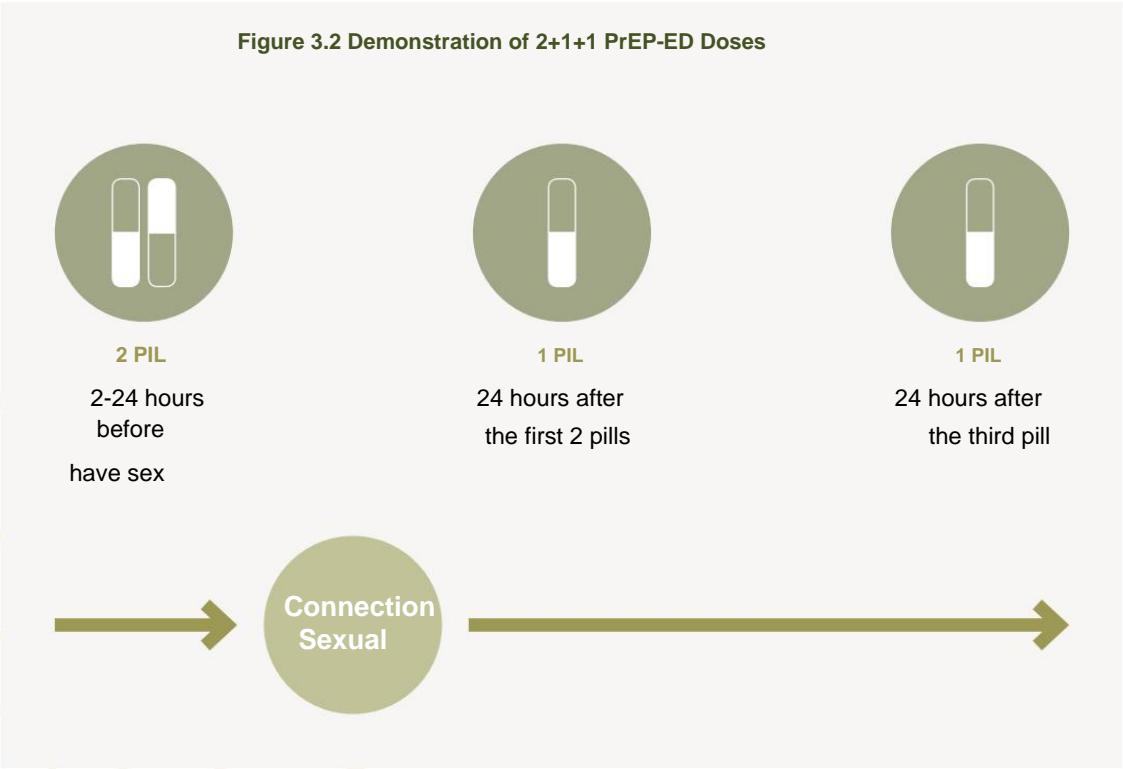
Table 3.12 When can PrEP-ED be considered

When can PrEP-ED be considered	
PrEP-ED is intended for:	PrEP is NOT intended for:
Men who have sexual relations with other men, who: <ul style="list-style-type: none">• Feeling that PrEP-ED is more effective and make it easier for him• Rarely have sexual intercourse (for example: once a week, or less)• Be able to plan sexual intercourse at least 2 hours in advance, or postpone sexual intercourse for at least 2 hours.	<ul style="list-style-type: none">• Women or transgender women/transpan• Male transgender people who have vaginal sexual intercourse• Men who have sexual relations with women, either vaginally or sexually anus• People with chronic hepatitis B infection.

A. *PrEP-ED dosage for men who have sexual relations with men (MSM)*

Event-driven Pre-Exposure Prophylaxis (PrEP-ED) for MSM consists of taking two doses (two pills, taken before intercourse) between 2-24 hours before exposure occurs; then one pill taken 24 hours after taking the first two pills, and one pill taken 48 hours after the first two pills. This dosage makes the PrEP-ED dose known as the “2+1+1” dose. This 2+1+1 dose is the dose that has been shown to be effective in reducing the risk of HIV infection in MSM.

The “2+1+1” dose in PrEP-ED can be adjusted if sexual intercourse continues after the first sexual intercourse. If sexual intercourse occurs after taking the first two pills, one of each pill can be taken daily as long as sexual intercourse continues. PrEP-ED can be stopped by taking one pill each for two days after the last sexual intercourse.



B. Benefits of Using PrEP-ED in Men Who Having Sexual Relations with Men

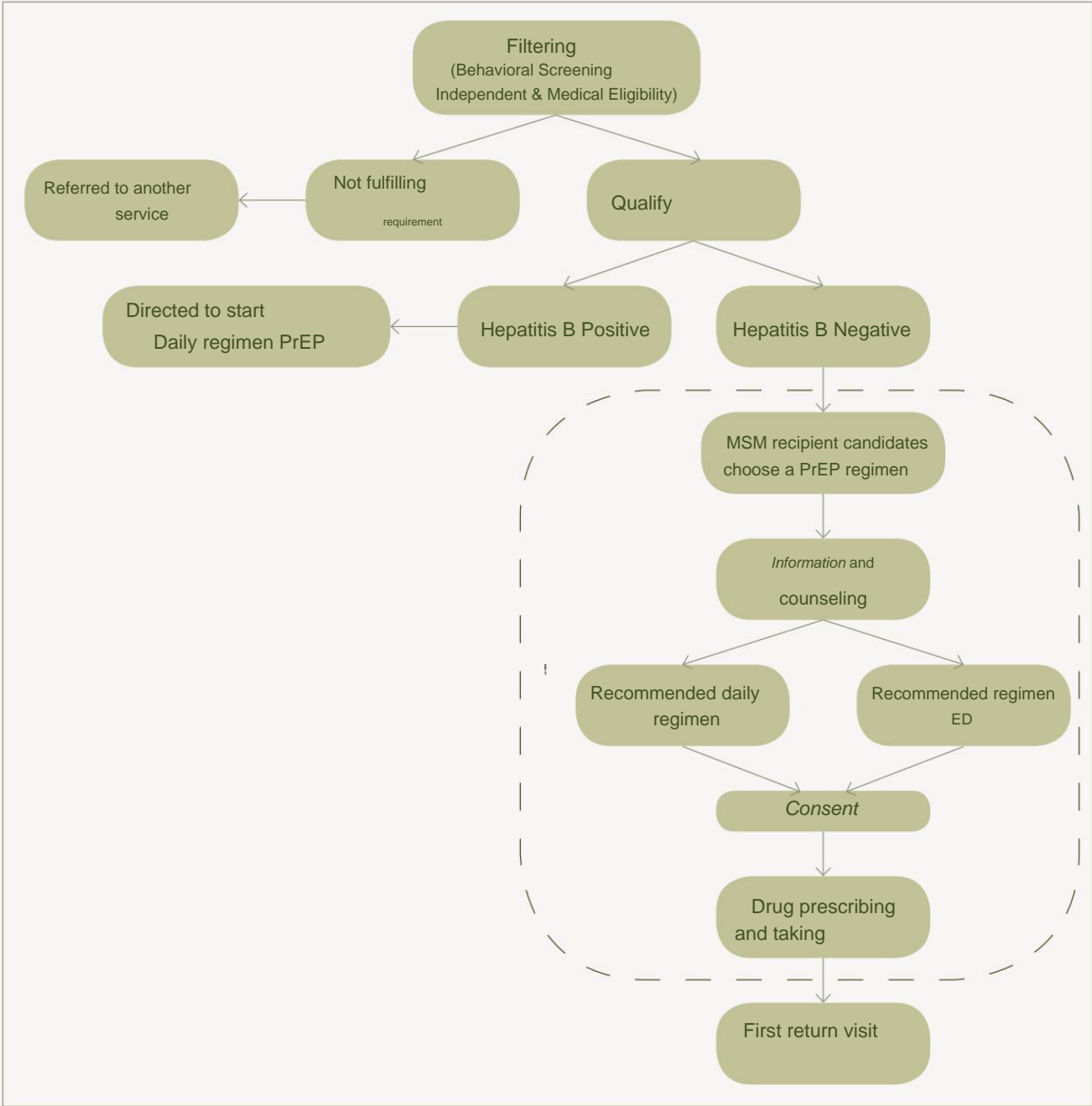
PrEP-ED has been shown to be effective in reducing the risk of HIV infection in men who have sexual relations with men (MSM). Apart from that, there are other benefits that PrEP users can get at this dose, namely:

- Providing options and convenience for MSM who are at risk of being infected with HIV for a short period, or who have sexual intercourse on average once a week, or less;
- Be an option for MSM who are able to anticipate, plan, or delay their sexual activity;
- Reducing the burden of taking medication;
- Economical in terms of costs, because the number of pills needed is not as much as the daily pill dose.

C. PrEP-ED management

Users of an Event-Driven PrEP regimen (PrEP-ED) will go through the same steps as users of a daily PrEP regimen, such as risk behavior assessment and medical eligibility screening. However, prospective PrEP-ED users will go through a slightly different counseling process when they want to start PrEP.

