



PRE-
EXPOSURE
PROPHYLAXIS

PrEP

Training for Community-based PrEP for Key Populations
Trainee Handbook, shortened version February 2024

Introduction

'Ending AIDS by 2030' through achieving United Nations 90/90/90 targets will be impossible at the current rate of HIV infections in South and Southeast Asia

New prevention innovations are needed to supplement condom use, post exposure prophylaxis, avoiding stimulant drugs before or during sex, and early HIV treatment.

Taking antiretroviral drugs before HIV exposure as prevention or pre-exposure prophylaxis (PrEP), is an innovation that is effective and can be implemented.

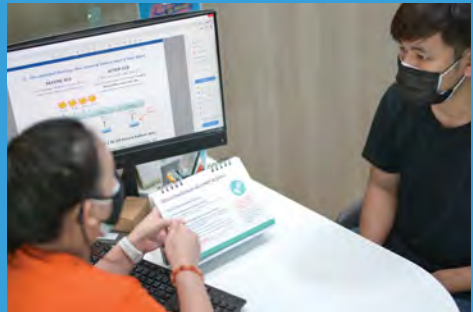
This handbook provides guidance on PrEP for men who have sex with men (MSM) and transgender women (TGW): what conditions are to be met by clients and infrastructure, and how PrEP can be most effectively promoted and provided.

In 2014, the United Nations adopted "Ending the AIDS epidemic by 2030" as part of the third sustainable development goal "Good Health and Wellbeing". Many countries in South and Southeast Asia implemented the targets of 95% of people living with HIV (PLHIV) knowing their HIV seropositive status, with 95% of those on antiretroviral therapy (ART), and 95% of those again having suppressed HIV viral load (VL) in blood. However, it is recognized that it will be impossible to achieve these targets and the 2030 goal in most countries at the current rate of ongoing HIV infections.

In order to reduce new HIV infections, new technology and innovations are needed in addition to current prevention methods. Studies have shown that relying on condom use only will not sufficiently impact on HIV incidence, as some people are not able to use condoms for all episodes of risky sex despite intensive counseling and sufficient condom supply. In Thailand, for example, this group of vulnerable people experience HIV incidence up to 5.3% per year (or equal to 1 in 20 of them becoming newly infected per year). Globally, the emphasis is therefore on the use of a combination of strategies, such as condom use; early diagnosis and treatment of HIV and sexually transmitted infections (STI); post exposure prophylaxis (PEP); and avoidance of substance use before or during sex. A relatively recent strategy that is gaining in popularity due to its efficacy is PrEP (pre-exposure prophylaxis) which is taking antiretroviral (ARV) drugs as prevention before exposure to HIV infection.

The purpose of this handbook is to enable community based and lay providers to share knowledge and understanding about PrEP with key population clients (MSM and TGW). Topics include who should receive PrEP, service provision standards, HIV counseling, risk assessment, assessment of PrEP readiness, PrEP counseling, promoting PrEP adherence, service tracking and follow-up, and PrEP management. The Handbook Task Force hopes that this PrEP Handbook will help maximize the benefits of PrEP in reducing the rate of new HIV infections among key populations.

PrEP service is a feasible and affordable strategy. PrEP service can be successfully implemented through both governmental facilities and community-based service outlets.¹



Abbreviations

| Abbreviation | Explanation | Definition |
|--------------|---|--|
| ARV | Antiretroviral drugs | Medications used in combination for HIV treatment |
| HIV | Human Immunodeficiency Virus | A virus that attacks the immune system until it is unable to fight various bacteria, viruses and other micro-organisms that can cause disease, leading to various infections not occurring in individuals with a healthy immune system |
| IHRI | Institute of HIV Research and Innovation, Bangkok | |
| KP | Key Populations | Populations who are particularly vulnerable and disproportionately affected by HIV due to certain risk behaviors, marginalization, and structural factors such as stigma, discrimination, violence, human right violations, and criminalization - all of which contribute to a lack of access to health services. These include sex workers, men who have sex with men, transgender people, people who inject drugs, and people in prisons and other enclosed settings |
| MSM | Men who have sex with men | Men who have sex with men |

