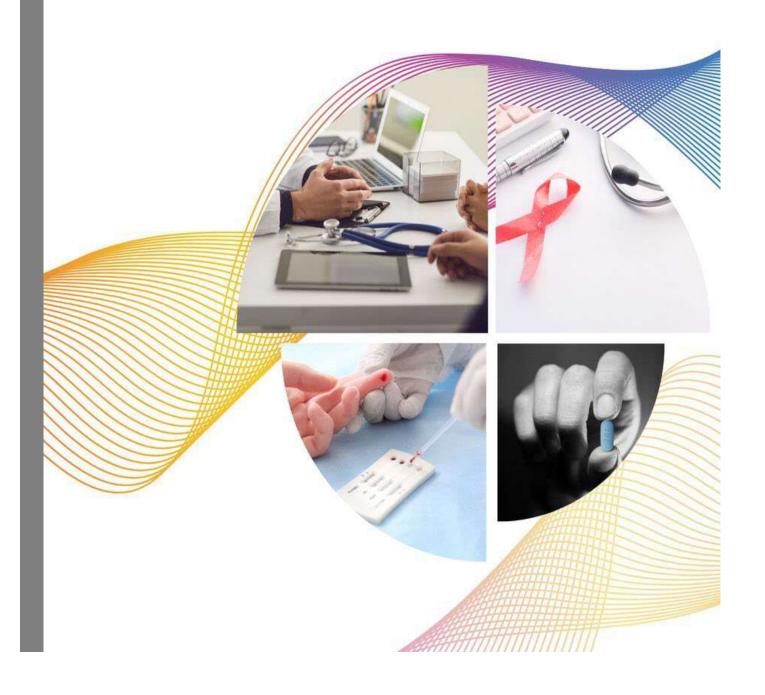


# National Guidelines on HIV PrEP Program Implementation 2025





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April 2025

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**HIV/STI/Hepatitis C Sector** 

**Disease Control Division** 

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# This report was coordinated and produced by HIV/STI/Hepatitis C Sector, Disease Control Division, Ministry of Health Malaysia

#### **Editorial Team:**

Dr Fazidah Yuswan, Head of HIV/STI/Hep C Sector, Disease Control Division, Chief Editor Dr

Mazliza Ramly, Public Health Medicine Specialist, Disease Control Division, Lead Author Dr

Norliza Ibrahim, Public Health Medicine Specialist, Disease Control Division

Dr Natalia Che Ishak, Public Health Medicine Specialist, Disease Control Division

Dr Narul Aida Salleh, Family Medicine Specialist, Kuala Lumpur State Health Department

Dr Sheela Bai Pannir Selvam, Family Medicine Consultant, Kuala Lumpur State Health Department

Dr Khairil Erwan, Infectious Disease Specialist, Hospital Kuala Lumpur

Dr Ismawati Ismail, Public Health Medicine Specialist, N Sembilan State Health Department

Dr Raudhah, Public Health Medicine Specialist, Kuala Lumpur State Health Department

Dr Sathya Rao, Family Medicine Specialist, Selangor State Health Department

En Steven Balasubramaniam Tambi Raja, Medical Assistant, Kuala Lumpur State Health

Department

En Yusral Md Hakim, Malaysia AIDS Council

En Wan Mohd Ikhtiaruddin, Malaysia AIDS Council

En Jabrullah Afiq, Malaysia AIDS Council

En Abdul Hadi Nasib, Program Coordinator PrEP Navigator

En Nazrul Ashraff Buang, PrEP Navigator

En Muhammad Harris Helmi b Hasan Husin, PrEP Navigator

#### List of contributors:

Dato' Indera Dr Shaari Ngadiman, Vice Chairman of CCM Malaysia

Dr Anita Suleiman, Former Director of Disease Control Division, MOH Malaysia

Dr Nurulaini Abdullah, Family Health Medicine, MOH Malaysia

Dr Mohd Izzar Anwari Abd Khani, HIV/STI/Hep C Sector, Disease Control Division

En Chung Han Yang, Malaysia AIDS Council

En. Awang Izzam Awang Keri, PrEP Navigator KK Greentown

Ustaz Zulkifli Awang, Pertubuhan Duat Al-Falah

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We express our sincere gratitude to the **editors and contributors** who played a pivotal role in drafting, reviewing, and refining these guidelines. Their expertise and commitment have been instrumental in ensuring that the guidelines align with Malaysia's national HIV prevention strategies and public health priorities.

We also acknowledge the valuable contributions of the Malaysia AIDS Council, The Global Fund, PrEP Navigators, Pertubuhan Duat Al-Falah, and various community-based organizations. Their insights and support have strengthened the PrEP implementation framework, ensuring equitable access and meaningful engagement with key populations.

Our appreciation extends to healthcare professionals, researchers, policymakers, and stakeholders who provided technical expertise, policy direction, and logistical support throughout the development process. Their dedication to evidence-based approaches and commitment to expanding HIV prevention services have been crucial in shaping these guidelines.

This document reflects our shared commitment to reducing HIV transmission and improving public health outcomes in Malaysia. We trust that these guidelines will serve as a key reference in advancing PrEP access, strengthening HIV prevention strategies, and contributing to the national goal of **Ending AIDS by 2030**.



## **Abbreviations**

HIV Human Immunodeficiency Virus

PreP Pre-Exposure Prophylaxis
STI Sexually Transmitted Infection

**nPEP** Non-Occupational Post-Exposure Prophylaxis

PWID People Who Inject Drugs
CBT Community-Based Testing

BP Blood Pressure
PR Pulse Rate

RDT Rapid Diagnostic Test
UPT Urine Pregnancy Test
CrCl Creatinine Clearance

**RP** Renal Profile

ART Antiretroviral Therapy
TasP Treatment as Prevention
WHO World Health Organization
MSM Men Who Have Sex with Men

TGW Transgender Women
PLHIV People Living with HIV
MoH Ministry of Health

CBOs Community-Based Organizations
FMS Family Medicine Specialists

MOs Medical Officers

OSCA One Stop Addiction Centre
VAS Value-Added Services

**GAD-7** Generalized Anxiety Disorder 7-item

**HCV** Hepatitis C Virus **HBV** Hepatitis B Virus

**HPV** Human Papillomavirus

VMMC Voluntary Male Medical Circumcision

**PEP** Post-Exposure Prophylaxis

**DTG** Dolutegravir

**TDF/FTC** Tenofovir Disoproxil Fumarate / Emtricitabine

**TAF/FTC** Tenofovir Alafenamide / Emtricitabine

CAB-LA Cabotegravir Long-Acting

INSTI Integrase Strand Transfer Inhibitor

**IEC** Information, Education, and Communication

**SOGIE** Sexual Orientation, Gender Identity, and Expression

UVL Undetectable Viral Load

ATS Amphetamine-Type Stimulants

MMT Methadone Maintenance Therapy





The Ministry of Health Malaysia remains committed to strengthening national efforts to prevent and control HIV transmission, aligning with the national health agenda and global commitments, including the Sustainable Development Goals (SDGs) and the UNAIDS 95-95-95 targets. The National Guidelines on HIV PrEP Program Implementation 2025 provide a standardised framework to support the integration and scale-up of Pre-Exposure Prophylaxis (PrEP) services in Malaysia.

Malaysia has made significant progress in addressing the HIV epidemic, mainly through the expansion of

antiretroviral therapy (ART) coverage and the reduction of new infections. However, key populations (KPs) continue to experience a disproportionate burden of new HIV cases. In response to these challenges, PrEP has been identified as a critical intervention to complement existing prevention strategies, including condom use, harm reduction programmes, treatment as prevention (TasP), and regular HIV testing.

This guideline offers evidence-based recommendations on PrEP eligibility, service delivery models, adherence support, and risk reduction counselling. It serves as a key resource for healthcare providers, policymakers, and implementing partners to ensure the effective and sustainable delivery of PrEP services.

The Ministry of Health Malaysia extends its sincere appreciation to all parties involved in developing this guideline. With collective commitment, PrEP will strengthen national HIV prevention efforts and contribute to improved health outcomes for those at risk of HIV infection.

[Director-General of Health Malaysia]

Ministry of Health Malaysia

April 2025

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# Quick reference guide for PrEP providers

This chapter provides an overview of the essential components of PrEP provision, including eligibility criteria, baseline assessments, laboratory investigations, initiation protocols, and follow-up care.

#### What is HIV PrEP?

HIV PrEP is a highly effective prevention strategy for individuals at high risk of acquiring HIV. It involves the use of antiretroviral medication taken to reduce the likelihood of HIV infection if exposed. PrEP is a key component of comprehensive HIV prevention efforts, complementing other measures such as condom use, regular HIV testing, and risk-reduction counselling.

## Approved medications for HIV PrEP in Malaysia



#### Tenofovir Disoproxil Fumerate / Emtricitabine (TDF/FTC)

- For all adults OR adolescents > 35kg, including PWID
- Requires CrCl > 60 ml/min



# Injectable, long acting Cabotegravir

- Once in 2 months
- For all adults and adolescents > 35 kg



#### Tenofovir Alafenamide / Emtraticibine (TAF/FTC)

- For cisgender MSM and transgender women
- Not for cisgender women / persons at risk via receptive vaginal sex
- Requires CrCl > 30ml/min

### Who can benefit from PrEP?

Anal or vaginal sex in the past 6 months with:

- HIV +ve sexual partner (partner has an unknown or detectable viral load)
- Partner with unknown HIV status
- HIV +ve PWID partner / sharing injecting equipment

Any individuals requesting for HIV PrEP

Any individuals diagnosed with STI in the past 6 months

Inconsistent use of condom for anal / vaginal sex

PWID / share injecting equipment

Recent use of nonoccupational post exposure (nPEP) / multiple nPEP use in the past

Any individuals engaging in chemsex

Any individuals engaging in transactional sex

#### Initial PrEP visit

Test for HIV (offer PrEP to HIV negative individuals only)



Assess the need for PEP (If the last unprotected sex was less than 72 hours)



Ask for Acute HIV Seroconversion Illness symptoms



Conduct baseline investigation and assess the need for referrals to other services e.g. methadone, counsellor for ATS use, mental health

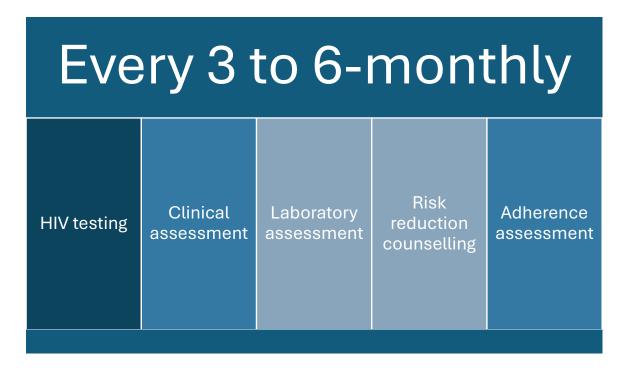


Confirm client's willingness to use PrEP and readiness to adhere to treatment and follow-up schedule



Give Pre-PrEP counselling

#### Follow-up visits



## Key counselling messages to clients

# PrEP effectiveness

- •All PrEP choices (daily vs event-drivent, oral vs longacting injectable)
- •Effectiveness depends on adherence tp PrEP

# PrEP is only for HIV prevention

 PrEP does not offer prevention against other STIs or pregnancy

# Safe and well tolerated

•Side effect typically mild and resolve on their own or can be treated symptomatically

# Importance of follow-up

•Regular follow-up are important to support PrEP effectiveness

## Important messages to PrEP providers

## PrEP is not for life

- •People on PrEP can stop, start and restart PrEP as their needs change
- •Empower clients to use PrEP effectively by giving enough information about PrEP

# Pregnancy and Prep

•Oral PrEP is safe during pregnancy and breastfeeding

# Adopt patientcentred approach

• PrEP service should tailored to the needs and preferences of clients

# Referral to other services

 Refer client accordingly for other medical services if needed such as for MMT services, mental health clinics or psychosocial support services

## Background

#### Global Context of HIV Prevention

Human Immunodeficiency Virus (HIV) remains one of the most significant global public health challenges. Over the past few decades, extensive research and advancements in medical science have paved the way for the development of various prevention methods aimed at curbing the spread of HIV. Among the most effective biomedical interventions is Pre-Exposure Prophylaxis (PrEP), a preventive strategy in which individuals at high risk of HIV infection take antiretroviral medications to significantly reduce their likelihood of acquiring the virus.