Figure 3.3 Specific flow of PrEP-ED management



After going through the Medical Eligibility Screening stage, prospective PrEP users will enter the stage of starting PrEP which consists of signing informed consent and counseling. At this stage, prospective PrEP users from the MSM group are allowed to choose an available regimen, namely the daily regimen or the ED regimen. However, the decision regarding the regimen to be accepted will depend on the judgment of the health professional/counselor. This is due to the need for consideration and adjustments between regimen choices and behavior patterns of potential ED regimen PrEP users. Prospective users who do not meet the criteria for using PrEP-ED as shown in Figure 3.3 will be recommended to use a daily PrEP regimen.

The regimen given to PrEP-ED users is 1 bottle (containing 30 pills) when starting PrEP. The visit schedule for PrEP-ED users is the same as the visit schedule for daily regimen PrEP users, namely one month after starting PrEP, then regularly every three months. The purpose of the return visit is no different from the return visit for daily regimen PrEP users. The difference in the purpose of the visit lies in the non-routine medication collection schedule for PrEP-ED users, depending on when the medication they have has been consumed. Apart from taking medication, non-routine visits can be made if there are side effects from taking medication.

In practice, the provision of PrEP-ED requires a strong role as a counselor, especially in determining whether potential users meet the criteria for PrEP-ED users and how to strengthen user compliance while taking the drug. The counselor has the right to recommend users to switch regimens according to their sexual behavior patterns and drug consumption.

D. Repeat visits for PrEP-ED users

Return visits for PrEP-ED users are no different from repeat visits for daily dose PrEP users. PrEP users are required to present to a health facility 1 month after starting PrEP and every 3 months thereafter. The following is a service package that will be received by PrEP-ED users during a return visit, every 3 months starting from the PrEP pilot program:

- HIV and STI testing
- Offers for adherence counseling, for setting the dosage strategy to be taken, and if a PrEP-ED user wants to switch from one dose of PrEP-ED to the next PrEP-ED dose, as well as the right way to take the drug according to the way or frequency of sexual activity carried out

- Risk behavior screening and risk reduction counselling, if it is known that PrEP-ED users are experiencing an increase in risky sexual activity then it is necessary to advise them to switch to daily doses of PrEP or other HIV prevention alternatives besides PrEP and to be given risk reduction counselling •

Adherence counseling is given when it is known that adherence of PrEP-ED users is poor and/or experiencing problems during the PrEP-ED

program. • PrEP medication. PrEP-ED users are not always going to receive a prescription every three months. PrEP drugs are given if the PrEP drug preparations received at the previous visit have run out and the PrEP ED user intends to continue or restart the use of PrEP, both ED and daily doses.

Counseling must also be carried out to ensure that PrEP-ED users regularly carry out HIV and STI tests, every 3 months. Creatinine checks every 6 months also need to be done if PrEP-ED users have comorbidities such as Diabetes and or Hypertension.

E. PrEP adherence to users of PrEP-ED dosage

Adherence to PrEP-ED use is related to the timeliness and amount of medication taken which is linked to the pattern of sexual intercourse. In this case, counselors need to provide a careful assessment of PrEP users to determine whether PrEP users are compliant in taking PrEP medication. A PrEP user can be considered compliant if:

1. PrEP-ED users take PrEP medication according to the recommended dosage and adjust it to their sexual behavior. Determination of PrEP user compliance can be determined by health workers, by looking at the remaining amount of medication and digital calendar markings contained in the PrEP application. This is because the amount of medication consumed can differ depending on the sexual behavior patterns of PrEP users. A person who has had sexual intercourse once and is distant from subsequent sexual intercourse should take PrEP medication according to the 2+1+1 regimen. However, someone who has sexual intercourse consecutively for three days will take PrEP medication in different amounts and doses.

If the amount of drug residue is in accordance with the calculation based on the number of sexual intercourse and the number of days of drug consumption, then the PrEP user can be said to be compliant. Conversely, if the number of drugs taken does not match the marking of sexual behavior on the digital calendar or based on the user's acknowledgment, then the PrEP user may be declared less compliant.

The amount of PrEP medication taken can be calculated from the remaining PrEP medication brought by the PrEP user during the return visit.

Most people can get PrEP right away, and the creatinine test can be repeated on different days from different blood samples. At the 6th and 12th month follow-up visits after starting PrEP a repeat creatinine check should be performed. If the creatinine clearance on the return visit is <60 mL/min, repeat the test 1 to 2 days later with a different sample. If the creatinine retest results do not change, PrEP needs to be stopped and immediately refer to an Internal Medicine Specialist.

The amount of PrEP medication taken can be calculated from the remaining PrEP medication brought by the PrEP user during the return visit.

- 2. No seroconversion occurs, that is, the HIV test result becomes positive, which is known based on the last periodic HIV test carried out.

If it is known that the number of remaining pills is more than it should be, then there is an indication that PrEP users are less compliant in taking PrEP-ED drugs so there is concern that protection against HIV transmission is not optimal. If the number of pills left over is less than it should be based on the count it could mean that PrEP users may experience an increase in the frequency of sexual intercourse performed, given or traded to other people, improper storage of PrEP medication or other problems. PrEP-ED users who are indicated to have poor adherence require adherence counseling with doctors, nurses, HIV counselors or pharmacy staff as counselors. Correct baseline information for PrEP users needs to be shared, and appropriate support for PrEP-ED users needs to be provided.

3.4 Management of the PrEP Program in Specific Situations

This section will explain the management of PrEP in certain situations, namely management of creatinine clearance or renal clearance rate, pregnancy and breastfeeding, changes in HIV status, management of side effects, and switching services when PrEP users are still on the PrEP program.

3.4.1 Creatinine clearance management/renal clearance rate

Very few individuals experience low creatinine clearance, and approximately 80 percent of elevations in serum creatinine are self-limiting (and can be managed without stopping PrEP) caused by dehydration, exercise, diet, diabetes mellitus, hypertension, liver failure, or the hepatitis C virus or may be a false positive test result. Treat other causes of the increased creatinine.

If the person wants to use PrEP again, then the creatinine test must be done again along with the HIV test. The expected creatinine test result for restarting PrEP is ≥ 60 mL/min, after converting to creatinine clearance.

3.4.2 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, the use of PrEP does not need to be stopped if a woman is identified as pregnant or has to 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 with partners who are HIV positive. The choice to start, continue, or stop PrEP while a woman is pregnant should be made by the woman herself, followed by a discussion of the risks and benefits with the healthcare professional.

3.4.3 Change in HIV Status

If PrEP users are found to be HIV positive while on PrEP, or after starting PrEP (even if not on PrEP or not on PrEP consistently), then the following should be done:

- Confirm HIV test results according to the nationally accepted HIV testing algorithm.
- Refer immediately for resistance testing NUMBER.
- Immediately refer to treatment and start ARV therapy (according to national ARV guidelines).
- Document/record seroconversion and possible causes of seroconversion (non-adherence, stopping PrEP, or PrEP failure, i.e. infection

3.4.4 Manajemen Efek Samping (*Side Effects and Adverse Drug Reactions/ADRs*)

- Side effects should be grouped by level (mild, moderate, severe).
Treatment measures can refer to the ARV guidelines published by the Indonesian Ministry of Health.
- In general, mild side effects are relatively more common with mild symptoms and are self-limiting and often do not require discontinuation of PrEP. Side effects that may occur include nausea and/or vomiting, diarrhea and/or flatulence, dizziness, headache, and weight loss. Side effects should be managed on a symptom basis, and counseling should also be provided.
- Major toxicity (including renal toxicity and metabolic complications) associated with TDF/FTC has been rare with PrEP exposure to date. Consult with an Internal Medicine Specialist if this happens.
- Any side effect should be noted on the PrEP user's return visit form regardless of severity.
- Report the side effect recording form according to procedure standard operational.
 - If PrEP is to be discontinued, record the results on the PrEP revisit form.
- Recording of side effects is done on the return visit form. After the assessment is complete, it can be decided whether the PrEP user will continue or discontinue PrEP.

3.4.5 Moving Service

PrEP users are allowed to change services while undergoing the PrEP program, provided that the selected service is still included in the services implementing the Indonesian PrEP Pilot Program. In switching services, PrEP users need to include the PrEP user registration number obtained when starting PrEP. PrEP users only need to log into the app and select the appropriate service and schedule for the visit.

Switching services will be recorded automatically in the application after the PrEP user makes a scheduled visit to a different service from the previous visit. Through the track record in the application, officers in the new service can find out how far the user has followed the program and taken medication.

Governance Pharmacy and Logistics

04

4. PHARMACY AND LOGISTICS GOVERNANCE

4.1 PrEP Logistics Team

4.1.1 Drug Supply for PrEP Users

The amount of supply of PrEP drugs available at a PrEP provider service at one time cannot be determined with certainty. The available supply of PrEP drugs will likely vary according to situation and population. This is influenced by factors such as the number of users, the level of adherence to repeat visits and taking drugs as well as the majority of regimen choices.

The service can prescribe a one-month supply on the first visit and then two months on subsequent visits. If visits to the PrEP provider's service are planned every three months, the health worker can advise PrEP users to come to the service a few days earlier than the regular return visit schedule to avoid users running out of medication. PrEP users who have a backup drug supply tend to show better adherence.