Abbreviations

| Abbreviation | Explanation | Definition |
|--------------|---------------------------------|--|
| NAT | Nucleic acid amplification test | Test which can detect HIV at very small amounts in the earliest stage of infection before antibodies are present |
| PEP | HIV-post exposure prophylaxis | Taking ARV within 72 hours after engaging in behavior which carries risk for HIV infection to prevent infection from establishing. |
| PrEP | HIV Pre-exposure prophylaxis | Taking ARV by someone who is not infected with HIV before engaging in behavior which carries risk for HIV infection to prevent infection |
| TGW | Transgender women | Women with female gender identity but who were assigned male at birth |
| VL | HIV viral load | Amount of human immunodeficiency viruses in the blood of an HIV positive individual, measured per ml blood |



Chapter 1

What is PrEP
and why is
PrEP needed?

What is PrEP and how is it administered?



PrEP

PrEP

PrEP

PrEP

PrEP

PrEP (pre-exposure prophylaxis) is taking antiretroviral (ARV) drugs by someone who is not infected with HIV before engaging in behavior which carries risk for HIV infection.

Approved PrEP in South and Southeast Asia consists of either 1) tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg in a single pill/tablet (TDF/FTC), taken once daily OR 2) tenofovir alafenamide fumarate (TAF) 25 mg + emtricitabine (FTC) 200 mg in a single pill/tablet (TAF/FTC), taken once daily.

Daily PrEP is suitable for all clients. So-called on-demand PrEP is suitable for all people assigned male at birth not taking gender affirming hormones who can plan when they have sex.

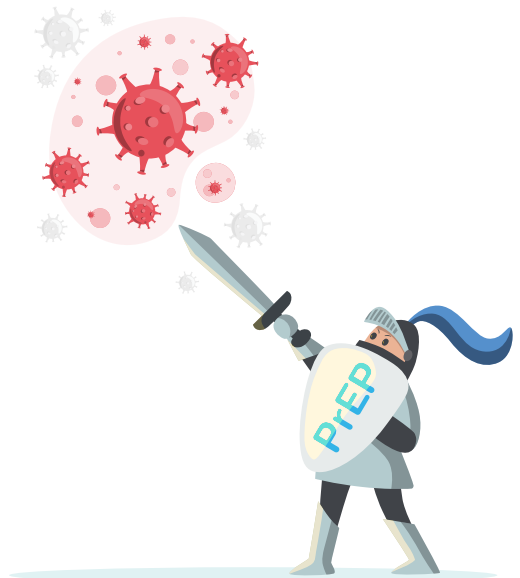
Taking PrEP to prevent HIV is highly effective across populations.^{2,3,4,5} IF taken as prescribed for each user group.

PrEP is to prevent HIV in individuals who are not yet infected but are exposed to risk. Taking PrEP as prescribed is the most important factor to ensure its efficacy. Irregular consumption of PrEP reduces its effectiveness to prevent HIV infection.

PrEP is different from PEP which has been used since the late 1980s and which is starting the use of ARV to prevent HIV infection within 72 hours after potential exposure to HIV, and continuing ARV for 28 days.

PrEP gels for vagina and rectum are under study, but currently only PrEP as a pill and injection have been proven effective for MSM and TGW, with only the pill form available in South and Southeast Asia at this time. A vaginal ring with the ARV dapivirine is somewhat effective as PrEP in heterosexual women and undergoing regulatory review in several countries. We will update this handbook once PrEP injections of the drugs carbotegravir plus rilpivirine, or other modalities become available in our region. This training book only refers to PrEP in pill form.

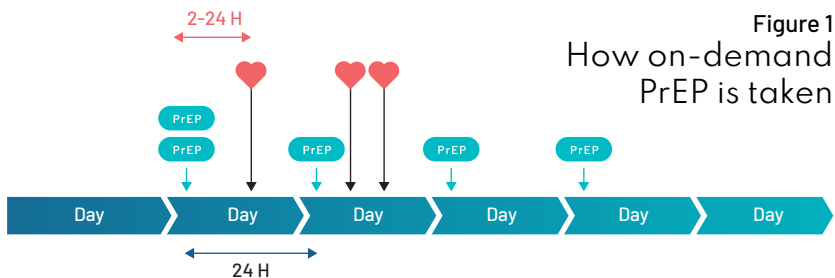
Current PrEP in pill form consists of a combination tablet of tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg (TDF/FTC) OR a combination tablet of tenofovir alafenamide Fumarate (TAF) 25 mg and Emtricitabine 200 mg (TAF/FTC). TDF/FTC is most widely used and available under many trade names including Teno-EM, Truvada, Ricovia-M, Ricovir-EM, and Tenof-M.