The World Health Organization (WHO) recommends PrEP as a key component of a comprehensive HIV prevention strategy, particularly for populations at substantial risk of acquiring HIV. Many countries have successfully integrated PrEP into their national HIV prevention programs, contributing to a significant reduction in new infections. By 2024, notable progress has been observed in key populations, such as men who have sex with men (MSM), transgender individuals, sex workers, and people who inject drugs (PWID). These advancements highlight the global momentum toward achieving the ambitious goal of ending AIDS as a public health threat by 2030.

#### The HIV Epidemic in Malaysia

Malaysia is not immune to the global HIV epidemic. Since the first reported case in 1986, the country has witnessed a steady rise in HIV cases. As of 2023, an estimated 85,283 people were living with HIV (PLHIV) in Malaysia, of whom 71,927 (84%) were aware of their status, as reported through the national surveillance system (MoH, 2024). However, there remains a significant gap in treatment uptake, with only 68% of diagnosed individuals receiving antiretroviral therapy (ART). Among those on treatment, 89% achieved viral suppression, underscoring the importance of improving access to care and retention in treatment programs.

Malaysia's HIV epidemic is concentrated primarily among key populations, including MSM, PWID, transgender individuals, and female sex workers. While the country has made notable progress in HIV management through the widespread availability of ART, the epidemic continues to pose significant public health challenges. Notably, the modes of transmission

have shifted over time, with sexual transmission—particularly among MSM—now being the leading cause of new infections (Figure 1 and Figure 2).

This evolving landscape highlights the urgent need for comprehensive, targeted prevention strategies. The introduction and scale-up of PrEP services represent a critical opportunity to address this challenge and further reduce the burden of HIV in Malaysia.

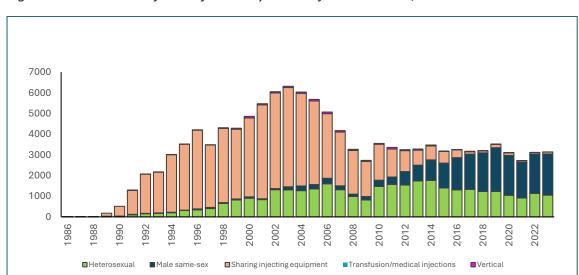
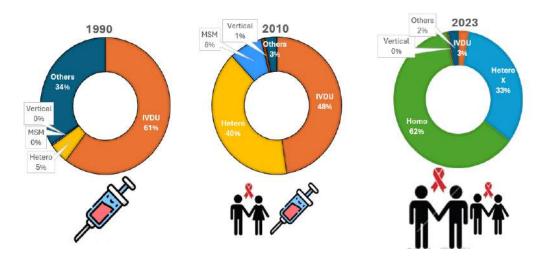


Figure 1: Distribution of HIV infection by Mode of Transmission, 1986-2023

Figure 2: Changes in HIV Landscape in Malaysia, 1990 - 2023



Others - includes blood transfusion, organ transplant, needle-prick injury and no information

# HIV Pre-Exposure Prophylaxis (PrEP) Program in Malaysia

#### Introduction

The National PrEP Program represents a significant step forward in Malaysia's HIV prevention efforts. By integrating PrEP into the broader HIV prevention strategy, Malaysia has the opportunity to reduce new infections and move closer to achieving the global goal of ending AIDS as a public health threat by 2030. However, to fully realise the benefits of PrEP, a multisectoral approach involving government, healthcare providers, civil society, and key populations is necessary.

The success of the PrEP program will depend on overcoming existing barriers, improving public awareness, and ensuring sustainable access to the necessary resources. By doing so, Malaysia can make meaningful progress in addressing the HIV epidemic and safeguarding the health and well-being of its most vulnerable populations.

The National PrEP Guideline serves as a framework for implementing PrEP programs nationwide. The guideline emphasises the need for culturally sensitive and comprehensive care to ensure equitable access to PrEP for individuals at high risk of HIV infection.

Having a standardised manual of procedures for the PrEP program roll-out at primary care, private clinics, and hospitals will enhance quality assurance and facilitate the monitoring of the program's effectiveness. It will also ensure that healthcare providers receive appropriate training and have access to the necessary tools and resources to provide effective care.

#### Barriers and Challenges to PrEP Implementation in Malaysia

While the PrEP program presents an effective tool for HIV prevention, its implementation faces several challenges that need to be addressed for successful scale-up:

- 1. **Stigma and Discrimination**: HIV-related stigma remains pervasive in Malaysia, particularly towards key populations. This social stigma can deter individuals from seeking PrEP services or openly discussing their risk of HIV infection.
- 2. **Awareness and Education**: Healthcare providers and potential users remain limited in their awareness and understanding of PrEP. Increasing awareness through education campaigns and targeted outreach is critical to the program's success.

- 3. **Access and Affordability**: Ensuring equitable access to PrEP, especially in rural and underserved areas, is a significant challenge. The cost of PrEP medication and services must be addressed to ensure it is accessible to those who need it most.
- 4. **Adherence to PrEP**: Effective PrEP use requires consistent medication regimen adherence. Challenges related to adherence may arise due to side effects, misconceptions, or irregular access to healthcare services.

#### Rationale for the National PrEP Program

The implementation of a national PrEP program in Malaysia is driven by several factors, as depicted in Figure 3. Key populations in Malaysia, such as MSM, TGW, and PWID, continue to face high rates of new HIV infections despite ongoing prevention efforts. PrEP offers a targeted prevention tool that can significantly reduce transmission rates within these groups. International guidelines, particularly from the WHO, have underscored the importance of PrEP in HIV prevention strategies, and Malaysia's adoption of these recommendations aligns with global best practices. By preventing new infections, the PrEP program is also expected to alleviate long-term healthcare costs associated with HIV treatment, which is especially important as Malaysia's healthcare system grapples with growing demands. Additionally, the program enhances access to broader healthcare services for vulnerable populations, including HIV testing, sexual health services, and harm reduction initiatives.

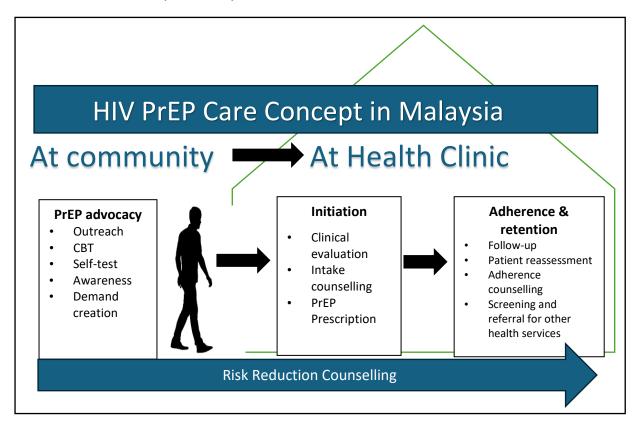


Figure 3: Key Drivers of the PrEP Program Implementation

#### HIV PrEP Care Concept in Malaysia

The HIV PrEP care concept is being implemented in Malaysia as part of its comprehensive HIV prevention strategy. The summary of the care concept for HIV PrEP in Malaysia starts with community-level initiatives, such as PrEP advocacy, which includes creating awareness about PrEP, HIV testing, and generating demand. This is followed by clinical care at the health clinic, which involves managing PrEP initiation, adherence, and retention. Figure 4 illustrates the HIV PrEP care concept in Malaysia.

Figure 4: HIV PrEP Care Concept in Malaysia



The HIV PrEP Care Concept in Malaysia outlines a comprehensive approach to HIV prevention, starting with community-level efforts to raise awareness and create demand for PrEP. Advocacy initiatives include outreach programs, community-based testing (CBT), self-testing, and educational campaigns targeting high-risk populations and the general public. These efforts aim to inform individuals about PrEP as an effective HIV prevention tool and encourage proactive health-seeking behaviours.

Once individuals express interest, the process shifts to health clinics, where they undergo clinical evaluations, including HIV testing, risk assessments, and STI screenings. Eligible individuals receive intake counselling and are prescribed PrEP with daily or event-driven dosing options. Adherence and retention are maintained through regular follow-ups, testing, and adherence counselling, while risk reduction strategies such as condom use and reducing sexual partners are emphasised. This integrated approach ensures comprehensive HIV prevention and holistic care for at-risk individuals.

#### Objectives of the PrEP guidelines

The guidelines aim to ensure that all healthcare providers involved in the PrEP program have access to standardised procedures and protocols for screening, eligibility assessment, initiation, and maintenance of PrEP, as well as clinical monitoring and adherence support. They also address concerns related to safety, confidentiality, and stigma associated with PrEP use.

#### Scope of the Guidelines

The National PrEP Guidelines for Malaysia provide guidance and recommendations for healthcare providers and other stakeholders implementing PrEP programs nationwide. The scope includes defining the roles of healthcare providers such as family medicine specialists, medical assistants, nurses, pharmacists, and community health workers—including outreach workers and PrEP navigators—in managing PrEP clinics.

#### Target Audience

These guidelines provide comprehensive guidance for key stakeholders involved in **HIV prevention, treatment, and policy development**. The intended audience includes:

- Family Medicine Specialists and Infectious Disease Physicians responsible for the clinical management and care of individuals at risk of HIV infection.
- General Practitioners and Medical Doctors engaged in HIV prevention, screening, and treatment efforts.

- **Pharmacists and Paramedics** involved in providing healthcare services to individuals at risk of HIV infection, including medication counselling and adherence support.
- **Community-based organisations (CBOs)** supporting key populations through advocacy, outreach, and service delivery.
- PrEP Navigators facilitating access to Pre-Exposure Prophylaxis (PrEP) and providing guidance on its use.
- Counsellors and HIV Testing Personnel, including those conducting point-of-care HIV testing, to support early diagnosis and linkage to care.
- Health Program Policymakers involved in formulating and implementing national HIV prevention strategies.

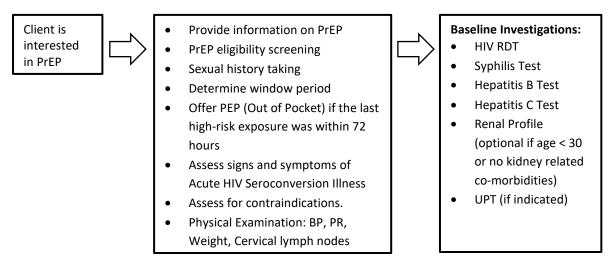
# **HIV PrEP Clinical Care Management**

#### **Starting PrEP**

#### Pre-PrEP assessment

When a client expresses interest in starting PrEP, a thorough pre-PrEP clinical assessment is necessary to ensure eligibility and safety (Figure 5).

Figure 5: pre-prep assessment procedure



#### Criteria for PrEP Suitability

In Malaysia, individuals at substantial risk of acquiring HIV are identified based on specific eligibility criteria for PrEP (Pre-Exposure Prophylaxis). These criteria help ensure that those who would benefit most from PrEP can access it as a preventive measure. The key populations at risk, based on these eligibility criteria, include:

- 1. HIV-Negative Individuals Without Acute HIV Seroconversion Illness
- 2. Individuals at Substantial Risk of HIV Infection
  - Inconsistent Condom Use:
    - Clients who have had vaginal or anal sex without consistent condom use in the past six months.
    - Clients who anticipate inconsistent condom use in the future.

#### • Recent STI Diagnosis:

 History of recent STI confirmed by laboratory testing, self-report, or syndromic screening.

#### • Recent Use of Non-Occupational Post-Exposure Prophylaxis (nPEP):

- Especially those who have used nPEP multiple times.

#### • Sexual Partner with Unsuppressed HIV:

- Clients whose sexual partner(s) is living with HIV and not virally suppressed on antiretroviral therapy (ART).

#### 3. Individuals Who Inject Drugs

• Clients who share injecting equipment or have HIV-positive injecting partners.

#### 4. Individuals Engaging in Chemsex

• Use of drugs to enhance sexual experience, increasing risk behaviours.

#### 5. Individuals Engaged in Transactional Sex

• Exchange of sex for money, housing, or other needs.

#### 6. Clients Requesting PrEP

• Self-identification of the need for PrEP even after pre-PrEP counselling, which is associated with a substantial risk of acquiring HIV.

#### **Pre-PrEP Counselling**

Pre-PrEP counselling focuses primarily on building rapport and trust between the provider and the client, fostering a safe, non-judgmental environment for open and honest discussions. It involves exploring the client's HIV risk behaviours, addressing any concerns or misconceptions about PrEP, and supporting informed decision-making. By establishing a strong foundation of trust, pre-PrEP counselling promotes adherence, encourages ongoing communication, and reinforces a client-centred approach to comprehensive HIV prevention.