The optimal amount of drug that should be given to a PrEP user depends on the PrEP regimen used and the schedule for regular return visits to the service for routine HIV and STI testing.

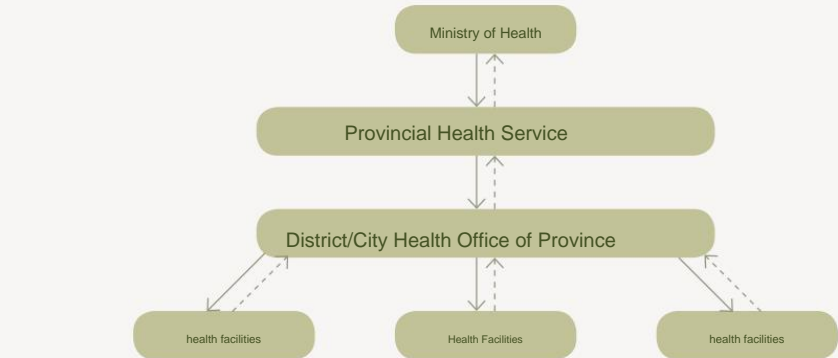
Table 4.1 Drug Supply for PrEP Users

Regiment	Start PrEP	Medication Dispensing on Routine Return Visit Schedule after starting PrEP				
		1st month	Month the 3rd	Month the 6th	Month the 9th	Month the 12th
Daily	1 Bottle	2 Bottles	3 Bottles	3 Bottles	3 Bottles	3 Bottles
PrEP ED 1 Bottle		The amount of drug stock given at each visit is 1 bottle. ED PrEP users can return to the service for PrEP medication dispensing on routine return visits or on visits outside the routine schedule (incidental).				

4.1.2 Procurement and Distribution

Procurement of PrEP drug logistics is fully the responsibility of the central government, in this case, the Ministry of Health. Provincial and City/District level Health Offices play a role in planning and ordering drugs, distributing them to health services and monitoring/supervising services implementing the PrEP program. Mechanisms for drug distribution and PrEP drug logistics follow the following flow:

Figure 4.1 Flow of Request, Distribution and Reporting of PrEP Drugs



Information:
→ Distribution Flow
- - - - -> Request and Reporting Flow

In the PrEP Pilot 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 integration of logistics reporting and distribution of PrEP drugs into the ARV reporting system will be able to be adapted at a later date if the pilot program can run well.

4.2 Storage of PrEP Medication

Storage of PrEP drugs (TDF/FTC) is the same as other HIV program drug deviations, namely stored at room temperature, which ranges from 15–30 °C, in a dry place, and not exposed to direct sunlight. This medication storage advice applies not only to in-service storage, but also to users regarding medication storage at home.

4.3 Monitoring the Effective Use of PrEP

The effectiveness of PrEP in HIV prevention depends on the adherence of PrEP users in taking their medication every day. Pharmacists can play an important role in supporting PrEP users to take their medication regularly. It is important for pharmacists to be open and non-judgmental when asking PrEP users about drug use; if PrEP users think that healthcare workers will be critical then PrEP users may report over-consumption of PrEP and hide adherence problems. Monitoring during return visits to services (to refill PrEP) can be a useful way of assessing whether PrEP users are taking medication regularly. One way to estimate the consistency of drug refills is to calculate the drug ownership ratio, which is the number of tablets dispensed divided by the number of days between refills.

4.4 The Role of the Pharmacist in the Implementation of the PrEP Program

Pharmacists and specialists can play a key role in the provision and monitoring of PrEP. Pharmacy workers are one of the easiest health workers to reach for people who use PrEP. When prescribing drugs to be used for PrEP, it is the pharmacist's responsibility to explain the effective and safe use of these drugs to PrEP users. Pharmacists also have important responsibilities including maintaining optimal storage conditions, such as temperature and humidity control.

Pharmacists need to ensure that the right drug is given at the right dose to the right person. Pharmacists may need to repackage medications for PrEP to make it more convenient for users and to support adherence. Pharmacists have many roles in administering PrEP, including:

- Manage supply chain and drug procurement
- Ensuring the accuracy of prescribing PrEP medication
- Provide information about PrEP, including counseling for supports compliance
- Provides information about possible side effects and the management
- Provide information about potential drug-drug interactions
- Ensure that there are no dietary restrictions while taking PrEP
- Monitor compliance of PrEP users when returning for prescription refills/drug dispensing

Monitoring and Evaluation

05

5. MONITORING AND EVALUATION Monitoring and

Health World
(WHO) recommends that pre-exposure prophylaxis (PrEP) should be offered as a prevention option for persons at high risk of infection with HIV as part of a combined HIV prevention package. PrEP also seeks to empower people who are at high risk of contracting HIV to take advantage of other prevention measures. As one of the biomedical preventive interventions, PrEP also requires adherence from its users to be effective, and needs continuous monitoring to maintain its safety through laboratory tests and repeated HIV tests.

Monitoring routine (monitoring) of PrEP programs is important for assessing and uptake, effective use of safety, as well as for forecasting demand and for ensuring the supply of necessary logistics is sufficient and uninterrupted. As health services offering PrEP grow, monitoring, monitoring and reporting systems need to be implemented alongside PrEP services, and progress evaluated periodically.

regularly
Monitoring and Evaluation (M and E) will ensure that the PrEP program is delivered safely and effectively, focuses on those most in need, and achieves maximum impact through a strategy of leveraging available resources. Wherever possible, PrEP programs can be integrated into existing HIV services and reporting systems.

Integrating PrEP program monitoring and reporting into existing HIV service monitoring is useful for linking and integrating services to make it easier for people to get care. To improve performance data must be analyzed and the results used to provide program, information and direction on program strategy.

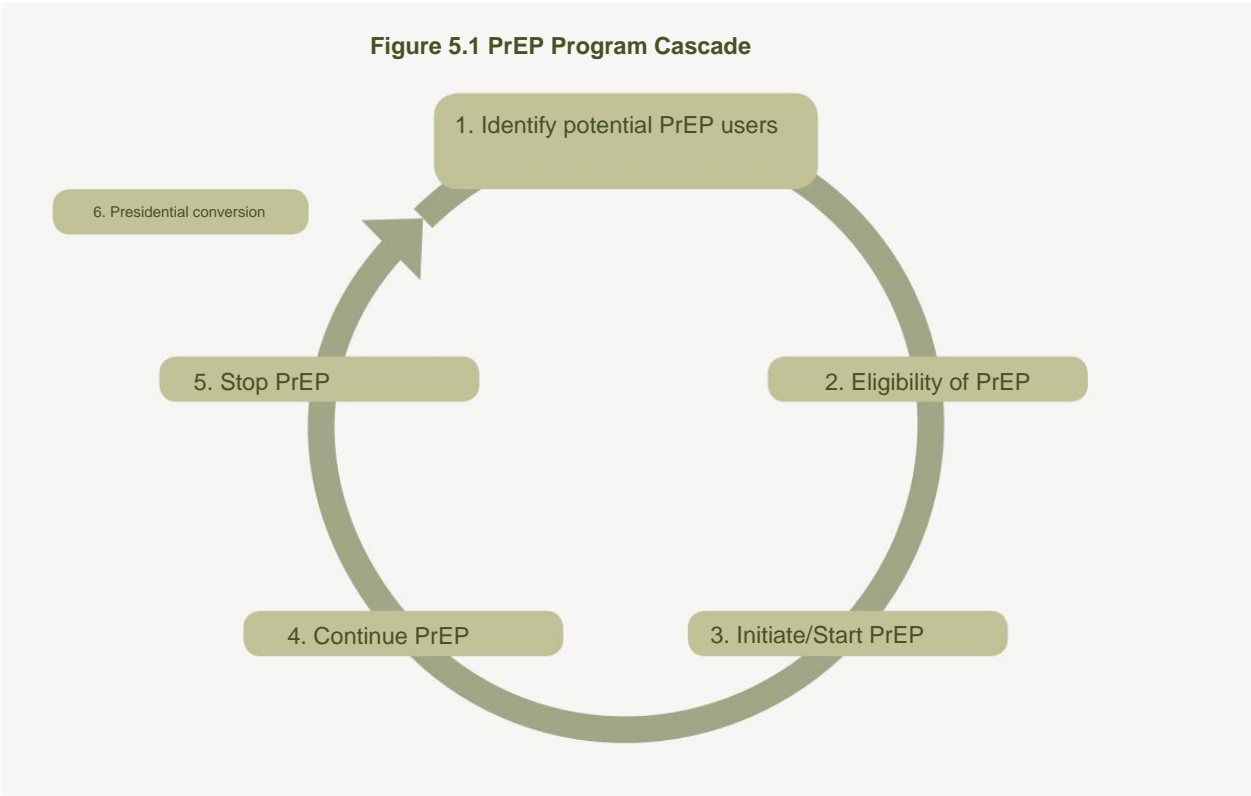
reporting strategies should also maximize data quality and minimize the burden on health workers in collecting and reporting data.