There are two ways to take PrEP:

- 1. Daily PrEP is suitable for all users, including MSM and TGW:** One tablet of PrEP is taken daily; during the first seven days of taking PrEP potential exposure to HIV must be avoided. After seven days there is sufficient drug level in all exposed tissues to prevent infection when exposed to HIV and research shows that the efficacy thereafter is maintained if at least 6 doses are taken per week by TGW or at least 4 doses per week by MSM. So for TGW, efficacy is still optimal if PrEP is forgotten once per week only.
- 2. On-demand PrEP is another option to prevent HIV infection for MSM, and for TGW who do not take hormone therapy** who do not want to take PrEP every day and can plan sex events, or do not have sex every week. The guidance for on-demand PrEP comes from the IPERGAY research project which found that four or more PrEP pills per week is effective in preventing HIV among MSM.⁵ Studies have shown that PrEP does not affect feminizing hormone levels in TGW, but feminizing hormones do slightly lower PrEP levels in the blood. For clients taking feminizing hormones, PrEP levels in the blood remain sufficient to provide protection with daily use, but may be insufficient with on-demand PrEP.^{5,6,7} Therefore, on-demand PrEP can be taken by TGW, but only if they do not use exogenous hormones.⁸

The recommended on-demand PrEP regimen is 2 – 1 – 1, as demonstrated in Figure 1 as follows:



- On-demand PrEP starts with taking two PrEP pills 2 – 24 hours before first sex.
- Then, for a single episode of sex, take one PrEP pill again at 24 and 48 hours after the first two pills.
- Or if there are multiple episodes/days of sex, then take one PrEP pill again at 24 hours after the first two pills, and repeat this every 24 hours until 2 doses after the last sex.

We recommend to deal with any forgotten dose as follows:

Daily PrEP – If the pill is missed by less than 12 hours (i.e. client remembers within 12 hours of usual intake time), then immediately take the pill and take next dose as usual. If more than 12 hours have passed, take the forgotten pill with the next dose of PrEP (so 2 tablets) at the usual time.

On-demand PrEP – This depends on how many pills are forgotten; mostly, the first two pills are not often forgotten. For subsequent pills, take the pill as soon as you remember and at the same time of day you took the first 2 pills before having the next sex.

Different MSM users will have different patterns of taking PrEP. For example, some users cannot easily plan when the next risky sex will occur and/or have sex more than two days per week (e.g., sex worker, sex partygoer). In those cases, PrEP should be taken daily. However, if sex is only weekly or less and can be anticipated, then on-demand PrEP may be more appropriate.

Considerations for MSM to take Daily or On-demand PrEP

| Daily PrEP | On-demand PrEP |
|---|---|
| <ul style="list-style-type: none"> • Is unable or does not want to anticipate or plan sexual encounters. • Is confused about or anticipates having trouble adhering to the on-demand regimen. | <ul style="list-style-type: none"> • Has sex occasionally and is able and willing to anticipate and plan sexual encounters. • Understands how to follow the on-demand regimen. • Is concerned about side effects of taking PrEP daily. |

Considerations for MSM to take Daily or On-demand PrEP

| Change to daily PrEP because: | Change to on-demand PrEP because: |
|--|---|
| <ul style="list-style-type: none"> • More frequent sex. • Having more difficulty anticipating sex. | <ul style="list-style-type: none"> • Having less sex than anticipated. • Using combination HIV prevention. • Having side effects from daily PrEP. • Have the ability to plan/control when sex occurs. |

PrEP Side Effects

PrEP side effects may occur in a minority of users, and include headache, abdominal pain, or weight loss. These side effects will usually resolve within 1 week after beginning PrEP.

Very few PrEP users experience long-term side effects, such as decreased kidney function or bone mass loss. Both of these will return to normal if PrEP is stopped timely. Hence clinical and laboratory side effects need to be appropriately monitored in individuals at risk.