#### **Introduce Yourself**

• Begin the consultation by warmly introducing yourself to the client

#### **Clarify the Purpose of Consultation**

- ✓ Clearly explain the purpose of the session to ensure the client feels informed and comfortable.
- ✓ Example: "I understand you're here to talk about PrEP today; is that correct?"

#### **Explore Ideas**

- ✓ Ask open-ended questions to gauge the client's current understanding of PrEP, as this can help identify knowledge gaps or misconceptions.
- ✓ Example: "What have you heard about PrEP so far?", "Have you come across any information about PrEP?"

#### **Addressing Concerns**

- ✓ Encourage the client to share any concerns they may have, fostering an environment where they feel comfortable discussing potential barriers.
- ✓ Example: "Do you have any worries about taking PrEP?", "Are there any specific concerns about the medication or how it works?"

#### **Understanding Expectations**

- ✓ Discuss the client's goals and expectations with PrEP to align their understanding with realistic outcomes and reinforce the benefits of consistent usage.
- ✓ Example: "What are you hoping to achieve with PrEP?", "Is there anything specific you'd like to discuss today?"

#### **Sexual History Taking**

#### 1. Opening the Conversation

- Example: "I'd like to ask you a few questions about your sexual health, which I discuss with all my patients annually to ensure comprehensive care. Everything you share is confidential. Do you have any questions before we begin?"

#### 2. Creating a Welcoming Environment

- Ensure Confidentiality
  - o Conduct the conversation in a private, designated room.
  - o Avoid interruptions and ensure privacy.
- Enable Open Communication
  - o Adopt a friendly and non-judgmental approach.
  - Build trust and rapport with the client.

#### 3. Approach: The 5 Ps

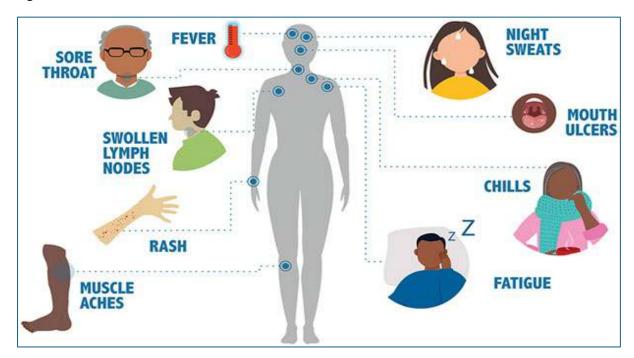
Partners	"Are you currently sexually active?"			
Parmers	"In the past six months, how many sexual partners have you had?"			
	"What is the gender of your partner(s)?"			
	"Do you or your partner(s) have other sexual partners?"			
D	"What types of sexual activities do you engage in? Vaginal, anal, or oral sex?"			
<b>P</b> ractices	"Do you identify as a top, bottom, or versatile?"			
	"Have you or your partners used recreational drugs during sexual activities?"			
	"Have you ever exchanged sex for money, goods, or services?"			
Protection from STIs	"Do you use condoms with your partners?"			
	"How often do you use them—always, sometimes, or never?"			
	"In which situations do you use or not use condoms?"			
	"Have you been vaccinated against HPV, hepatitis A, or hepatitis B?"			
Past	"Have you ever been diagnosed with an STI?"			
History of	"When was your last STI screening?"			
STIs				
<b>P</b> regnancy	"Are you currently planning or considering pregnancy?"			
0				
Intention (if				
applicable)				

**Note:** If a client is hesitant to discuss their sexual practices but is interested in PrEP, prioritise initiating PrEP and revisit detailed history in future consultations.

#### Acute HIV seroconversion illness assessment

The client should be assessed for any signs or symptoms of acute HIV seroconversion illness, which could indicate recent HIV infection, as well as for potential contraindications to PrEP. Figure 6 illustrates the common symptoms associated with acute HIV seroconversion illness, which typically occurs 2 to 4 weeks after initial HIV exposure. These symptoms are often nonspecific and may resemble the flu or other viral infections.

Figure 6: Acute HIV Seroconversion Illness



#### HIV Window period assessment

The window period refers to the time between a potential HIV exposure and when an HIV test can reliably detect the virus in the body. During this period, even if HIV is present, the infection may not be detected by specific tests, which can impact the timing of PrEP initiation and other preventive measures. Figure 7 shows a summary of management after the window period.

#### Types of HIV Tests and Their Window Periods:

The window period varies depending on the type of HIV test used:

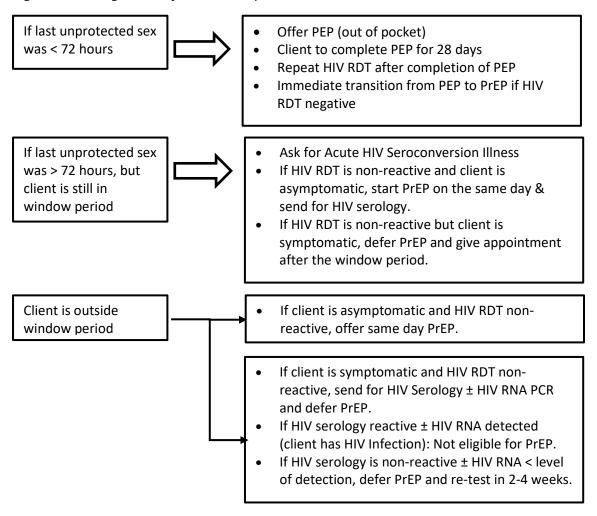
#### • Fourth-generation HIV Rapid Diagnostic Test (RDT)

This test detects HIV-specific antibodies (IgG, IgM) and the p24 antigen. The median window period is 18 days, with an interquartile range of 13 to 24 days.

#### • Third-generation HIV Rapid Diagnostic Test (RDT)

This test detects HIV-specific antibodies (IgG, IgM) only. The median window period is 26 days, with an interquartile range of 22 to 31 days.

Figure 7: Management after window period assessment



Reference: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline

#### Laboratory assessment

- 1. HIV Testing: HIV Rapid Diagnostic Tests (RDT) are used for initial HIV screening at baseline (M0). To ensure ongoing monitoring and safety, HIV RDT should be conducted every three months thereafter, regardless of whether clients are on Daily or Event-Driven PrEP. These tests can be performed between clinic visits to maintain adherence to the PrEP regimen and detect any potential HIV infections promptly. If the test result is reactive, a confirmatory HIV PCR test should be performed. RDT testing methods include:
  - <u>HIV Self-Testing (HIVST)</u>: Clients can use self-testing kits for convenience, particularly between scheduled clinic visits (e.g., at month 3, month 9, etc.).
  - <u>Community-Based Testing (CBT)</u>: Testing conducted at community outreach events or local healthcare facilities to expand access and ensure regular monitoring.
- 2. **Syphilis Testing:** Syphilis screening is conducted using a rapid diagnostic test (RDT) at baseline (M0) and then every six months.
- 3. **Gonorrhea Testing:** Gonorrhea testing is optional and performed if the client reports symptoms suggestive of a gonorrhoea infection. Tests include a gram stain, culture and sensitivity (C&S), or the Xpert CT/NG assay when necessary.
- 4. **Hepatitis C Testing:** Hepatitis C serological testing (HCV) or Hep C RDT should be conducted at baseline (M0) or when deemed necessary based on risk factors or clinical suspicion. HCV infection is not a contraindication for oral PrEP. If positive, refer for further assessment and treatment for HCV infection.
- 5. **Hepatitis B Testing:** Hepatitis B surface antigen (Hep B Ag) testing should be performed at baseline (MO) or as needed, depending on the individual's vaccination status and exposure risks. Hepatitis B Virus (HBV) infection is not a contraindication for oral PrEP. Where people with chronic HBV infection use oral PrEP, regular monitoring to detect relapse and management of HBV after stopping TDF-based PrEP is essential. If positive, refer for further testing and assessment for HBV treatment.
- 6. **Renal Profile Testing:** Renal function testing is crucial for assessing creatinine clearance at baseline (M0). Additional testing is recommended:
  - Every 6 months for individuals aged 50 years and above, or
  - Every 12 months for individuals with creatinine clearance (CrCl) ≤ 90 ml/min, or more frequently if clinically indicated.

#### Same-day PrEP initiation

Whenever possible, efforts should be made to start PrEP on the same day as the client's initial consultation without waiting for test results. The decision to initiate same-day PrEP should be evaluated on a case-by-case basis, considering factors such as the chosen PrEP regimen, the client's risk of HIV acquisition if PrEP is delayed, and the potential risk of HIV drug resistance if PrEP is initiated during an undiagnosed acute HIV seroconversion illness.

In most cases, the benefits of providing PrEP to prevent HIV far outweigh the risks of potential drug resistance for the following reasons:

- Acute Retroviral Syndrome (ARS) is rare, and most suspected ARS cases are not due to HIV infection.
- 2. **PrEP is highly effective** in preventing HIV infection, which would otherwise lead to lifelong therapy that carries its risks, such as virological failure and drug resistance.

Given that AHI is uncommon and the likelihood of developing HIV drug resistance is low, providers should emphasise the importance of attending follow-up visits, especially the one-month follow-up visit, which is crucial for repeating HIV testing and ensuring the client's HIV-negative status.

Although there is a small risk of drug resistance developing in clients who are in the acute phase of HIV infection when starting PrEP, the incidence remains low. Studies have shown that the overall benefit of same-day PrEP initiation in preventing HIV transmission outweighs this risk (Parikh, 2016).

However, PrEP initiation should be delayed if the client is exhibiting symptoms of acute seroconversion illness to prevent the risk of starting PrEP during an undiagnosed HIV infection.

#### Starting same-day PrEP

- Decide regime- daily or event driven
- Prescribe PrEP for 1 month
- Provide adherence & risk reduction counselling
- Provide condom
- Offer effective contraception for female client
- Give appointment in 1 month



- Trace RP within 1 week
- Calculate creatine Clearance (CrCl)
- If CrCl <60 ml/min, call back client for repeat RP. If result is still < 60 ml/min, stop PrEP and discuss other methods of HIV Prevention (ABC)
- If CrCl > 60 ml/min: continue PrEP

#### Follow-up visits (ongoing monitoring)

Follow-up visits for oral PrEP are typically conducted at month 1 and every six months thereafter. However, these schedules can be adjusted based on the client's needs and preferences. For example, clients who frequently travel for extended periods may require a more flexible follow-up plan to accommodate their circumstances.

Follow-up visits serve as critical touchpoints for PrEP providers and clients to discuss sexual health goals, concerns, and PrEP-related experiences, including side effects and adherence strategies.

During follow-up consultations, healthcare providers should offer comprehensive counselling and assessments, focusing on the following areas:

- 1. **Assessment for AHI:** Providers should be vigilant for signs of AHI, particularly in individuals who have discontinued PrEP or have not used it consistently. If AHI is suspected due to ineffective PrEP use, a similar approach to initial PrEP screening and assessment should be applied.
- 2. **Discussion of Sexual Health Goals and Concerns:** Providers should engage clients in open discussions about their sexual health, addressing any behavioural, emotional, or social factors that may impact PrEP use

- 3. **Reinforcement of key PrEP Messages:** Guidance on the correct use of the PrEP regimen, including how to safely discontinue PrEP and steps to take if PrEP adherence is compromised.
- 4. **Management of Side Effects:** Identify and manage common side effects to improve adherence and user experience.
- 5. **Evaluation of PrEP Continuation or Switching Preferences:** Assess the client's intention to continue PrEP or explore potential switching to alternative PrEP formulations based on their needs and preferences.
- 6. Provision of additional health services (as needed):
  - a. Prevention and testing for STIs
  - b. Sexual and reproductive health
  - c. Testing for HBV and HCV and linkage to care
  - d. Mental health, drug and alcohol use

A summary of the assessments conducted during each clinic visit is outlined in Table 1.

Table 1: Summary of assessment during clinic visits as per schedule.