Indonesia has now implemented a reporting system for HIV, namely SIHA (HIV and AIDS Information System), and it is hoped that PrEP monitoring can be integrated into it. However, PrEP programs will require separate reporting forms and registers to track individual PrEP users through a cascade from initial screening to regular follow-up visits over several months. The PrEP program will be implemented in phases in the future so that there are opportunities to and improve revise the inclusion of PrEP in the current HIV reporting system or develop a cross-referral mechanism between the two. Finding a balance between obtaining useful data and reporting burdens on service providers and health systems is critical.

Preferably, core indicators measuring key elements of a program should be measured at all levels of the health system (service, City/Regency, Provincial or National), while additional indicators should be collected depending on feasibility and timeliness for decision making according to the level. PrEP program provider services can collect more detailed information to assess eligibility, follow PrEP users, measure their adherence and respond to any adverse events that occur over time, whereas at the City/Regency or Provincial and even National levels may not require very detailed data . Minimal reporting requirements have the advantage of increasing accuracy, enabling more timely reporting and enabling quicker reviews.

5.1 Scope of the PrEP Program

The goals of monitoring and evaluating a PrEP program will include increasing PrEP coverage among target populations, setting program delivery targets, monitoring the PrEP cascade, identifying clinical or structural areas for service improvement, and evaluating the program and its impact. Implementation of the PrEP program follows a cascade that is almost the same as the HIV treatment cascade as follows:



PrEP program coverage can be calculated using the following indicators:

Table 5.1 Program Coverage Indicator			
Coverage Indicator No	Program	Operational definition	Data source
1	Candidate identification potential PrEP users	Number of people recommended to join the PrEP program based on screening results: Risk Behavior Screening, in the reporting period*	Screening Form : Behavioral Screening Risky
2	PrEP Eligibility	Number of people declared eligible to join the PrEP program based on screening results: Medical Eligibility Screening, in the reporting period*	Screening Form : Eligibility Screening Medical
3	Initiated/started PrEP	Number of people who started PrEP program, in reporting period*	Getting Started Form PrEP
4	Continue PrEP	Number of PrEP users who continued using PrEP (daily dose and ED dose) based on evaluation results at routine follow-up visits, in the reporting period*	Visit Form Repeat**
5	Stopping PrEP	Number of PrEP users who stopped or discontinued their PrEP use for certain reasons in the reporting period*	Visit Form Repeat**
6	Presidential conversion	Number of PrEP users whose known HIV status changed to positive at the time of routine follow-up visit, in the reporting period*.	Visit Form Repeat**

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

** Routine return visits were made at 1, 3, 6, 9 and 12 months after starting PrEP in the PrEP pilot program

The PrEP program coverage indicator displays the number of participants the PrEP program has reached and is a simple monitoring and evaluation indicator to determine interest and utilization of the PrEP program by the target group.

5.2 Main Indicators of the PrEP Program

The four main indicators below are the recommended minimum set for routine monitoring of PrEP programs to assess uptake, sustainability and safety. Each indicator measures an important aspect of PrEP implementation that can serve as a measure of progress and a marker of areas that may require further investigation. This selection was based on global applicability, feasibility and utility for assessing PrEP program performance.

Table 5.2 PrEP Indicators 1 PrEP Uptake

Indicator	PrEP 1 PrEP uptake
Definition	Percentage of people eligible to start PrEP in the last 12 months.
Overview	<p>This indicator is key to assessing PrEP uptake among people deemed eligible. People who started using/initiated PrEP, including first-time PrEP users and PrEP users who had stopped and then restarted PrEP in the reporting period. This indicator can be disaggregated based on:</p> <ul style="list-style-type: none">• age• gender• key population <p>The eligibility assessment to start PrEP includes as a minimum:</p> <ol style="list-style-type: none">1) HIV-negative status2) no signs and symptoms of acute HIV3) have a high risk of HIV and may benefit from PrEP <p>The main factors influencing HIV risk are the individual and their partner's sexual and drug use behavior, the partner's HIV status, background HIV prevalence and incidence in the place of residence and the sub-population from which they originate. Priority groups for PrEP offers include MSM (men who have sex with men), female sex workers, IDU (injecting drug users), transgender, and serodiscordant partners.</p> <p>Contraindications to PrEP include: HIV infection, signs/symptoms of acute HIV infection in persons who have had recent HIV exposure, possible HIV exposure, estimated creatinine clearance of less than 60 ml/min (if known) and allergy or contraindication to any drug in the regimen PrEP.</p>
Priority Level	National, Province, Regency/City, Health Facilities
Numerator/Counter	Number of people who started/initiated PrEP in the last 12 months
Denominator/Denominator	Number of people who have met the eligibility criteria for PrEP in the past 12 months
Calculation	Numerator/denominator
Data source	<ul style="list-style-type: none">• PrEP Screening Form• Individual PrEP Initiation Form
Method of collecting data	<p>The numerator was generated by calculating the number of people who initiated PrEP during the past 12 months, among those assessed as eligible for PrEP in the reporting period. The numerator included people receiving PrEP for the first time, and those who had previously stopped PrEP and restarted PrEP within the reporting period.</p> <p>Regular users of PrEP who are continuing PrEP must be excluded from both the numerator and denominator. The numerator must count each individual only once in a given reporting period.</p> <p>The denominator is generated by counting the number of people who have met the eligibility criteria for PrEP. An individual should only be counted once in a given reporting period even if they started PrEP more than once after the discontinuation period.</p> <p>Age was defined as the age at which a person started PrEP.</p> <p>If a person is identified as part of more than one MARPs, all must be recorded. The amount of data is disaggregated by type of key population, therefore, it can be greater than the total.</p>

Frequency	Data must be collected continuously at the health service level, collected periodically and aligned with the reporting frequency of other indicators that are collected regularly (often monthly or quarterly). This data must then be aggregated for annual reporting.
disaggregate	<ul style="list-style-type: none">• People receiving PrEP for the first time in their life• Age (15–19, 20–24, 25–49, and 50+ years)• Gender (male, female or transgender)• Key population (MSM, FSW, IDU, transgender, and serodiscordant couples.• Geographical area and other important administrative data
Related indicators	<p>UNAIDS Global AIDS Monitoring indicator 3.15: Number of people who received oral antiretroviral PrEP at least once during the reporting period.</p> <p>PEPFAR Monitoring Evaluation and Reporting indicator PrEP_NEW: Number of individuals newly enrolled in antiretroviral pre-exposure prophylaxis (PrEP) to prevent HIV infection in the reporting period.</p> <p>The Global Fund HIV indicators KP-6a, 6b, 6c: Persentase: a) LSL; b) transgender dan c) FSW sex workers using PrEP, in priority populations using PrEP.</p>

Table 5.3 PrEP Sustainability Indicators

Indicator	PrEP 2 Continuation of PrEP
Definition	Percentage of PrEP users who continued the program for three consecutive months after starting/ initiating PrEP in the last 12 months
Overview	<p>This indicator measures continued use of PrEP among people who started PrEP and those who lost to follow-up.</p> <p>Results from pilot projects and other PrEP programs show that many PrEP users stop in the first few months. This indicator provides a measure of early PrEP discontinuation as well as an indication of the number who are likely to continue PrEP use.</p> <p>Furthermore, HIV risk (and, therefore, need to take PrEP) is unlikely to change in a period shorter than three months, although it may. If the percentage of people continuing PrEP at three months is low, the need for further investigation as to why reasons for stopping PrEP (whether due to side effects, behavioral/risk changes or structural factors) can be determined and programs adjusted as needed.</p>
Priority Levels	National, Province, Regency/City, Health Facilities
Numerator/ Counter	Number of people who continued PrEP for three consecutive months after starting/ PrEP initiation in the last 12 months.
Denominator/ Denominator	Number of people who started PrEP in the last 12 months.
Calculation	Numerator/denominator
Data source	<ul style="list-style-type: none">• PrEP Initiation Form;• PrEP Follow Up Forms Data should be collected
Frequency	continuously at the health service level, collected periodically and aligned with the reporting frequency of other indicators which are collected regularly (often monthly or quarterly). This data must then be aggregated for annual reporting.
disaggregate	<ul style="list-style-type: none">• Age (15–19, 20–24, 25–49, and 50+ years)• Gender (male, female or transgender)• Key population (MSM, FSW, IDU, transgender, and serodiscordant couples.• Other important geographical and administrative areas
Related indicators	PEPFAR Monitoring Evaluation and Reporting indicator : PrEP_CURR: Number of individuals, including those newly enrolled, receiving pre-exposure prophylaxis (PrEP) to prevent HIV during the reporting period.