TDF-based daily or on-demand oral PrEP can be safely used by people with hepatitis B⁸.

PrEP rarely has adverse effects on the liver, while one of the drugs, tenofovir, is beneficial for people with hepatitis B. However, when tenofovir is stopped, hepatitis B may flare up. People with hepatitis B should therefore never abruptly stop tenofovir without monitoring by a physician.

PrEP food and drug interactions

PrEP can be taken with or without meals, as this does not affect the PrEP drug level in the body.

PrEP does not affect feminizing hormone levels in TGW.

Tenofovir blood level is somewhat decreased in the presence of feminizing hormone therapy (FHT) in TGW but levels remain adequate for HIV protection if PrEP is taken daily.^{7,9,10}

PrEP interacts with very few other drugs used for the treatment of HIV and hepatitis C. Nevertheless, if the client uses other drugs, supplements, or herbal medicines, it's good practice for the service provider to advise the client to provide details of all drugs taken, and record the information in the client's history.

PrEP users should be cautioned against unnecessary use of medications that affect the kidneys, including non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or naproxen. Kidney function in PrEP users is checked as appropriate for age and comorbidities (see below). If NSAIDs are taken as painkillers, it may be advisable to substitute another painkiller such as paracetamol. If there is uncertainty about the combination of medications a client takes, a physician should be consulted.

How does PrEP fit in? The concept of Combination Prevention

PrEP is only effective against HIV and is not effective in preventing other STIs or hepatitis. Thus, users of PrEP should still be advised to wear condoms during sex. Using a combination of effective prevention methods concurrently is the best way to prevent HIV and STI, and this is referred to as

“Combination Prevention.”

In the past, when the topic of HIV prevention was raised, the focus was often on condom use. However, there are multiple options for HIV prevention with proven but variable degrees of efficacy, such as needle/syringe exchange; male circumcision; screening and treatment for STIs; use of PrEP; use of PEP; avoidance of substance use before or during sex; prevention of mother-to-child transmission; and rapid start of ART for ‘Treatment as Prevention’ (TasP). Treatment as Prevention is the strategy to diagnose HIV as early as possible and to provide ART immediately after diagnosis. After taking regular ART for about three to six months, HIV viral load should be suppressed and the virus cannot be transmitted. This is the undetectable equals untransmittable (U=U) concept.

A vaginal ring with the ARV dapivirine is somewhat effective as PrEP in heterosexual women and is undergoing regulatory review in several countries.

Long-acting cabotegravir (CAB-LA) is an integrase strand transfer inhibitor (INSTI) that is being developed as extended duration PrEP, reducing the frequency of dosing compared to current oral options. CAB-LA offers improved adherence to medication regimens, as it is administered via intramuscular injections at longer intervals, such as once every 1-2 months. Clinical trials have shown promising results thus far.

In addition to these proven methods, other methods of HIV prevention are still under investigation, including microbicide gels which can be applied topically to the vagina or anus, and HIV vaccines.

Who should use PrEP?

In our region, PrEP is recommended for any MSM and TGW client who:

- Asks for PrEP, even if risk assessment is unclear
- Has inconsistent condom use with a partner living with HIV who is either waiting to start ARV or still has a detectable viral load
- Had sex without a condom with a partner of unknown serostatus within the last 6 months
- Used PEP within the last 6 months
- Is a sex worker
- Has now or had an STI during the past 6 months, in particular syphilis, anal chlamydia, anal gonorrhea, or undefined purulent anal discharge
- Used stimulant drugs (oral, inhalation or injection) within the last 6 months before or during sex

This list is a basic guide based on research at IHRI in Bangkok and on the WHO recommendation that PrEP is appropriate for groups with HIV incidence greater than 3 per 100 person-years in the absence of PrEP. That means that if 100 HIV negative people from a group are followed for a year, 3 or more would become HIV infected within that year without PrEP.¹¹ In South and Southeast Asia, these groups include MSM and TGW. However, that does not mean that all individual MSM and TGW should take PrEP or that other men and cisgender women do not need to take PrEP. A behavioral screening should be given to all clients to evaluate the need for PrEP.