Test	0 month (baseline)	1 month	3 months	Every subsequent 3-6 months	Comment
HIV test	>	>	>	>	
Assess for: - Symptoms of seroconversion - Need for PrEP - Adherence	>	>	>	<b>&gt;</b>	
Renal profile to calculate eGFR (Depending on age & kidney-related comorbidities)	>			6 monthly if > 50 years old	12 monthly if CrCl ≤ 90 ml/min
STI screening (Syphilis serology, GC/CT NAAT)	>			>	Consider risk reduction counselling. GC/CT: if needed
HBsAg	Perform at baseline. Annual screening if not vaccinated.				
HCV RDT	Perform at baseline				
Urine pregnancy test	Consider if delayed/missed menses.				
Optional					
Anti-HepBs	Perform at baseline and to Vaccinate if antibody ≤10 IU/L.				
Anti-HCV	Strongly recommended at or within the 1st 3 months of PrEP initiation and 12 monthly in populations at high risk of HCV infection.				
Anti-HAV or IgG-HAV	Consider vaccinating if antibody negative (MSM and others at risk)				

## Types of HIV PrEP available in Malaysia

#### Oral PrEP - Tenofovir disoproxil fumarate / emtricitabine (TDF/FTC)

In Malaysia, oral PrEP (TDF/FTC) has been included in the Ministry of Health (MOH) drug formulary and approved for use in government healthcare facilities since 2024. Has been approved as HIV PrEP by the National Pharmaceutical Regulatory Agency (NPRA). These medications are widely used for HIV prevention and are accessible through government healthcare services. It is effective in preventing HIV acquisition through parenteral exposure

or sexual exposure (vaginal and anal sex). This regimen is also suitable for individuals taking exogenous feminising or masculinising hormones.

Two dosing regimens are currently recommended for TDF-based oral PrEP: daily and event-driven dosing. The selection of the appropriate regimen depends on the individual's specific characteristics, lifestyle, circumstances, and the route of potential HIV exposure.

Table 2 provides an overview of the dosing regimens and eligibility criteria, guiding healthcare providers in determining the most appropriate regimen for each individual.

Table 2: Comparison of Daily and Event-Driven Dosing Strategies for PrEP Eligibility

Daily PrEP Dosing	Event-Driven PrEP (ED PrEP) Dosing
Eligibility: Anyone with a substantial risk of HIV infection The only option for:	Cisgender men     Trans/gender diverse people assigned male at birth who are not taking feminising hormones
Lead time: 7 days.  * Cisgender men can initiate Event-Driven dosing	Lead in time - At least 2 hours (ideally 24 hours) before sexual exposure with a loading dose of 2 tablets.
Stopping - 7 days after last exposure * Cisgender men - may stop 48 hours after last sexual exposure	Stopping - 48 hours after the last sexual exposure

#### Daily PrEP dosing

Daily dosing PrEP is recommended for individuals who:

- 1. Experience ongoing HIV exposure lasting more than one day.
- 2. Prefer a consistent daily routine over repeatedly starting and stopping PrEP.
- 3. Face unpredictable exposure risks with uncertain timing of potential HIV exposure.
- 4. Desire continuous protection against HIV.

# Key considerations

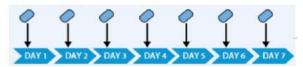
- Switched between regimen: ED-PrEP can transition to daily simply by continuing the medication
- Empowerment: No difference in how to start or stop oral PrEP
- No time limits: No restriction on how long someone can take PrEP or how often they can restart

### Missed doses

- Single missed dose: Take the misssed dose as soon as remembered, but do not take more than 2 doses in one day
- Stopped PrEP (> 2 days):
  Restart the regimen
  whenever there is a renewed
  risk of exposure, following the
  guidance for initiating PrEP

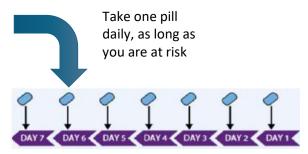
Daily PrEP should be continued for as long as desired and at least two days after the last potential exposure to maximise protection and simplify management (Figure 8).

Figure 8: Daily PrEP



Take one pill daily for seven days before potential sexual exposure

- Cisgender men
- Cisgender women
- Transmen
- Transwomen who are taking estradiol-based hormones
- IVDU



Planned to stop PrEP: Take 1 pill daily for seven days after last potential exposure, then stop

Reference: WHO PrEP Implementation Tool 2023

#### Event-driven dosing for PrEP (ED PrEP)

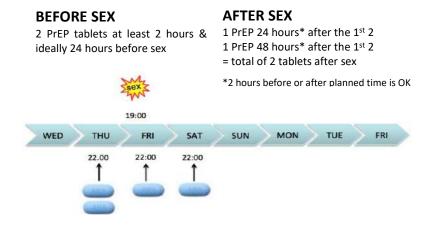
ED PrEP, also known as "on-demand" or "intermittent" PrEP, is a flexible strategy designed for individuals at substantial risk of HIV infection through sexual transmission but who do not require daily medication. This dosing method is particularly suitable for people who engage in infrequent, planned, or predictable sexual activity, as it allows them to take PrEP only when needed rather than every day.

#### **Eligibility criteria:**

- Only for sexual transmission
- Individuals who would find ED-PrEP more practical and convenient
- Individuals engaging in infrequent sexual encounters or planned sexual activity
- Sexual activity with predictable timing and those who can plan for sex at least 2 hours
   in advance or who can delay for at least 2 hours
- Individuals must be able to adhere to the dosing schedule.
- Only for cisgender men/trans and gender diverse people assigned male at birth

Figure 9 explains how to start a client with event-driven PrEP.

Figure 9: Event-driven PrEP



#### Contraindications to TDF/FTC

PrEP should not be initiated in individuals with the following conditions:

- Known HIV-positive status.
- Creatinine clearance less than 60ml/min
- Hypersensitivity to any components of the PrEP regimen

#### Other HIV PrEP Options

In scenarios where oral PrEP (TDF/FTC) is not an option, alternative PrEP options should be considered.

- 1. Tenofovir Alafenamide (TAF/FTC):
  - TAF/FTC is indicated in at-risk adults and adolescents weighing at least 35Kg to reduce the risk of HIV infection from sexual acquisition
  - It has to be taken only daily dosing
  - It is only for cisgender MSM and transgender women. It is not for cisgender women and other persons at risk via receptive vaginal intercourse
  - It is safe to be used for CrCl more than 30 ml/min
  - Associated with less bone and renal toxicity
  - Has not yet been approved by the NPRA for HIV PrEP indication and is not listed in the MOH drug formulary.

#### 2. Cabotegravir (CAB-LA):

- CAB-LA is a second-generation INSTI recommended as PrEP for adults at risk of sexually acquiring HIV
- Injections are to be provided at 8-week intervals with 600 mg administered IM after an initial 4-week interval separating the first two injections (Figure 9)
- Its dosing schedule provides an alternative to daily oral PrEP, potentially improving adherence and efficacy, particularly among individuals facing challenges with daily pill regimens
- Highly effective in preventing HIV through sexual transmission
- Approved by NPRA as HIV PrEP but not yet listed in the MOH drug formulary

Follow-up injection

• 1 injection

• 1 injection, after 4 weeks

Maintenance

• 1 injection every 8 weeks

Figure 10: Dosing Schedule for Cabotegravir Long-Acting (CAB-LA) Injections

#### Stopping and restarting PrEP

#### 1. Stopping PrEP:

PrEP should be discontinued in the following situations:

- **HIV Seroconversion:** If HIV infection is confirmed, PrEP must be stopped immediately to facilitate the initiation of appropriate antiretroviral therapy.
- Significant Side Effects: PrEP should be discontinued if the client experiences severe side effects, and necessary support should be provided to manage these adverse effects.
- Client Choice or Risk Reassessment: PrEP may be safely stopped if the client decides to switch to another HIV prevention method or no longer perceives themselves to be at risk of HIV.

#### 2. Restarting PrEP

When a client chooses to restart PrEP, the following steps should be taken:

• **Re-initiation Protocol:** Follow a process similar to the initial PrEP initiation, ensuring the client is well-informed and comfortable resuming PrEP.

- HIV Screening: Perform an HIV test before restarting PrEP, even if a recent test
  was conducted within the last three months, to confirm the client remains HIVnegative. Additionally, screen for any new contraindications.
- Tailored Approach: Adopt a personalised approach based on the client's medical history. If recent relevant test results are available, unnecessary retesting can be avoided to streamline re-initiation.

## Management of Side Effects and Adverse Events

- Mild side effects (start-up syndrome) such as transient nausea, abdominal cramping and headache may resolve with continued use but should be monitored closely.
- Generally, discontinuing PrEP is not necessary and can be managed with simple analgesics and antiemetics if necessary.
- Address any concerns promptly, considering alternative PrEP regimens or discontinuation if side effects persist or worsen.
- Rare adverse events like renal insufficiency and the potential for a decrease in bone mineral density should be made aware of.

## PrEP in special situations

#### Post-exposure prophylaxis (PEP) following sub-optimal daily PrEP

- Anal sex: If less than four tablets have been taken within the last seven days or if the last dose was taken more than seven days ago, PEP should be initiated.
- Vaginal sex: If more than 48 hours have elapsed since the last dosing or if less than six tablets have been taken within the last seven days, PEP should be initiated.

#### Acute kidney injury while on PrEP

- If creatinine clearance (CrCl) < 60 mL/min, repeat the test on a separate day before discontinuing oral PrEP. Discontinue TDF/FTC if acute kidney injury is persistent (CrCl <60 ml/min).</li>
- Discuss alternative HIV prevention options when stopping PrEP.
- If a different cause for acute kidney injury is identified and treated and renal function improves (CrCl ≥ 60 mL/min), PrEP may be reinitiated with close renal monitoring.
- If CrCl is between 30 59 ml/min, daily TAF/FTC may be considered where available (only for cisgender MSM and transgender women).

#### HIV seroconversion while on PrEP

- If HIV infection is confirmed, refer the individual to an Infectious Disease Physician as soon as possible.
- Conduct HIV viral load and resistance testing before transitioning to antiretroviral therapy (ART).
- A dolutegravir (DTG)-based regimen should be considered when initiating ART, with adjustments based on resistance testing results.

<sup>\*</sup>For sub-optimal ED PrEP, PEP is recommended if the last sexual exposure is within 72 hours.

## PrEP for individuals with Chronic Hepatitis B

- TDF/FTC can be used concurrently for both HBV treatment and HIV PrEP.
- Discontinuing PrEP may cause HBV rebound viraemia and hepatic flare; comanagement with a hepatologist should be considered.
- Both daily and event-driven PrEP can be safely offered to individuals with HBV infection.

#### PrEP for individuals with Hepatitis C

- Daily or event-driven oral PrEP can be safely offered to persons with HCV infection.
- Individuals with reactive HCV serology should undergo further assessment for active
   HCV infection and be offered appropriate treatment.

#### PrEP for individuals with STI

 Given the high rates of bacterial STIs among PrEP users, and as part of a comprehensive risk reduction strategy, 3-monthly STI screening (gonorrhoea, chlamydia NAAT and syphilis serology) is recommended for MSM and trans women.

#### PrEP with Feminising and Masculinising Hormones

- There are no known interactions between TDF/FTC and feminising and masculinising hormones.
- Oral PrEP does not significantly affect gender-affirming hormone levels.
- Feminising hormones taken by transgender women may result in lowering activated
   TDF levels, but not enough to affect the efficacy when taken daily.

#### PrEP for Adolescents under 18 years old

- PrEP is recommended for adolescents weighing more than 35 kg who report sexual or injection behaviours that indicate a risk of HIV acquisition.
- However, adolescents below the age of 18 are bound to the Child Act 2001 and are legally incompetent to give consent. Thus, their parents or guardians act as decisionmakers.

- Providing PrEP for adolescents has multiple challenges, like age-related legal, policy, regulatory and social barriers to accessing PrEP, including the age of consent laws that limit access to HIV testing and/or HIVST can be a barrier to PrEP.
- Tailored interventions to facilitate adherence among adolescents and young people
  may be needed, including regular follow-up and support groups for clients using PrEP,
  such as social media groups for peer-to-peer sharing of experiences and challenges.

#### PrEP for Pregnant and Breastfeeding Women

- PrEP may be considered for HIV-negative partners in serodiscordant relationships, especially when attempting conception if the HIV-positive partner is not on suppressive ART.
- If a pregnancy occurs during PrEP use, a discussion should be held to weigh the risks and benefits of continued PrEP use during pregnancy.
- PrEP continuation during breastfeeding should be based on an informed decision,
   balancing potential risks and benefits.
- Generally, oral PrEP is considered safe during pregnancy and breastfeeding.