Table 5.4 Prevalence Indicators of Toxicity in PrEP Users

Indicator	PrEP 3 Prevalence of toxicity among PrEP users
Definition	Percentage of people receiving PrEP who have discontinued or interrupted because of a serious illness related to ARV toxicity in the past 12 months
Overview	<p>The prevalence of toxicity associated with PrEP is thought to be low. However, experience with PrEP in large scale programs and longer exposures has been limited.</p> <p>Therefore, active surveillance and toxicity monitoring for people taking PrEP is important to identify potential adverse outcomes that may arise as PrEP programs scale up and reach more people.</p> <p>The main toxicities associated with PrEP use are bone and kidney toxicity associated with tenofovir and associated risk factors in this population. During pregnancy, there is growing evidence for the safety of tenofovir and/or</p> <p>or emtricitabine if used for the treatment and prevention of mother-to-child transmission of HIV – or to pregnant women who are infected with HBV. Additional surveillance programs are needed to evaluate the safety of PrEP during: pregnancy and breastfeeding.</p> <p>The 2016 WHO Consolidated ARV Guidelines state that there is no reason for safety to prohibit or discontinue PrEP used during pregnancy and breastfeeding for HIV-negative women who are at risk of acquiring HIV.</p> <p>Adverse drug reactions that result in discontinuation or interruption of PrEP should be routinely recorded in the appropriate PrEP registry for each PrEP user. Action should be taken at the healthcare level as soon as an adverse drug reaction is noticed.</p>
Priority Levels	National, Province, Regency/City, Health Facilities
Numerator/ Counter	Number of people who were using PrEP and had stopped or interrupted using PrEP because of serious ARV-related toxicity in the last 12 months.
Denominator/ Denominator	Number of people who took PrEP at least once in the last 12 months.
Calculation	Numerator/denominator
Data source	<ul style="list-style-type: none">• PrEP Starting Form;• Individual PrEP Follow Up Forms
Method Data collection	<p>The quantifier is generated by counting the number of people taking PrEP who have been discontinued or interrupted due to serious PrEP-related adverse drug toxicity in the past 12 months, defined as life-threatening illness, death, hospitalization or disability or adverse drug reaction resulting in discontinuation of PrEP .</p> <p>The denominator is generated by counting the number of people who received PrEP at least once during the last 12 months according to national guidelines or WHO standards/ UNAIDS. People who received PrEP at least once included those starting PrEP for the first time and those who may have stopped PrEP and restarted PrEP in the reporting period, as well as those who continued PrEP.</p> <p>If an individual is identified as part of more than one key population, all must be recorded. The amount of data is disaggregated according to key population types, therefore, it can be greater than the total.</p>
Frequency	Data should be collected continuously at the health service level, aggregated periodically and aligned with the reporting frequency of other routinely collected indicators (often monthly or quarterly). This data must then be combined for annual reporting.
disaggregate	<ul style="list-style-type: none">• Age (15–19, 20–24, 25–49, and 50+ years)• Gender (male, female or transgender)• Key populations (MSM, FSW, PWID, transgender, and serodiscordant couples.• Other important geographic and administrative areas
Special considerations during pregnancy	Presence of adverse maternal drug reactions and births in PrEP users during pregnancy should be collected through birth defect surveillance and the pregnancy register expanded to include infants aged 18 months and mother-infant pairs while breastfeeding. Existing national registries and surveillance programs could be expanded into antenatal clinics where it is envisaged to cover more PrEP use in pregnancy. The forms and registers in this reporting system need to be adapted to include the PrEP program.

Related indicators	UNAIDS Global AIDS Monitoring indicator 3.15: Number of people who received oral antiretroviral PrEP at least once during the reporting period. WHO guidelines on key approaches to monitoring ARV toxicity.
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Table 5.5 Indicators of HIV Positive Incidence among PrEP Users

Indicator	PrEP 4 Incidence of HIV positivity among PrEP users
Definition	Percentage of people who tested HIV-positive among PrEP users at least once in the past 12 months and at least one follow-up HIV test.
Overview	<p>This indicator measures the percentage of people who test positive for HIV after being prescribed PrEP. HIV testing is required before starting PrEP, and regularly thereafter while on PrEP. An HIV test to determine PrEP eligibility is not included in the numerator or denominator. The last recorded HIV test in the reporting period was the one counted. Using quality-assured HIV testing is important, and referring people who test positive for HIV to treatment services in a timely manner is also very important.</p> <p>PrEP is most effective when taken as prescribed. Positive HIV test results in PrEP users may be due to the fact that when they started PrEP they had an undetectable acute HIV infection. Another potential reason is poor adherence resulting in reduced concentrations of PrEP and reduced effectiveness in the event of exposure, or acquisition of drug-resistant viruses.</p> <p>Measuring the proportion of PrEP users with positive HIV test results is problematic in the absence of longitudinal surveillance data at the individual level. Determining the denominator as “all PrEP users” is hampered by differences in follow-up and unknown HIV status of those lost to follow-up. Therefore, using the denominator as all people who used PrEP in a certain period can be misleading, because very low HIV positivity rates may result from high PrEP adherence or from PrEP users with non-adherence and lost to follow-up. Therefore, this indicator should be interpreted with caution, especially in cases of high loss to follow-up and may not be suitable for comparison across different types or locations of service delivery.</p> <p>These indicators are not measures of PrEP efficacy. It serves as a program performance indicator to further investigate potential reasons for seroconversion, and if appropriate, to adjust the program (such as for eligibility screening or adherence counseling) as needed. It is difficult to accurately determine the reason for seroconversion, or to assess compliance retrospectively. To minimize recall bias, asking PrEP users about recent adherence (over the past week or month) may be beneficial.</p>
Priority Levels	National, Provincial, District/City, health service units
Numerator/Counter	Number of people with a positive follow-up HIV test result among people who received PrEP at least once in the past 12 months.
Denominator/Denominator	Number of people who received PrEP at least once in the past 12 months, and who had at least one follow-up HIV test.
Calculation	Numerator/denominator
Data source	<ul style="list-style-type: none">• PrEP Initiation Form;• Individual PrEP Return Visit/Follow Up Form

Method	The numerator was generated by calculating the total number of people who had a follow-up HIV test – with positive results among people who received PrEP at least once in the past 12 months and who had at least one follow-up HIV test.
Data collection	<p>The counter cannot include people who last used PrEP more than 12 months before the HIV test date.</p> <p>The denominator was generated by calculating the number of people who received PrEP at least once in the past 12 months and had at least one follow-up HIV test performed in the reporting period. Only the most recent HIV test results are counted. For example, if a person takes PrEP for 12 months, and during that time has 4 HIV tests with negative results, which would allow them to continue PrEP, their contribution to the denominator is 1.</p> <p>Similarly, if PrEP users had only 2 recorded HIV tests in the reporting period, one of which was HIV-positive, they would contribute 1 to the numerator and 1 to the denominator. The first HIV test performed to determine PrEP eligibility should not be included in the numerator or denominator. This test must be HIV-negative as a condition for eligibility to be prescribed PrEP. Individuals who test positive for HIV as part of the PrEP eligibility screening should not be included in the numerator or denominator because they will not be prescribed PrEP.</p> <p>If a person is identified as part of more than one MARPs, all must be recorded. The amount of data is disaggregated by type of key population, therefore, it can be greater than the total.</p>
Frequency	Data must be collected continuously at the health service level, collected periodically and aligned with the reporting frequency of other indicators that are collected regularly (often monthly or quarterly). This data must then be aggregated for annual reporting.
disaggregate	<ul style="list-style-type: none">• Age (15–19, 20–24, 25–49, and 50+ years)• Gender (male, female or transgender)• Key population (MSM, FSW, IDU, transgender, and serodiscordant couples.• Other important geographical and administrative areas

5.3 PrEP Program Recording and Reporting Flow

5.3.1 Community or Health Facility Level

Table 5.6 Community or Health Facility Level Reports				
No	PrEP Program Stages	Form PrEP used	Registration Officer	Reporting
1	Screening (Behavioral Screening Risk and Medical Eligibility)	Form Filtering	Risk Behavior Assessment <ul style="list-style-type: none">• Prospective PrEP users independently, or• Peer Counselor/HIV Counselor/ doctors/nurses in the community or health facilities	Online form
			Medical Eligibility <ul style="list-style-type: none">• Doctor• Nurse• Laboratory staff or RR Officer	Online form
2	Start PrEP	Form Start PrEP and Informed Consent	Peer Counselor/ HIV Counselor/ Doctor/Nurse/Pharmacist/ RR Officer	Online form
3	Follow up visits (visit in the first month and third month after starting PrEP then continued every 3 months)	Form Visit Repeat	Peer Counselor/ HIV Counselor/ Doctor/Nurse/Pharmacist/ Lab Officer / RR Officer	Online form

5.3.2 District/City, Provincial and National Levels

Table 5.7 District/City, Provincial and National Level Reports				
Timeframe	Program Report No		Data source	Indicator
1	3 months Quarterly Report		Database Program PrEP	a. Output dari Program PrEP : Kaskade Program PrEP
2	Annual report	12 months	Database Program PrEP	b. Outcome of the PrEP Program, which consists of: <ul style="list-style-type: none">• PrEP uptake• PrEP continuation• Prevalence of toxicity among PrEP users• HIV positive incidence among PrEP users

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APPENDIX

Appendix 1: Forms

Forms can be accessed and downloaded at the following link: <https://bit.ly/formgulang-prep>

Appendix 2: Information and Education Package

A. Basic PrEP Information

Question	Explanation
What is PrEP?	<ul style="list-style-type: none">• PrEP stands for Pre-Exposure Prophylaxis or in Indonesian can also be called Pre-Exposure Prophylaxis.• PrEP is an effort to prevent HIV by taking medication according to rules of use.• PrEP begins to be used by someone who is at high risk before he takes action/behavior that can put him at risk of HIV transmission.
Who can access PrEP?	<p>PrEP is recommended for people who are at greater risk for HIV infection, have a negative HIV status, have no indication of acute HIV infection, and have no contraindications to a PrEP regimen.</p> <p>The goals of PrEP are:</p> <ul style="list-style-type: none">• Men who have sex with men (MSM)• Female Sex Workers (WPS)• Waria/Transgender• Injecting Drug Users (IDUs)• Someone who has a sexual partner with positive HIV status (Spouse serodiscordant) <p>Criteria for people who have a higher risk of being infected with HIV, namely:</p> <ol style="list-style-type: none">1. Having more than one sexual partner2. Not using condoms consistently3. Having sexual intercourse through the anus (anal sex) without a condom4. There is a history of STIs in the last 3 months5. Have ever used PrEP or PPP6. Having an HIV positive partner with the following conditions (at least one):<ul style="list-style-type: none">- have not used ARVs, - used ARVs irregularly in the last 6 months,- HIV is not suppressed (viral load >1000 copies/ml) after 6 months of treatment,- viral load count is unknown,- planning to have children, with a partner whose HIV has not been suppressed. <p>If one of the criteria above has been met, then the prospective PrEP user is eligible to access the PrEP program and can carry out a PrEP screening to see the feasibility of using PrEP.</p> <ul style="list-style-type: none">• People who have positive HIV
Who can't use PrEP?	<p>status cannot use PrEP, but must be referred for ARV therapy</p> <ul style="list-style-type: none">• People who have impaired kidney function.
Is PrEP effective in protecting someone from HIV?	<p>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 delivered by health workers.</p>
Can taking PrEP prevent STIs?	<p>PrEP does not prevent STIs, so consistent condom use is still a must.</p>
When does PrEP start to be effective in risky sex?	<ul style="list-style-type: none">• In non-MSM groups, PrEP can be effective within 7 days after taking PrEP medication.• In the MSM group, PrEP can be effective in risky sexual intercourse for at least 2-24 hours after taking PrEP medication.
Where can I access PrEP services?	<p>PrEP services can be accessed at several community health centers/referral clinics</p>
Are there risks to using PrEP?	<p>Not everyone will have side effects from taking PrEP. However, if it occurs, the side effects that usually occur are nausea, dizziness, headache, fatigue, stomach cramps, and diarrhea. Usually these side effects will stop after a few weeks. If the pain persists and cannot be tolerated, contact your doctor or health worker immediately.</p>
Is PrEP the same as ARV therapy?	<p>PrEP programs are not the same as ARV therapy. The PrEP program is aimed at people who have negative HIV status as a prevention effort. Meanwhile, ARV therapy is intended for people who have positive HIV status as a treatment effort. What PrEP and ARV therapy have in common is the use of drugs. The PrEP program uses types of ARV drugs, namely TDF and FTC.</p>

Is PrEP the same as PPP?	PrEP is different from PPP (Post Exposure Prophylaxis). PPP is an effort to prevent HIV infection by taking prescribed drugs after a person is exposed or exposed to HIV or experiences conditions that put him at risk of HIV infection within 72 hours.
Are there other ways to protect against HIV besides PrEP?	<ul style="list-style-type: none">• Condoms (and lubricant). Effective if used consistently with all sexual partners. Condoms also protect against STIs and prevent pregnancy.• If you have a partner who is HIV positive, ARV treatment can reduce the risk of HIV transmission. Protection against HIV is obtained if the HIV positive partner has an undetectable viral load.• Post-exposure prophylaxis (PPP), namely treatment taken after someone has been exposed to HIV. If used properly, PPP can protect against HIV.• Only have one sexual partner• For injecting drug users, use sterile needles and do not share them with other people
When can I start using PrEP and when can I stop?	To start PrEP, it is necessary to consult a health worker at the puskesmas/ referral clinic. Prior to starting PrEP, potential users will undergo screening such as a risk behavior assessment and medical eligibility screening. Users can stop PrEP for the following reasons: <ul style="list-style-type: none">• HIV risk decreases, for example, using condoms consistently.• Not wanting to take medication as prescribed or often skipping medication.• Experiencing side effects that are detrimental to health.• Blood tests done in the laboratory show that the body has a negative reaction towards PrEP use.

B. Information for PrEP users

This information can be submitted by:

- Doctors who prescribe PrEP, • HIV counselors, and
- Pharmacy Officer • KIE Media

Purpose of providing information: To provide PrEP users with appropriate information

Caution for informers: Use simple language when administering PrEP medication

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

- This medicine needs to be taken every day, the time to take the medicine can be at any time of the day.
- In general, PrEP is easy to use because it can be taken with or without food interact with alcohol.
- PrEP provides a high level of protection in people who take it regularly. • 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 dosage and time is very important so that the medication has enough time to become optimal.

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

- a. Take PrEP medication according to the regimen used every day. Probably the easiest to keep in mind if you take the tablets at the same time every day.
- b. Rules for taking PrEP medication:

Daily Regimen Users of Population Groups <small>Apart from MSM</small>	Daily Regimen Users from the MSM Population Group	Users of Event-Driven (ED) Regimen
Take 1 PrEP tablet daily for 7 consecutive days prior to exposure to get maximum results, then continue taking one PrEP tablet daily at approximately the same time for 7 days after the last potential exposure.	Take 2 PrEP tablets 2-24 hours before sexual intercourse. One tablet should be taken daily at approximately the same time thereafter. To safely stop PrEP, one PrEP tablet should be taken daily for up to two days after the last potential HIV exposure.	<ul style="list-style-type: none">• Two PrEP tablets should be taken 2-24 hours before sexual intercourse to get maximum results. For 2 consecutive days after the last potential HIV exposure, take 1 tablet at the same time as the initial dose. This process must be repeated for each period of exposure to the potential for acquiring HIV.• During the window period, PrEP users need to practice safer sex (including abstinence from sex and using condoms).

- c. PrEP is highly effective in preventing HIV infection, but does not protect against sexually transmitted infections others or prevent pregnancy.
- d. PrEP provides a high level of protection in people who take the medication regularly. As time is needed to build up protective levels of the drug in the blood and other tissues, additional HIV prevention should be administered within a predetermined time period according to the regimen of choice and risk group criteria for PrEP use.
- e. If you miss a dose of PrEP on a certain day and notice it on the same day, you should take the medicine as soon as you remember. If you don't remember until the next day, there is no need to take two tablets on the same day. Just take one tablet every day as usual.
- f. In general, store the tablets in a bottle with a drying agent (silica gel). However, you can bring a few tablets to take with you on the go.
- g. Try to keep the bottles and tablets away from intense heat or cold and away from sunlight and humidity.

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: Counselors.* Geneva: WHO; 2017.

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

For those who are not on PrEP, counseling can explore reproductive health and current substance abuse and raise awareness about PrEP and other HIV prevention strategies. Counseling for those interested in PrEP should focus on raising awareness of PrEP as a preventative option and helping counselees to decide whether PrEP is right for them.

For those who choose PrEP, counseling then continues with individual preparation to start PrEP, explaining its use and making specific plans for PrEP use.

For PrEP users, follow-up counseling may aim to examine reproductive and sexual health and/or current drug use behavior; intent 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.