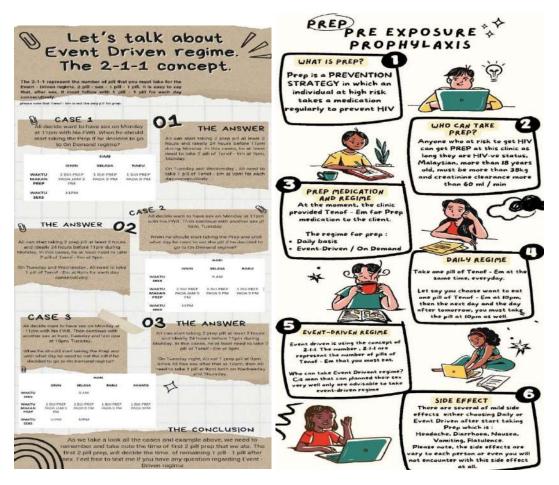
## Adherence and Retention Strategies

When developing adherence and retention strategies, a comprehensive assessment of the factors and barriers contributing to non-adherence to PrEP should be conducted. Identified issues and barriers should be systematically addressed through targeted intervention strategies and effective implementation.

No.	Issue	Intervention strategy	Implementation
1	Low literacy on PrEP among clients and healthcare workers leading to misconceptions.  Lack of confidence in PrEP among healthcare workers due to culture and religious beliefs.	Education and Counselling  Peer Support Group	<ul> <li>Regular education and counselling by PrEP clinic staff and PrEP Navigators, providing clear, accessible information on PrEP benefits, side effects, and adherence using physical/digital IEC materials (Figure 11).</li> <li>Conduct sensitisation workshops for healthcare workers to enhance understanding of PrEP care within cultural and religious contexts.</li> <li>Peer Support Groups, led by PrEP Navigators, address misconceptions and foster support among PrEP clients.</li> </ul>
2	Side effects of PrEP medication affecting adherence motivation	Managing Side Effects of PrEP medication	<ul> <li>Educate clients on expected side effects and management strategies.</li> <li>Provide reassurance that most side effects are temporary and encourage continued adherence.</li> </ul>
3	Internal stigma leading to fear of disclosure Stigma and discrimination among healthcare workers	Stigma Reduction	<ul> <li>Reassure clients that their privacy and confidentiality will be fully protected.</li> <li>Train healthcare workers on preserving client confidentiality and non-discriminatory practices.</li> <li>Introduce a stigma diary (survey form) to identify and address stigma-related issues through investigations and sensitisation workshops for healthcare workers, particularly for key populations.</li> </ul>
4	Behavioural challenges, such as lack of discipline and forgetfulness	Adherence Monitoring and Reminder Tools	- Encourage clients to use adherence
5	Missed appointments and difficulty accessing healthcare services	Regular and Flexible	- Provide flexible clinic hours to accommodate client availability.

		Appointment Scheduling	- Offer telehealth services for stable clients to improve follow-up adherence.
6	Missed medication refills due to logistical barriers	Refill Coordination and Drug Delivery	<ul> <li>Monitor missed refills and proactively follow up with clients.</li> <li>Implement value-added pharmacy services (VAS), including:</li> <li>Medication postage services</li> <li>Clinic locker systems for convenient medication collection.</li> </ul>
7	Underlying mental health issues (e.g., anxiety, depression, substance use) leading to non-adherence	Addressing Mental Health and substance abuse	<ul> <li>Establish linkages to psychosocial support, including:</li> <li>Psychologists/Psychiatrists for mental health care.</li> <li>One Stop Addiction Centre (OSCA) referrals for substance use support.</li> </ul>
8	Polypharmacy (medication fatigue)	Motivational Interviewing	- Doctors and pharmacists should provide counselling on managing multiple medications and reducing pill burden.

Figure 11: PrEP education materials



## Monitoring and Evaluation

#### Patient monitoring database (MyHCC)

All data related to PrEP client management will be recorded in the patient monitoring database, MyHCC. This system is a centralised platform for tracking individuals enrolled in the HIV PrEP program across public and private healthcare facilities.

Healthcare professionals can efficiently capture demographic information, clinical data, and adherence metrics through an intuitive user interface and secure authentication mechanisms. Each participant is assigned a unique identifier, ensuring confidentiality while allowing for longitudinal monitoring of PrEP service engagement.

Data entry is conducted by all facilities providing PrEP services, including government and private healthcare clinics. This enables District Health Offices, State Health Offices, and the HIV/STI/Hepatitis C Sector to monitor and evaluate PrEP program implementation at all levels systematically.

#### Behavioural monitoring

While clinical outcomes are essential in assessing the effectiveness of PrEP interventions, behavioural monitoring plays a crucial role in understanding the context and risk factors associated with high-risk sexual behaviours among PrEP users.

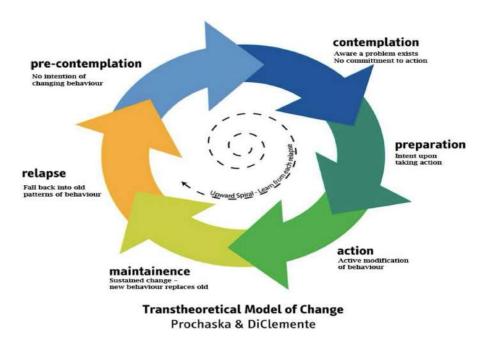
To complement the clinical data captured in MyHCC, a Google Drive-based survey collects information on sexual behaviours, risk factors, and adherence challenges among PrEP clients (refer to Annex 7).

# Risk reduction counselling and adherence counselling strategies

#### Understanding the stages of change in an individual

Individuals go through discrete stages of change, and the processes by which people change seem to be the same with or without treatment. When engaging a client for intervention, the HCP needs to understand the stage of change in which the individual is, as shown in figure 12.

Figure 12: Stages of Changes



Stages of change are also dynamic, wherein an individual may progress or regress to different phases.

The HCP may engage and support the individual through these phases:

- Identify the client's stage of change before proceeding with brief intervention (BI)
- Understand that the responsibility of change is the client's
- Be non-judgemental while counselling
- Avoid being distressed if the client is in the precontemplation stage.

## BRIEF intervention (BI)

Brief Interventions (BI) are structured, short-term counselling sessions (5–30 minutes) designed to motivate individuals to take specific actions, such as initiating treatment or adopting behavioural changes. Led by trained healthcare providers, BI aims to identify and address concerns early, particularly substance use-related concerns, before they develop into more significant health issues.

Steps for BRIEF Intervention using the **FRAMES** method:

F	<b>Feedback:</b> Provide clear, non-judgemental feedback on the individual's behaviour and its potential risks.
R	<b>Responsibility</b> : Emphasise that the decision to change lies with the individual
A	Advice: Offer practical and evidence-based recommendations for reducing risks
M	Menu of options: Present various strategies or support services to encourage positive change
E	<b>Empathy:</b> Use a compasionate and understanding approach to foster trust
S	<b>Self-efficacy:</b> Reinforce confidence in the individual's ability to make changes

If the individual is not ready to change, acknowledge their resistance and encourage solutionfocused discussions without confrontation. If they express willingness to change, refer them to the appropriate professionals for further support, such as paramedic counsellors, OSCA counsellors, Family Medicine Specialists (FMS), or psychiatrists.

## Risk reduction counselling by PrEP Navigator

Risk reduction counselling provided by PrEP Navigators is a key component of the PrEP program, aimed at supporting individuals in minimising their risk of HIV acquisition. PrEP Navigators offer personalised guidance and education on safer sexual practices, medication adherence, and STI prevention strategies. Through individualised counselling, clients are encouraged to assess their risk behaviours, identify adherence challenges, and develop practical solutions to ensure PrEP is used effectively.

This counselling approach fosters trust and empowerment, enabling clients to make informed decisions about their sexual health. Table 3 outlines the role of PrEP Navigators during the initial and follow-up visits for different key populations.

Table 3: Role of PrEP Navigator during the initial and follow-up visits

#### **First Visit** Follow up 1. Pre-PrEP Counselling Reinforce key ABCD prevention strategies ABCD counselling (refer annex 3) and assess client understanding of PrEP, e.g., "Last time we discussed the usage of 3. Address individual concerns—tailor counselling based on personal risk condoms and drugs, what do you factors. (e.g., If a client is in a remember from that?". monogamous relationship, focus on If the clients have a wrong understanding, other relevant risks). repeat or correct the information. 4. Emphasize PrEP adherence and 2. Address non-adherence issues, discuss follow-up appointments. (e.g., challenges, and provide solutions, e.g.: "Taking PrEP daily is 99% effective "After taking a look at your pill diary, I can against HIV among MSM"). see that you are having problems adhering 5. Screen for mental health/substance to the PrEP. May I know what challenges you are facing?" use issues. Encourage partner testing. 3. Evaluate the impact of mental 7. For serodiscordant couples, assess health/substance use on PrEP adherence. the HIV-positive partner's viral load 4. Encourage partner testing. status, confirm ongoing ART, and For serodiscordant couples, review the 5. provide U=U (Undetectable = partner's viral load status, confirm ART Untransmittable) counselling adherence and reinforce U=U counselling

Note: Clients presenting with substance use or mental health concerns should be referred to Paramedics, Medical Officers (MOs), or Family Medicine Specialists (FMS) for further evaluation and intervention.

## Risk reduction counselling by medical officers / paramedic

Risk reduction counselling provided by paramedics, medical officers (MO), and Family Medicine Specialists (FMS) is an essential component of comprehensive HIV prevention. Unlike PrEP Navigators, who primarily focus on guidance and adherence support, medical professionals bring clinical expertise to address individual health needs, risk behaviours, and underlying medical conditions that may impact PrEP efficacy and safety.

During counselling sessions, healthcare providers discuss safer sexual practices, adherence strategies, STI prevention, and potential side effects, offering evidence-based, individualised guidance. This structured, medically informed approach ensures that clients receive comprehensive support, empowering them to make informed decisions about their sexual health while maximising the preventive benefits of PrEP. It is particularly crucial for managing complex risk factors and reinforcing safe behaviours among PrEP clients.

Table 4: Topics to be discussed during risk reduction counselling

	Topic to be discussed	Justification
1.	Adherence to PrEP (based on dosing regimen) Discuss adherence challenges based on feedback from PrEP Navigators.  Example: "Has the PN discussed a more suitable regimen for you? What are your challenges in adhering to the regimen? How can we improve your	PrEP is not 100% effective without adherence. Ensuring the correct regimen and consistent use is essential for optimal HIV prevention.
2.	adherence?"  Suitability of the PrEP regimen (Event-Based or Daily PrEP)  If discussed with PN, reconfirm the most suitable regimen during the visit.	Risk factors are dynamic, and clients may need to switch regimens based on their evolving HIV risk profile.
3.	Assess patient's knowledge on HIV risk due to non-adherence Double-check the client's understanding of how non-adherence increases HIV risk.	Reinforces adherence motivation and ensures clients are fully aware of the risks.

	Topic to be discussed	Justification
4.	Evaluate client's understanding of the ABCD risk reduction model  Example: "The PrEP Navigator would have explained the ABCDs of HIV prevention. Can you recall what they discussed?"  Correct any misinformation or misunderstandings.	Clients may forget or misinterpret information provided in previous sessions. A reminder ensures accurate knowledge retention.
5.	STI history and condom use  Example: "When was your last episode of an STI? If a condom was not used, what was the reason?"  Explore the reasons and provide individualised guidance.	<ol> <li>PrEP is not a standalone HIV prevention method—other strategies, such as consistent condom use, remain crucial.</li> <li>Recurrent STIs can lead to complications and antibiotic resistance.</li> <li>STIs can be transmitted to pregnant partners, leading to mother-to-child transmission.</li> </ol>
6	Use of supplements, hormones, and herbal medications Example: "Are you currently taking any supplements, hormones, or herbal remedies?"	<ol> <li>Some supplements interact with PrEP, potentially causing renal impairment (e.g., excessive protein/whey supplements can reduce creatinine clearance).</li> <li>Transgender women (TGW) on hormonal therapy must adhere to daily PrEP, as event-based PrEP is not recommended.</li> </ol>
7.	Mental health screening  Example: "How has your mental health been over the past month? Have you experienced anxiety, stress, or depression?"  Offer mental health screening (Whooley Screening).	Mental health concerns are often underreported, particularly among key populations. Routine mental health screening is essential for early detection and intervention (Refer to Chapter 8).
8.	Open-ended discussion • Example: "Before we end, is there anything else you'd like to discuss?"	Many clients may have concerns they are hesitant to bring up. This open-ended question allows them to express hidden concerns and seek further clarification.

## Adherence counselling by the pharmacist

Pharmacists play a crucial role in ensuring adherence to PrEP by assessing clients' understanding of the medication's purpose and reinforcing compliance strategies. Adherence counselling should be conducted at every visit.