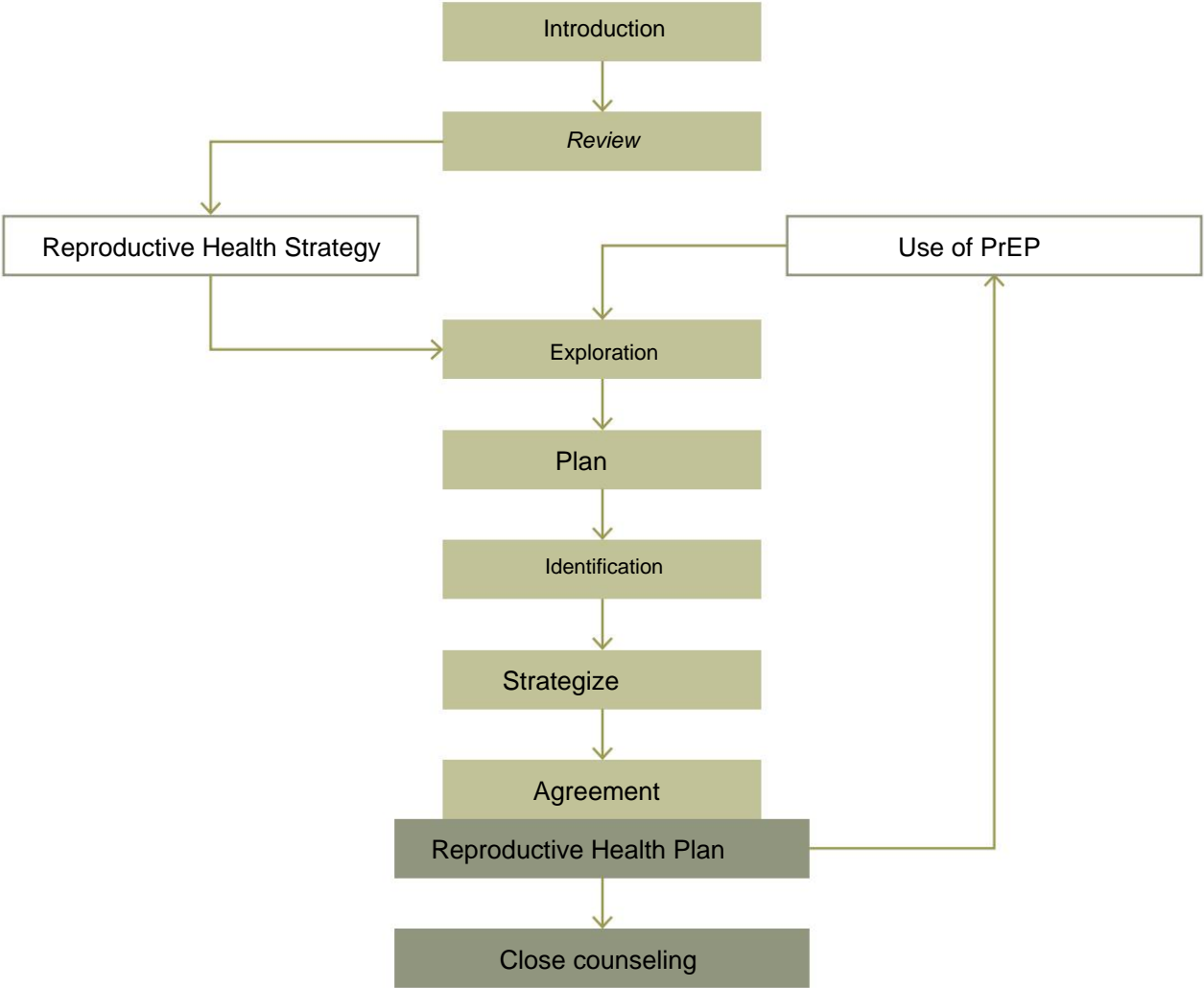
Counselors in the PrEP program can be played by health workers, peer counselors, HIV counselors or outreach/support officers from HIV programs who are trained in the PrEP program. In addition, the preferences of the client/PrEP user should be considered, such as preferring to speak with peer or lay counselors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

- For PrEP extension counseling, the counselor can convey the following important information:
- Dosage requirements for optimal protection from PrEP drugs
 - What to do if a dose is missed?
 - General compliance strategy
 - The importance of ongoing monitoring while on PrEP
 - Side effects and side effect management
 - How to safely stop and restart PrEP
 - Reproductive and sexual health protection strategies outside of PrEP
 - Harm reduction for drug users
 - Comprehensive HIV prevention planning

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 and client-centered approach/PrEP user focused specifically on PrEP adherence. This method was developed to address challenges in informing PrEP choices, developing adherence plans, and developing broader plans for reproductive and sexual health. This method is interactive, brief, centered on counselees/PrEP users and focuses on problem solving, starting with identifying personal goals and obstacles as well as supporting factors for achieving these goals.

Note: PrEP counselors can use the step guide in the diagram below to ensure counseling is working according to its goals. This Guide Sheet can be reproduced as needed. The counselor can mark the steps that have been taken. An explanation for each step can be seen in the table below the diagram. information on time, identity of the counselee and counselor, as well as counseling notes can be written on the following sheet. At the next meeting the counselor can view the counseling notes and evaluate the changes that have occurred to the counselee.

Step Guide to Conducting Counseling with the *Integrated Next Step Counseling* Method



Day/Date/Location

...../...../.....

Counselor Name

.....

Name of Counselee/PrEP User

.....

Counseling Notes

Steps	Key Components	Sample Speech
Introduce the counseling session to be conducted	Describe what you are going to talk about and why. Ask for approval to continue.	<i>Good afternoon, Today we are going to discuss about your goals and how we will achieve those goals. What do you think?</i> <i>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.</i>
Counselee experience review/ PrEP users	Ask what PrEP users already know about PrEP and where did you find out?; or experience using PrEP, if you have.	<i>Thank You. Can you tell us what you already know about PrEP?</i> <i>Or How was your experience while using PrEP?</i>
Exploration of the context of obstacles and factors that support the client/ PrEP users.	Use open-ended questions to explore factors or situations that can make taking medication easier and those that can make it more difficult.	<i>Can you tell us about your experience with PrEP since you last came here?</i> <i>What would make PrEP easier to do? What makes it difficult?</i>
Design discussions that focus on things that make taking the 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>
Identification of needs related to compliance	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/ 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?</i> <i>What ideas could help you achieve it?</i>
Agree on which strategy to try next	Ask what strategies PrEP users are willing to try or continue.	<i>Of the things we've talked about, which one would you try to start with now until the time we meet again?</i>
Closing	Provide a conclusion from the discussion that has been held, then thank the PrEP user.	<i>You realize that... will ease this in your life and... is something that can help. You will try to do that from now until our next meeting. Thank you for our current discussion time, I look forward to having another discussion with you in the next session.</i>

Appendix 4: Frequently Asked Questions (FAQ)

A. Frequently asked questions by PrEP candidates/users

Storing PrEP medication

- Each bottle typically contains 30 tablets of the PrEP regimen for one month of use. Store the bottle at room temperature, and don't store it in a cold room like a refrigerator or a hot room like a car.
- Keep the tablets in the medicine bottle with the small object that came with the medicine bottle (to keep the medicine dry).

How to take PrEP medication

- WHO recommends taking one tablet per day. This daily dose is a safe dose and is able to provide the best protection from HIV infection.
- PrEP can be used at any time of day and at different times of the day.
- Linking an activity to a medication schedule can help remind you to always use PrEP regularly
- PrEP can be taken at the same time as food
- PrEP can be taken while using medications or while drinking alcoholic beverages
- PrEP can be taken while using hormonal contraception, sex hormones, or other drugs doctor prescribed
- It takes as long as 7 days on a daily regimen of PrEP to get sufficient amounts of the drug in the body to provide adequate protection from HIV infection for non-MSM risk groups and 2 days for MSM risk groups. • Prior to starting the PrEP program, each potential user will take a test to confirm negative HIV status. If a positive HIV result is obtained, the potential PrEP user will be referred to ART services.

- While using PrEP, each user will undergo an HIV test every 3 months ensure that your HIV status remains negative.
- The risk of HIV infection varies according to the situation and conditions of the user. A person may decide to stop taking PrEP if they feel that the risk of infection is no longer great, such as if they have only had one sexual partner.

How to remember to take PrEP medication

- Most people find it helpful to establish a habitual pattern of taking medication, for example at the same time every day (eg after breakfast, after brushing their teeth, or while watching the same television shows every day).
- Create reminders, for example from a mobile phone or write down notes that can be seen every day the day.
- Support from a partner, family or friends can also help and encourage you to continue drinking PrEP medication consistently.
- If the schedule for taking medication is disrupted (for example due to a change in routine, or forgetting to eat), always carry one more tablet just in case.
- Running out of medication is a common case where a person misses a dose of medication. get used to it to request a new dose before the old dose runs out.

What to do if you miss a dose of medication

- 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 tablet right away. The routine can return to normal according to the previous schedule the next day
- If you are not sure whether you have taken the medicine in one day, you can take one more tablet to make sure you don't forget to take the medicine.
- Protection against HIV infection is still high in individuals taking daily PrEP regimens despite occasional missed daily doses. If you forget or miss your daily dose more than once a week, think about ways or methods that can help you to keep taking your medicine every day.

Side effects

- Side effects do not occur in every PrEP user, but they are common. These side effects include a stomach that feels tight, or a tendency to be nauseous and/or have more frequent bowel movements.
- The side effects above are usually not bothersome and will disappear in the first weeks taking PrEP.
- Common strategies for managing stomach upset: take medication with food, and take medication just before bed.
- For some people, PrEP drugs affect how their kidneys work. After starting PrEP, people who have certain problems with their kidneys will be monitored and will have to take regular tests. If the test results show a problem, PrEP use will be temporarily discontinued. If kidney function has improved, then the use of PrEP can be resumed.
- PrEP may affect bone mineral levels in some people. These changes occurred in the early months of using PrEP, but will not continue any further. If the user decides to stop taking PrEP, the levels of these minerals will return to normal.

Services available while using PrEP

- Contraception to prevent unplanned pregnancies
- Screening and treatment for sexually transmitted infections
- Hepatitis B test along with vaccination
- Condoms and lubricant
- Counseling to support taking PrEP medication regularly every day and assistance if there are complaints, such as problems with a partner, etc.
- Harm reduction and treatment for users who use drugs.

Pregnancy plans while using PrEP

- It is recommended to convey pregnancy plans to a doctor or other health professional
- Choose one of the following two ways to have children safely (if one of the couple HIV positive status):
 - Consistent taking ARV pills for positive partners, and checking 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 for positive partners, and PrEP use by partners who are HIV negative.

Telling others about PrEP

- Telling the closest people who are trusted can help accept PrEP in undergoing optimal PrEP program, for example support for taking medication regularly
- There is no pressure to tell others if you are on PrEP. Even so, one might need to come up with a scenario if someone else found out about it 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 other people don't understand PrEP and ask about this program, provide clear facts that PrEP is a recommendation from WHO and governments and health services.

Stopping PrEP

- Sexual behavior and injecting drug use in a person can change over time, so that the risk of HIV infection can also change. Starting PrEP doesn't mean a person will be on it for life. If the risk of infection is seen as low, then a person can stop PrEP and use another method of prevention to protect themselves from HIV, such as condoms.
- A person may be exposed to HIV. During this time, take PrEP for at least 28 days after exposure.
- Convey the desire to stop PrEP to health workers who have been helping in this the PrEP program being undertaken.
- Before restarting PrEP, be sure to repeat HIV testing to confirm HIV status negative.

B. Frequently Asked Questions to Pharmacy Officers

How to take PrEP tablets every day

Take one tablet daily. 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 can greatly help your compliance if it is taken at the same time every day. While it is safe to take PrEP with many other medications, it is necessary to check each one specifically. We can help you check if there might be a problem. Please tell me what other medicines you are taking.

Long time taking PrEP

Until you are no longer at risk of HIV infection

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.

The effect of PrEP on body weight

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

Effective time of PrEP

The level of protection was obtained after two days of taking the PrEP medication; however, maximum protection is obtained after seven days.

How does PrEP work?

Blocking HIV from spreading in the body.

How to remember to take your PrEP tablets every

day Try to choose a time that fits your daily routine, for example taking the tablets after brushing your teeth every morning. Or, if you have a cell phone, you can set a reminder on your phone when you plan to bring your tablet.

What to do if you forget a dose

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

What to do if you vomit after taking one dose of PrEP

If you see the tablet being vomited up, wait an hour for the vomiting to pass and take another tablet. If vomiting occurs an hour or more after taking the tablet, or you do not notice that the tablet has been vomited, take the next tablet 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
- Ensuring the active involvement of various stakeholders (health services, community and stakeholders).
other related)
- Receive monthly monitoring results from recording and reporting officers and recap the results
- Analyze the results of the monthly recap for program purposes
- Provide feedback to services regarding the quality of the PrEP program in services
- Provide regular reports to the Provincial Health Service and the Ministry of Health (Subdit
AIDS)

B. Implementing doctor/counselor

- Explain the procedures for using PrEP, eligibility and follow-up procedures and requirements, risks and benefits, importance of compliance, rules for starting and stopping, alternatives to PrEP and and related laboratory tests if any
- Perform HIV risk eligibility screening
- Conduct counseling related to HIV and STIs, including behavior risk reduction and the need to use condoms when taking PrEP (including distributing free condoms and water-based lubricants to PrEP users), conducting history taking, counseling and physical examinations
- Evaluate PrEP users for STI status and decide to start PrEP
- Examining PrEP users for the possibility of Acute HIV infection (AHI)
- Interpret laboratory test results
- Decide on final eligibility and continuation of PrEP
- Evaluate possible PrEP side effects
 - If necessary, can request the collection of additional specimens and laboratory testing
- Write down PrEP prescriptions for follow-up by pharmacists
- Record relevant information on the PrEP form. •
Evaluate side effects and refer to a specialist if necessary

C. Nurse/Phlebotomist/Counselor

- Explain about the procedures for using PrEP, eligibility and follow-up procedures and requirements, risks and benefits, the importance of compliance, rules for starting and stopping, alternatives to PrEP and and related laboratory tests if any
- Perform HIV risk eligibility screening
- Conduct counseling related to HIV and STIs, including behavioral risk reduction and the need to use condoms while taking PrEP (including distribution of free condoms and water-based lubricants to PrEP users)
- Perform blood sampling 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 performed
- Ensure access to ARV therapy for HIV-infected PrEP users and make referrals
- Re-evaluate HIV risk during follow-up
- Performs compliance counseling and pill counting
- Complete documents for review by the implementing doctor
- Record relevant information on data forms.

D. Laboratory Officer/Analyst

- Receive blood samples and other specimens for processing and testing
- Responsible for managing relevant test kits, other laboratory materials, and devices
collection of specimens and related clinical supplies
- Conduct serological tests for HIV, HCV, syphilis and other STI screening
- 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 form to
notify the attending 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

E. Pharmacy Officer

• Process prescriptions and record dispensed medications •
Explain and repeat medication usage rules to PrEP users • Ensure continuous medication supply and prevent stock outs • Complete relevant forms for data entry in recording and reporting applications for purposes monitoring

F. Recording and Reporting Officer • Fill

out data record forms and supervise data entry • Store data information for monthly reports between sources and databases • Perform daily backups and store data in the cloud recording and reporting system application • Produce weekly and monthly monitoring reports to evaluate PrEP program performance

Appendix 6: Laboratory Tests for PrEP

No	Deep stages Program	Test Activity Lab	Test Conditions	Test Indication	Pilot Program	test used	Results	Follow-up
	Filtering (Medical eligibility screening)	HIV	Prerequisites, outcomes determine taking PrEP	All candidates PrEP users	Follow the program	Standard HIV test kits are available at health facilities	Reactive (R)	Unable to use PrEP, referred to ARV services
							non reactive (NO)	Can start PrEP
		STI examination with a simple laboratory (including syphilis)	Baseline, outcome is not decisive following PrEP	All candidates PrEP users	Follow the program	Simplified syndromic and laboratory approach	IMS	Start STI treatment, start PrEP
							Not an STI	Start PrEP
		Hepatitis B (HBsAg)	Baseline, outcome is not decisive following PrEP	All candidates PrEP users.	Preferable for LSL, and eligible for ED regimen. Included in the cost of the pilot program	Standard test kits available at the health facility or refer to the cooperating laboratory	Reactive (R)	Start PrEP. The use of PrEP can act as a treatment for Hep B. Hep B is contraindicated with PrEP ED, so daily PrEP is recommended.
							non reactive (NO)	Start PrEP. If HBsAg is nonreactive but at risk for Hep B, recommend Hep B vaccine.
		Hepatitis C	Baseline, results did not determine adhering to PrEP	All candidates PrEP users	Offered to all prospective PrEP users at their own expense/ Hepatitis C program	Standard test kits available at the health facility or refer to the cooperating laboratory	Reactive (R)	Hepatitis C can be tested when starting PrEP. There are no contraindications, so you can start while waiting for the test results to come back.
							non reactive (NO)	

		Baseline serum creatinine (priority is made at the return visit 1 month after starting PrEP, if there are problems it can be done at the 3 month return visit after starting PrEP), if there is an indication.	For age >30 years and over, and age <30 with a history of hypertension and/or diabetes	For PrEP users aged >30 years and over, and aged <30 with a history of hypertension and/or diabetes, included in the pilot program fee	As a standard test kit available, results are converted to Creatinine Clearance/Kidney Clearance Rate results, calculated using the Cockcroft Gault formula. done before starting PrEP up to 1 month after starting PrEP,	<60 m L/ minute:	Can start PrEP, but needs special attention and stress for Perform routine creatinine checks at 6 and 12 months after starting PrEP.	
					Cockcroft-Gault formula: [[140 - age(years)] * body weight(kg)] /[72*serum Cr(mg/dL)] (multiply by 0.85 for female calculation)	≥60 mL/minute	Start PrEP	
2	Repeat visits every 3 months	STI testing with a simple laboratory (including Syphilis)	Regular check-ups	All PrEP users	Follow the program	Syndrome approach and simple laboratory	IMS	PrEP treatment is continued with abstinence from sex, if this is not possible then sexual intercourse must use a condom
							Not an STI	PrEP is continued
		HIV	Routine inspection	All PrEP users	Follow the program	Standard HIV test kits available at health facilities	Reactive (R)	Unable to continue PrEP, referred to ARV services
							non reactive (NO)	Can continue PrEP

3.	Repeat visits every 6 months	creatinine serum	If there is any indication	For all PrEP users with: - age >50 years and over, - cleaning results creatinine/ kidney clearance rate at baseline (1-3 months from starting PrEP) <90ml/ min, - have comorbidities hypertension and diabetes (at any age)	For PrEP users as indicated, included in the pilot program fee	As a standard test kit available, results are converted to Creatinine Clearance/Kidney Clearance Rate results, calculated using the Cockcroft Gault formula. Performed every 6 months	<60 mL/min	If the creatinine result is <60 mL/min, repeat the test 1-2 days after the first test with a different sample. If the repeat test results still show the same results, stop PrEP. Discuss other HIV prevention options and refer to an Internal Medicine Specialist. Creatinine clearance/renal clearance rate will usually return to normal levels after stopping PrEP, and PrEP can be restarted if it is confirmed that creatinine clearance is \geq 60 mL/min 1-3 months after stopping PrEP.
						Cockcroft-Gault formula: [[140 - age(years)] * body weight(kg)] / [72*serum Cr(mg/dL)] (multiply by 0.85 for female calculation)	\geq 60 mL/min	PrEP can be continued

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