#### 1. Missed / Delayed Pills

- Assess any missed or delayed doses over the past day, week, or month based on the client's daily or event-based (EB) regimen.
- Identify reasons for missed or delayed doses (e.g., timing issues, side effects).
- Discuss potential barriers to adherence and strategies to overcome them.
- Review previous adherence records to identify trends and solutions.
- Conduct a pill count for clients with suspected non-adherence or verify if a PN has already completed it.

#### 2. Medication Tolerability and Adverse Reactions

- Evaluate the client's experience with PrEP, including any side effects.
- Discuss how the client has managed side effects and suggest mitigation strategies.
- Assess potential interactions with other medications or supplements; consult the MO/FMS if necessary.
- Ensure that any adverse drug reactions (ADRs) are reported by the MO/FMS using the appropriate ADR form.

#### 3. Medication Responsibility and Integrity

- Instruct clients to notify the pharmacist immediately if their medication supply is insufficient.
- Advise clients against sharing their medication, as it may lead to shortages and is legally prohibited.
- Remind clients that selling PrEP is illegal and may result in legal consequences.

#### 4. Value Added Services

- Discuss options for PrEP collection, such as WhatsApp pre-ordering, postal delivery (PosLaju), or drive-through services.
- Clarify that WhatsApp messages cannot be used for direct communication regarding medication issues and that clients must contact the clinic pharmacist for such matters (e.g., changing pick-up dates).

#### Risk reduction counselling: The "ABCD" Approach

The ABCD approach is a comprehensive strategy for HIV prevention, incorporating four key components that can be used individually or in combination:

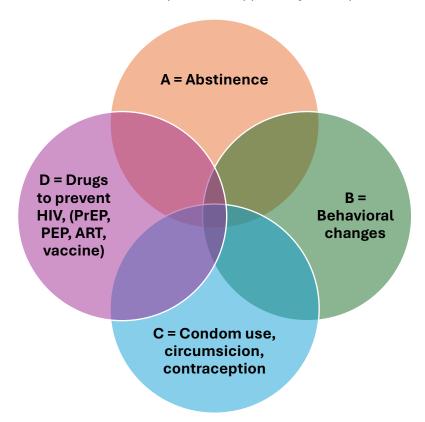


Figure 13: Interconnected relationship in ABCD approach for HIV prevention

For detailed information on the ABCD approach, refer to **Annex 3**.

### Probing questions on sexual orientation and Gender identity (SOGIE)

Sexual Orientation, Gender Identity, and Expression (SOGIE) is a framework that acknowledges the diversity of individuals in terms of their sexual orientation, gender identity, and gender expression. A clear understanding of SOGIE is crucial for healthcare providers, particularly in PrEP clinics, to ensure personalised, non-judgmental care that effectively supports HIV prevention.

Healthcare providers must recognize that each client, based on their SOGIE, has unique experiences, concerns, and health needs. Creating an inclusive and respectful clinical environment enhances the quality of care and promotes trust between clients and providers.

A strong understanding of SOGIE helps to:

- Build trust by fostering open communication about sensitive topics such as sexual behaviour and HIV risk.
- **Provide personalised care** that respects the client's identity and tailors' prevention strategies, including PrEP, to their specific needs.
- Reduce stigma and discrimination within healthcare settings, ensuring all clients feel safe and comfortable seeking care.

For guidance on probing questions related to sexual orientation, gender identity, and sexual history, refer to **Annex 1**.

## Other Health-Related Support

Many PrEP clients, particularly key populations (KPs), experience higher rates of anxiety, depression, and other mental health concerns, which may contribute to risky behaviours. Counselling is vital in helping individuals develop coping strategies and facilitating referrals to additional support services as needed.

PrEP services should adopt a holistic approach by extending support beyond clinical care. This includes mental health, psychosocial, and psychospiritual support, as well as harm reduction services, ensuring comprehensive well-being for clients.

#### Clients' Mental Health Support

Integrating mental health support into PrEP services is essential for a well-rounded approach to HIV and STI prevention in Malaysia. Mental well-being directly influences PrEP adherence and overall health outcomes.

A structured mental health support package should be available within PrEP services, comprising psychosocial and psychospiritual interventions delivered by healthcare providers and community health workers. Routine mental health screenings using tools such as the GAD-7 and Whooley questionnaires (refer to Annex 4) should be included in PrEP assessments to identify clients at risk for anxiety and depression.

Strengthening referral pathways within PrEP clinics allows clients to access additional mental health services beyond the scope of PrEP, ensuring comprehensive care. Creating a supportive environment that addresses both physical and mental aspects of HIV prevention is crucial for long-term success.

Additionally, various NGOs and national hotlines in Malaysia provide emotional support, information, and referrals for individuals facing personal or mental health challenges. The table below provides a detailed list of these services.

Table 5: Mental Health Helpline in Malaysia

Website	Contact	Operating hours
Talian Kasih kpwkm.gov.my	Call: 15999 WhatsApp: 019-2615999	24 hours
Talian HEAL Talian Krisis Kesihatan Mental Kebangsaan kkm.gov.my	Call: 15555	Every day 8am - 12am

## Psychosocial support

Psychosocial support services play a crucial role in addressing the broader social and emotional needs of PrEP clients. These services can be provided by health facilities and community-based organisations, as outlined in the table below:

Table 6: Psychosocial support services activities and roles and responsibilities

Setting	Activities	Roles and responsibilities
Health facilities	<ul> <li>Psychosocial assessment (i.e referral for financial support, temporary shelter)</li> <li>Conduct and facilitate referrals</li> </ul>	FMS/MO/Paramedics/ Counsellor
Community-based Organization	<ul><li>Group discussion</li><li>Peer support groups</li></ul>	Community health workers

Psychosocial assessments should address key areas such as financial assistance (e.g., Baitulmal, Zakat, PERKESO), housing support for clients experiencing homelessness, and legal or enforcement-related concerns (e.g., SUHAKAM, news portals) related to stigma and discrimination.

## Psychospiritual support

Some PrEP clients may experience internalised shame or guilt due to cultural or religious beliefs. Psychospiritual support integrates mental health care with spiritual or religious guidance, helping individuals reconcile their health needs with their faith while fostering self-acceptance and reducing internal stigma.

Clients seeking psychospiritual support may be referred to religious personnel or faith-based services according to their personal beliefs and preferences. This form of support can complement mental health services, particularly for individuals who value guidance within a spiritual framework.

Table 7: Psychospiritual Helpline in Malaysia

Organization	Website
Bahagian Keluarga, Sosial dan Komuniti JAKIM - Hijrah Diri	https://hijrahdiri.com/
Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism	https://www.hati.my/malaysian-consultative-council-of-buddhism-christianity-hinduism-sikhism-and-taoism-mccbchst/

#### Harm reduction in the context of chemsex for PrEP users

#### **Understanding Chemsex and Its Risks**

Chemsex refers to the use of psychoactive substances to enhance or prolong sexual experiences. Among PrEP users, chemsex presents significant health risks, including increased vulnerability to HIV transmission, other sexually transmitted infections (STIs), and mental health challenges. Substance use in this context can lead to risky sexual behaviours, reduced adherence to PrEP, and higher susceptibility to mental health issues.

To mitigate these risks, harm reduction strategies for PrEP clients engaging in chemsex focus on comprehensive support, including:

- Education on safer sex practices
- · Regular health screenings
- Access to mental health services

These strategies empower clients to make informed decisions about their health by emphasising the importance of combining PrEP with other preventive measures, such as consistent condom use and regular STI testing. An integrated approach helps reduce health risks and supports the overall well-being of PrEP users involved in chemsex.

#### Common drugs used in Chemsex

For healthcare providers, recognising the substances commonly associated with chemsex is crucial for open and informed discussions with PrEP clients. Understanding these substances enables providers to offer appropriate guidance and harm reduction support. For a detailed list of the most frequently used drugs in chemsex, please refer to Annex 5.

## **Identifying Chemsex Users Among PrEP Clients**

Early identification of PrEP clients engaging in chemsex is critical to providing targeted interventions and ensuring client safety. Healthcare providers can screen for chemsex behaviour by incorporating specific questions into routine assessments.

Indicators of Chemsex Involvement:

- Frequent drug use during sexual encounters Clients may disclose using substances commonly associated with chemsex.
- Multiple partners or group sex Chemsex is often linked to having multiple partners or participating in group sex.
- **Inconsistent PrEP adherence** Drug use may disrupt regular PrEP intake due to disorientation or unpredictable sexual encounters.
- Risky sexual behaviours Reports of condomless sex, recurrent STIs, or frequent requests for post-exposure prophylaxis (PEP).
- Behavioural signs of drug use Signs such as weight loss, mood swings, or memory gaps related to recent sexual activities.

#### Interventions for Chemsex Users on PrEP

Once identified, chemsex users benefit from tailored interventions to reduce the risks of drug use and HIV. A holistic care approach combining medical, behavioural, and social support is essential, with coordination across HIV clinics, substance use services, mental health providers, and community organisations.

#### Key interventions:

#### 1. Enhanced Adherence Support:

- **Event-Driven PrEP:** On-demand PrEP may be better suited for clients who engage in chemsex, allowing use around times of sexual activity.
- Reminders and Check-ins: Texts or mobile app notifications can help support consistent PrEP use.

#### 2. Counseling and Support Services:

- **Substance Use Counseling:** Referrals to addiction specialists can help clients manage or reduce drug use.
- Psychosocial Support: Addressing mental health and social issues can help clients who use drugs to cope.
- **Peer Support Groups:** Group sessions provide a safe space for clients to share experiences and reduce chemsex behaviours.

#### 3. Harm Reduction Strategies:

- Safer Drug Use Education: Guidance on not sharing needles, using sterile equipment, and staying hydrated can reduce risks.
- Safe Sex Practices: Emphasizing condom and lubricant use lowers STI and HIV risks.

#### Regular STI and HIV Testing:

• Frequent testing is recommended: Clients engaging in chemsex are at higher risk and may require quarterly rather than biannual STI and HIV testing.

For PrEP clients who require substance use intervention, the following organizations provide support services and referrals:

Table 8: Addiction Support in Malaysia

Organization	Website	Contact Number
Narcotics Anonymous Malaysia	www.namalaysia.my	0 11-1511 4022
LEV8 Peer-to-peer Helpline		0192760313

#### Support for Other Behavioural Addictions

In addition to substance use, behavioural addictions—such as pornography addiction, internet gaming disorder, and hypersexual disorder—can significantly impact PrEP clients' mental health, social well-being, and adherence to PrEP. These behaviours may contribute to isolation, emotional distress, and engagement in risky sexual practices, increasing vulnerability to HIV and other STIs.

To effectively support clients facing behavioural addictions, healthcare providers should integrate counselling, psychoeducation, and referrals to specialised services into PrEP care. Addressing these underlying challenges can improve PrEP adherence, well-being, and sexual health outcomes.

#### Interventions

Clients struggling with behavioural addictions should be referred to:

- Family Medicine Specialists (FMS) for comprehensive medical and mental health assessment
- One-Stop Crisis Centre (OSCA) Counsellors for psychosocial support
- Addiction Psychiatrists for specialised counselling or psychotherapy as needed

A client-centred, holistic approach that includes mental health and behavioural support enhances PrEP effectiveness and long-term health outcomes.

## Community Engagement and Advocacy

## Stakeholder collaboration to increase PrEP uptake

Effective stakeholder engagement fosters collaboration in PrEP program implementation, enabling stakeholders to leverage resources, expertise, and skills for more efficient service delivery. The table below outlines key stakeholders and their respective roles and responsibilities.

Table 9: Key Stakeholders and Their Roles in PrEP Implementation

Stakeholders	Roles and Responsibilities
Ministry of Health, Sector HIV/STI/Hepatitis C, Disease Control Division, Ministry of Health	Coordinates policy-making and national PrEP program implementation with relevant divisions.
Ministry of Health, State Health Departments and District Health Offices	Collaborate with NGOs and health facilities to ensure PrEP accessibility within communities.
Ministry of Higher Education	Promote health-seeking behaviour among students and staff at universities and colleges.
Malaysian AIDS Council and Malaysian AIDS Foundation	Lead PrEP promotion, campaigns, and advocacy efforts to increase uptake.
Implementing Partners (CBOs)	Conduct outreach activities and ensure PrEP linkage through Community Health Workers (CHWs) and Peer Navigators.
Private Clinics and Hospitals	Provide comprehensive PrEP service options, including referrals to Klinik Kesihatan.
Religious Department	Offer psychospiritual support and address myths and stigma related to PrEP within communities.

#### Roles and Responsibilities in Demand Creation for PrEP

Increasing demand for PrEP requires a multisectoral approach, involving healthcare providers, community organizations, policymakers, and advocates. Each plays a critical role in promoting awareness, accessibility, and acceptance of PrEP within key populations. Key roles include:

#### 1. Community Health Workers:

- a. Raise awareness about PrEP, its benefits, and accessibility through online and offline outreach.
- b. Promote PrEP among existing clients and identify new potential clients within their networks.
- c. Refer potential clients to Peer Navigators for additional support.

#### 2. Peer Navigators/PrEP Navigators:

- a. Encourage PrEP clients to share information with their partners and peers.
- b. Collaborate with STI-friendly clinics to introduce PrEP services to their clients.
- c. Lead PrEP promotion efforts through both online and offline channels.

#### 3. Clinics and Health Departments:

- a. Actively promote PrEP to high-risk individuals, particularly those in STI clinics or serodiscordant couples not yet achieving undetectable viral load (UVL).
- b. Connect potential PrEP clients from STI clinics with nearby Peer Navigators for counselling.
- c. Conduct awareness sessions at district and state levels for healthcare providers to enhance PrEP promotion.

Refer to Annex 6 for examples of demand-creation strategies.

## References

- 1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3728665/
- Anderson PL, Glidden DV, Liu A, Buchbinder S, Lama JR, Guanira JV, McMahan V, Bushman LR, Casapía M, Montoya-Herrera O, Veloso VG. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. Science translational medicine. 2012 Sep 12;4(151):151ra125-.
- 3. Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, Tappero JW, Bukusi EA, Cohen CR, Katabira E, Ronald A. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. New England Journal of Medicine. 2012 Aug 2;367(5):399-410.
- 4. Choopanya K, Martin M, Suntharasamai P, Sangkum U, Mock PA, Leethochawalit M, Chiamwongpaet S, Kitisin P, Natrujirote P, Kittimunkong S, Chuachoowong R. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. The Lancet. 2013 Jun 15;381(9883):2083-90.
- 5. Hoornenborg E, et al. Change in sexual risk behaviour after 6 months of pre-exposure prophylaxis use: results from the Amsterdam pre-exposure prophylaxis demonstration project. Aids 32, 1527–1532 (2018). [PubMed: 29762169]
- 6. Lal L, et al. Medication adherence, condom use and sexually transmitted infections in Australian preexposure prophylaxis users. Aids 31, 1709–1714 (2017). [PubMed: 28700394]
- 7. Montano MA, et al. Changes in Sexual Behavior and STI Diagnoses Among MSM Initiating PrEP in a Clinic Setting. AIDS Behav 23, 548–555 (2019). [PubMed: 30117076]
- 8. Liu AY, et al. Preexposure Prophylaxis for HIV Infection Integrated with Municipal- and Community-Based Sexual Health Services. JAMA Intern Med 176, 75–84 (2016). [PubMed: 26571482]
- Heffron R, et al. Objective Measurement of Inaccurate Condom Use Reporting Among Women Using Depot Medroxyprogesterone Acetate for Contraception. AIDS Behav 21, 2173–2179 (2017). [PubMed: 27699594]

- 10. Sander PM, Raymond EG & Weaver MA Emergency contraceptive use as a marker of future risky sex, pregnancy, and sexually transmitted infection. Am J Obstet Gynecol 201, 146 e141–146 (2009). [PubMed: 19646565]
- 11. Kasaie P, et al. The Impact of Preexposure Prophylaxis Among Men Who Have Sex With Men: An Individual-Based Model. J Acquir Immune Defic Syndr 75, 175–183 (2017). [PubMed: 28498144]
- 12. Eisinger RW & Fauci AS Ending the HIV/AIDS Pandemic (1). Emerg Infect Dis 24, 413–416 (2018). [PubMed: 29460740] dentiality Guidelines 2011
- 13. Malaysian Medical Council (MMC) Confidentiality Guidelines (2011).
- 14. <a href="https://pharmacy.moh.gov.my/en/apps/fukkm?generic=tenofovir&category=&indicatio">https://pharmacy.moh.gov.my/en/apps/fukkm?generic=tenofovir&category=&indicatio</a>
  <a href="mailto:ns="
- 15. Ministry of Health Malaysia Guide to Good Dispensing Practice (2016). https://pharmacy.moh.gov.my/sites/default/files/document-upload/gdsp-2016-final.pdf
- 16. Ministry of Health (2023). Global AIDS Monitoring Country Report. Putrajaya: Disease Control Division
- 17. Ministry of Health (2024). Global AIDS Monitoring Country Report. Putrajaya: Disease Control Division
- 18. Ministry of Health (2022). Integrated Biological and Behavioural Surveillance (IBBS) Survey. Putrajaya: Disease Control Division.

## **Annexes**

## Annex 1: Probing questions on sexual orientation, Gender identity (SOGIE) and sexual history

Understanding a client's sexual orientation, gender identity, and sexual history is essential for providing personalised, non-judgmental PrEP services. Healthcare providers (HCPs) should create a safe, inclusive, and respectful environment, encouraging clients to openly discuss their concerns and behaviours.

#### **Key definitions:**

- Sexual orientation A person's sexual attraction to individuals of the same sex, opposite sex, or both.
- Gender identity An individual's sense of gender may be male, female, transgender, or non-binary.
- Gender expression How an individual outwardly expresses their gender identity, including clothing, hairstyles, and behaviour.

Clients from key populations (KPs) may hesitate to disclose sensitive information due to concerns about stigma and discrimination. The right probing techniques can help build trust and rapport between clients and providers.

#### **Strategies for Probing Sensitive Questions**

#### 1. Establish Rapport

HCPs should enhance verbal and non-verbal communication skills to ensure clients feel comfortable. Avoid apologising when asking about sexual history, as it may create an awkward environment. HCPs' confidence and professionalism in conducting a detailed sexual history will help clients feel more comfortable sharing information.

#### Example for New Patients:

"Because PrEP is related to sexual activity, I need to ask you some detailed questions. I ask these same questions for all patients. Your responses will help us determine the best PrEP regimen for you. Before we begin, do you have any concerns or questions?"

## Example for Regular Patients:

"As we discussed before, we need to review your sexual activity to assess whether continuing PrEP is the best option for you."

OR

"How has your sex life been since your last visit?"

#### 2. Emphasise Confidentiality

Clients should be reassured that their personal information is confidential and will not be disclosed outside the healthcare team.

## **Example:**

"I want to assure you that everything we discuss today is strictly confidential and will not be shared outside this team."

#### 3. Ask Open-Ended Questions

Open-ended questions encourage clients to provide **more detailed responses**, helping HCPs better understand their experiences and needs.

## Example:

"We all have a gender identity, sexual orientation, and ways we express ourselves. To better understand you, can you share how you identify yourself?"

However, in some cases, **closed-ended questions** may be necessary to clarify specific details.

## Example of a Focused Question:

"To whom are you usually attracted—males, females, or both?"

#### 4. Use Conversational Phrases

Using **empathetic and conversational phrases** can make clients feel more comfortable, avoiding the impression of being interrogated.

## Examples:

"I understand that this might be a sensitive topic to discuss."

<sup>&</sup>quot;I appreciate your honesty in sharing this with me."

## Annex 2: Do's and don'ts during counselling

Effective PrEP counselling requires a safe, non-judgmental, and professional approach to ensure clients feel comfortable discussing sensitive issues. The following guidelines outline best practices and common pitfalls to avoid during counselling sessions.

## ✓ Do's

#### 1. Ensure Privacy and Safety

 Conduct counselling in a private space to ensure confidentiality, particularly for marginalized clients.

#### 2. Use Client-Friendly Language

- Familiarize yourself with common terms and alternative explanations to improve communication:
  - Nausea → Discomfort in tummy/stomach
  - Regimen → Diet plan
  - Adherence → Compliance
  - **Prophylaxis** → *Preventive measure*
  - Sexual intercourse → Sexual activity
  - Window period → Time after exposure

#### 3. Maintain Friendly Eye Contact

o Engage with the client by maintaining **appropriate** and **friendly** eye contact.

#### 4. Introduce Yourself and the Healthcare Team

Clearly introduce yourself and any nurse assistants or other healthcare providers
present in the room.

#### 5. Assure Confidentiality

- o Reassure clients that their **information** is **protected**.
  - Example: "I assure you that everything we discuss remains confidential within our team."

#### 6. Create a Comfortable Environment

o If the client feels uncomfortable with multiple people in the room, adjust accordingly to maintain comfort.

#### 7. Be Attuned to Non-Verbal Cues

- Observe signs of anxiety or distress, such as when a patient shares experiences of sexual abuse.
- Be mindful of body language indicating frustration, such as anger due to long waiting times or signs of emotional distress.

## X Don'ts

#### 1. Do Not Be Judgmental

o Maintain a **neutral**, **professional** approach without imposing personal biases.

#### 2. Avoid Bringing Up Religion Unless the Client Mentions It First

o **Religious beliefs** should only be discussed if initiated by the client.

#### 3. **Do Not Avoid Eye Contact**

 Engage with the client directly rather than looking at the wall, table, or computer screen.

#### 4. Avoid Using Stigmatizing Language

- Refrain from using **judgmental or moralistic terms** such as:
  - X "Salah" (wrong)
  - X "Haram" (forbidden)
  - X "Sleeping around"
  - X "Jangan buat lagi" (don't do it again)

#### 5. Do Not Show Visible Reactions to Client's Responses

Keep a neutral facial expression regardless of the client's disclosures.

#### 6. Avoid Negative Body Language

o Do not cross your arms, lean back dismissively, or appear disengaged.

#### 7. Minimize Distractions

 Avoid excessive writing, typing, or looking at the computer while speaking to the client.

#### 8. Do Not Assume Certain Clients Do Not Need Sexual History or Counselling

- Sexual history should be assessed for all clients, including those who are:
  - Elderly
  - Religious figures (e.g., teachers, clergy)
  - Married individuals

## Annex 3: "ABCD" Counselling for Risk Reduction.

Healthcare providers can use the ABCD framework to ensure that all aspects of HIV prevention are addressed during each clinic visit. Counselling should be personalized to align with the client's risk factors and social circumstances.

#### A: ABSTINENCE

#### 1. Total Abstinence:

- Refraining from all forms of sexual activity (kissing, oral, vaginal, or anal sex)
   ensures complete protection from STIs and HIV.
- For clients who find total abstinence challenging, discuss combining abstinence with other preventive methods.

#### 2. Delaying Sexual Debut:

Encourage clients who are not sexually active to delay sexual initiation.

#### 3. Post-Treatment Abstinence:

 Remind clients undergoing STI treatment to abstain from sexual activity for at least seven days after both they and their partners have completed treatment.

#### **B: BEHAVIOR MODIFICATION**

#### 1. Health-Seeking Behavior:

- o Encourage sexually active clients to screen for STIs at least once a year.
- Recommend registering with JomTest (https://testnow.com.my/) for anonymous self-testing.
- Advocate for premarital HIV testing to ensure serodiscordant couples achieve U=U
   before marriage or pregnancy.

#### 2. Mutual Monogamy:

 Promote sexual activity with one mutually exclusive partner to reduce exposure risks.

#### 3. Reducing Partners:

If monogamy is not feasible, advise clients to reduce the number of sexual partners
 or limit engagement to one partner at a time.

#### 4. Healthy Coping Methods:

- Address unhealthy coping mechanisms, such as substance use or risky sexual behaviours, and recommend stress management strategies.
- o Refer clients to in-house counsellors if needed.

#### 5. Substance Use Management:

- Recognize that substance use disorders increase HIV risk.
- Support clients with substance use challenges to manage their condition safely.
   (Refer to Chapter 8.4 for guidance.)

### THE 3 Cs: CONDOMS, CONTRACEPTION, CIRCUMCISION

#### 1. Condoms:

- o Promote condom use for all clients, regardless of self-assessed risk.
- Highlight the importance of using approved lubricants (e.g., water-based lubricants for anal sex) and avoiding unapproved alternatives (e.g., oils, butter).
- Offer free condoms and demonstrate correct usage.

#### 2. Contraception:

- Counsel sexually active women not planning pregnancies on contraceptive methods to prevent unplanned pregnancies and reduce the risk of mother-to-child transmission of HIV/syphilis.
- o Educate couples that PrEP does not prevent pregnancy.
- Discuss options based on the WHO Medical Eligibility Criteria for contraceptive use.

#### 3. Circumcision or Voluntary Male Medical Circumcision (VMMC):

 WHO and UNAIDS have recommended VMMC for heterosexual men in settings where heterosexually transmitted HIV prevalence is high. The need may be discussed in a personalised manner with men who are at risk.

## **D: DRUGS (MEDICATIONS)**

#### 1. Vaccination:

o **HPV** Vaccination: Prevents HPV-associated cancers and genital warts.

 Hepatitis B Vaccination: Prevents hepatitis B transmission, particularly in high-risk groups.

#### 2. Antimicrobial Treatment for STIs:

Ensure timely and complete treatment for STIs with appropriate antimicrobials.
 Partners should also be treated adequately.

#### 3. Pre-Exposure Prophylaxis (PrEP):

Provide PrEP for clients at risk of acquiring HIV.

#### 4. Post-Exposure Prophylaxis (nPEP):

o Offer nPEP for individuals potentially exposed to HIV.

#### 5. Antiretroviral Therapy (ART):

- Ensure rapid ART initiation for HIV-positive individuals to achieve viral suppression.
- Reinforce the U=U (Undetectable = Untransmittable) message at every clinic visit,
   emphasising that achieving viral suppression eliminates the risk of sexual HIV transmission.

## Annex 4: GAD-7 and Whooley questionnaires

## **Generalized Anxiety Disorder 7-item (GAD-7) scale**

Over the last 2 weeks, how often have you beer	n Not at al	l Several	Over hal	f Nearly	
bothered by the following problems?	sure	days	the days	every day	
1. Feeling nervous, anxious, or on edge	0	1	2	3	
2. Not being able to stop or control worrying	0	1	2	3	
3. Worrying too much about different things	0	1	2	3	
4. Trouble relaxing	0	1	2	3	
5. Being so restless that it's hard to sit still	0	1	2	3	
6. Becoming easily annoyed or irritable	0	1	2	3	
7. Feeling afraid as if something awful migh	t 0	1	2	3	
happen					
Add the score for each column	+	+	+		
Total Score (add your column scores) =					

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	
Somewhat difficult	
Very difficult	_
Extremely difficult	

## **WHOOLEY QUESTIONS (Malay Version)**

Dalam sebulan yang lepas, adakah anda terganggu oleh masalah berikut? Over the past one month, have you been bothered by the following problems?

Bil	Soalan/Questions	Jawapan/
		Answer
1.	Merasa murung, sedih atau tiada harapan?	Ya/Tidak
	Feeling down, depressed or hopeless?	
		Yes/No
2.	Kurang minat atau keseronokan dalam melakukan kerja-kerja? Having	Ya/Tidak
	little interest or pleasure in doing things?	
		Yes/No

Annex 5: Common drugs used in chemsex

Common name (street name)	Modes of delivery	Typical effects	Typical duration
Crystal methamphetamine (Christine, Tina, T, crystal, ice, syabu, batu)	Snorted as powder, smoked in pipe, or injected	Stimulation: exhilaration, alertness, disinhibition; agitation, paranoia, confusion, aggression	4 to 12 hours
Amphetamine	Swallowed (tablet), smoked, or injected	Stimulation: exhilaration, alertness, disinhibition; agitation, paranoia, confusion, aggression	4 to 8 hours
GHB/GBL (G, Gina, liquid ecstasy)	Swallowed diluted in liquid	Sedation and anaesthetisation: euphoria, disinhibition; drowsiness	Up to 7 hours
Ketamine (Special K, K, kitkat, horse trank)	Swallowed, snorted or injected	Sedation, dissociation, disinhibition, agitation, anxiety, agitation, confusion	45-90 minutes
Cocaine (Coke, Blow, or Snow)	Intranasal (snorting), injected or smoked	Euphoric rush, increased energy, heightened alertness, and feelings of confidence, but these effects are accompanied by potential side effects like anxiety, paranoia, and cardiovascular issues.	20 minutes to a few hours
Ecstasy (MDMA): ( <i>Molly</i> or <i>E</i> .)	Tablet or capsule form, can also be ingested as a powder.	Stimulant and empathogenic effects.	3 to 6 hours
Poppers (Amyl Nitrite): (Rush, Locker Room, or Jungle Juice)	Inhalants	Euphoria, relaxation, enhance sex	30 seconds to 5 minutes

## Annex 6: Example of Demand creation strategies

- 1. CBO and Clinic-based strategies: Clinics, together with Peer Navigators, CHWs from CBOs may conduct awareness and educational sessions in interactive and engaging ways tailored to the community preferences such as:
  - Hands-on sessions (online or face-to-face) where participants can ask questions and engage in discussions.
  - Utilize community members to share personal experiences and insights about PrEP.
  - Engage the community through activities that involve potential PrEP clients, such as health fairs, youth health festivals, pageants, sports events, and interactive workshops.
  - Conduct sexual reproductive health sessions that include information about PrEP and set up booths at strategic locations such as universities, gyms, spas, nightclubs, bars, community centers, and popular event venues.
- **2. Digital strategies:** A digital strategy is essential for effectively reaching younger, techsavvy key populations, who are now more visible and engaged online than ever before: These strategies include:
  - Utilize specific platforms popular among different key population groups to share content about PrEP—such as Grindr for MSMs, Telegram for sex workers, and MiChat for transgender individuals. This outreach can be conducted regularly on a weekly or monthly basis
  - Utilize targeted advertising and campaigns to reach specific demographics, highlighting the benefits of PrEP. For example, create compelling visual messages on Grindr for MSM, and use appropriate hashtags like #PrEPforTrans on Twitter and TikTok to engage with transgender individuals.
  - Include PrEP information in HIV self-test kit packaging to promote PrEP.
  - Promote tools like the PrEP Locator, ProtectNow and TestNow to help community members to access services in one stop center for HIV/AIDS services including Prep.



## Annex 7: Sexual behaviour questionnaire



## Soal-selidik Risiko Tingkah Laku Jangkitan HIV bagi klien PrEP

2.	No kad pengenalan / No Passport * Sila isikan no kad pengenalan tanpa (-). cth: 811221145381
3.	Status perkahwinan *
	Mark only one oval.
	Berkahwin
	Bujang
	Telah bercerai
	Memilih untuk menjawab soalan ini
M	aklumat tambahan pengguna PrEP
4. non	Dalam tempoh 6 bulan yang lepas, adakah anda pernah menggunakan Post
11011	occupational Post-exposure Prophylaxis (nPEP) ?
	Mark only one oval.
	Ya
	Tidak
5.	Tarikh hari pertama haid yang terakhir (LMP) Untuk wanita sahaja
	Example: 7 January 2019

## Maklumat tingkah laku seksual

Sila jawab soalan ini dengan jujur

Mark only one oval.			
Ya Skip to question 7			
Tidak Skip to question 10			
ktiviti seksual yang terakhir			
Bilakah kali terakhir anda melakukan aktiviti seksual? *			
Mark only one oval.			
Kurang dari 4 minggu yang lepas			
Antara 4 ke 6 minggu yang lepas			
Lebih dari 6 minggu yang lepas			
Nyatakan kekerapan anda menggunakan kondom ketika melakukan hubungan	*		
seksual dengan pasangan anda			
Mark only one oval.			
Sentiasa (100%)			
Kadang-kadang (<100%)			
Tidak pernah (0%)			
	Ya Skip to question 7  Tidak Skip to question 10  ctiviti seksual yang terakhir  Bilakah kali terakhir anda melakukan aktiviti seksual? *  Mark only one oval.  Kurang dari 4 minggu yang lepas  Antara 4 ke 6 minggu yang lepas  Lebih dari 6 minggu yang lepas  Lebih dari 6 minggu yang lepas  Nyatakan kekerapan anda menggunakan kondom ketika melakukan hubungan seksual dengan pasangan anda  Mark only one oval.  Sentiasa (100%)  Kadang-kadang (<100%)		

9.	Dalam 6 bulan yang lepas, berapa bilangan pasangan seksual anda?				
	Mark only one oval.				
	1 pasangan				
	2 - 5 pasangan				
	Lebih dari 5 pasangan				
Si	tatus HIV pasangan				
10.	Adakah anda tahu status HIV pasangan seks anda? *				
	Mark only one oval.				
	Ya, pasangan saya adalah positif HIV Skip to question 11				
	Ya, pasangan saya adalah HIV negatif Skip to question 12				
	Saya tidak tahu status HIV pasangan saya Skip to question 12				
S	tatus VL pasangan				
11.	Adakah anda tahu status viral load terkini pasangan seks anda? *				
	Mark only one oval.				
	Ya, viral load pasangan saya adalah "boleh dikesan" atau lebih dari 200 copies/ml				
	Ya, viral load pasangan saya "tidak boleh dikesan" atau kurang 200 copies/ml				
	Saya tidak tahu status viral load terkini pasangan saya				

Sejarah jangkitan STI

12.	Dalam tempoh 6 bulan yang lepas, adakah anda pernah dijangkiti jangkitan penyakit kelamin (STI)?	*
	Mark only one oval.	
	Ya	
	Tidak	
13.	Dalam tempoh 6 bulan yang lepas, adakah anda pernah mengalami simptom seperti diberikut? (Boleh beri lebih dari 1 jawapan)	*
	Tick all that apply.	
	Terasa sangat pedih dan sakit ketika membuang air kecil Ulser pada zakar/penis	
	Lelehan nanah pada zakar/penis	
	Keputihan / pendarahan pada dubur	
	Tidak pernah mengalami apa-apa simptom seperti di atas	
Se	jarah penyalahgunaan substan	
14.	Dalam tempoh 3 bulan yang lepas, adakah anda pernah menggunakan bahan terlarang seperti dadah atau alkohol?	*
	Mark only one oval.	
	Ya Skip to question 15	
	Tidak Skip to question 17	
Pe	nggunaan dadah/alkohol	
15.	Dalam tempoh 3 bulan yang lepas, adakah anda pernah menghadiri Chemsex, ChemFun atau parti high-sex?	*
	Mark only one oval.	
	Ya	
	Tidak	

16.	Adakah anda dan/atau pasangan anda menggunakan kondom pada kali terakhir anda melakukan hubungan seks semasa mabuk atau khayal disebabkan dadah atau alkohol?			
	Mark only one oval.			
	Ya, saya menggunakan kondom semasa melakukan hubungan seks walaupun mabuk/khayal			
	Saya tidak menggunakan kondom semasa melakukan hubungan seks ketika mabuk/khayal			
	Saya tidak ingat			
	Saya tidak pernah mabuk/khayal semasa mengadakan hubungan seks			
Pe	ngetahuan dalam HIV/AIDS			
17.	Adakah anda pernah mendengar tentang penyakit HIV/AIDS sebelum ini? *			
	Mark only one oval.			
	Ya			
	Tidak			
18.	Adakah anda merasa diri anda berisiko dijangkiti HIV? *			
	Mark only one oval.			
	Ya Skip to question 19			
	Tidak Skip to question 20			

Merasa diri berisiko dijangkiti HIV/AIDS

19.	dari 1 jawapan)	^
	Tick all that apply.	
	Kerana saya sering bertukar-tukar pasangan seksual	
	Kerana saya jarang menggunakan kondom	
	Kerana saya menggunakan dadah jenis suntikan	
	Tidak pasti / Tidak tahu	
	Other:	
Me	erasa diri tidak berisiko dijangkiti HIV	
20.	Mengapa anda merasakan diri anda tidak berisiko dijangkiti HIV? (Boleh beri lebih dari 1 jawapan)	*
	Tick all that apply.	
	Kerana saya setia pada pasangan saya / Saya tidak bertukar-tukar pasangan	
	Kerana saya selalu menggunakan kondom	
	Kerana saya tidak pernah menggunakan dadah jenis suntikan	
	Kerana saya yakin pasangan saya tiada HIV	
	Kerana saya tidak melakukan seks dubur	
	Kerana saya tidak pernah/jarang melakukan hubungan seks dengan pekerja seks	
	Other:	
So	palan tamat	

Pastikan anda makan ubat PrEP yang diberikan seperti yang dinasihatkan oleh doktor. Jangan jual atau berikan ubat PrEP yang diterima kepada orang lain. Sentiasa amalkan A: Abstinence; B: Behavior change seperti tidak menggunakan dadah dan bertukar-tukar pasangan; C: Condom iaitu pakai kondom ketika mengadakan hubungan seks



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## HIV/STI/Hepatitis C Sector Disease Control Division

Ministry of Health Malaysia

Block E10, Federal Government Administrative Centre
62590 Putrajaya

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