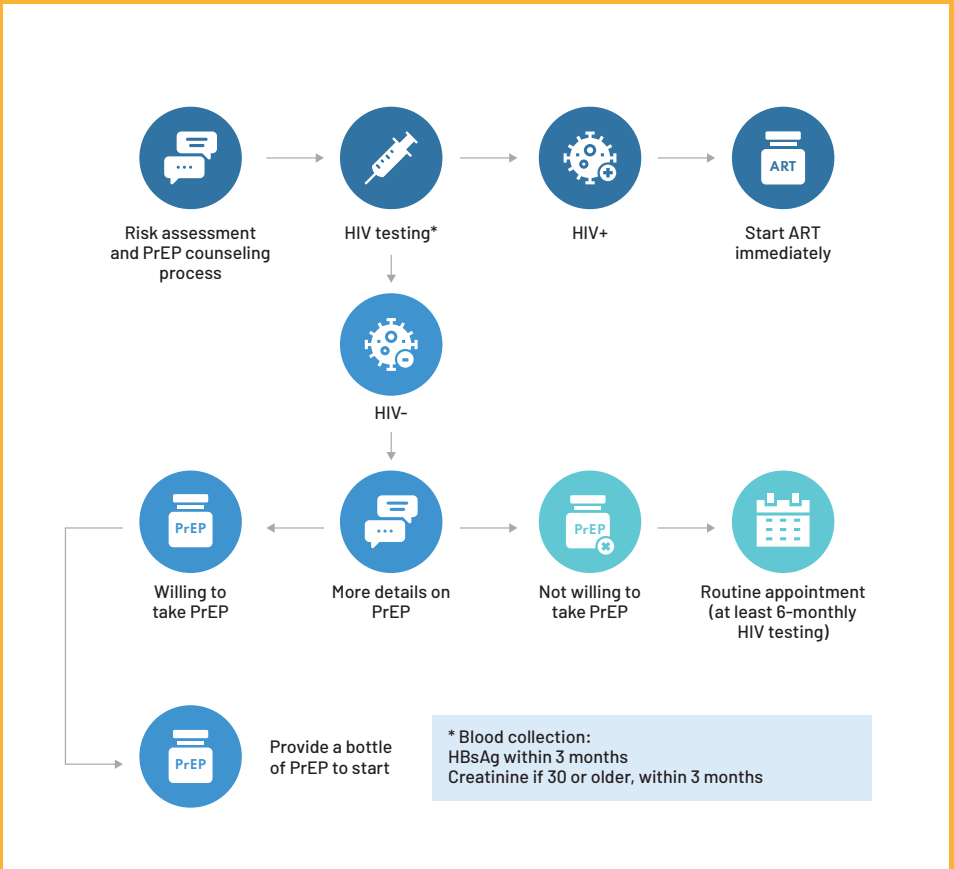


Chapter 2

Guidelines for providing PrEP and PEP services

Flow of PrEP services

PrEP can be initiated and provided in a single day at the community health center. Successful PrEP services as provided by Key Population (KP) lay providers at community health centers under the KP-led PrEP Program in Thailand are summarized as follows.



Starting and stopping PrEP

The key steps are:

1. Risks and readiness assessment: This is done through counseling to assess the risks for HIV infection, introducing the benefits of PrEP tailored to a client's situation (so-called gains based counseling), and its possible side effects, as well as discussing any possible barriers and contributing factors. This is to support clients at risk for HIV infection to start PrEP immediately with good adherence. See Chapter 3 for further details.

2. Necessary lab tests and acute HIV infection assessment

2.1 HIV testing: Same-day HIV testing is essential for providing PrEP since users should be HIV-negative. In addition to a negative HIV test, the provider will try to establish that acute HIV infection is unlikely (see 2.2). Many higher risk clients may be frequently or always in the window period of the HIV test used, the period when an infected person does not have enough virus or antibodies yet to get an HIV+ test result. If there is no indication of acute HIV infection and since the majority of such clients are HIV negative yet at high risk, PrEP should not be delayed for repeat HIV testing.



2.2 Assess for possibility of acute HIV infection: Assessment for acute HIV infection is needed, in particular in clients with high risk or who present in the HIV test window period, as PrEP users should be HIV-negative. This assessment can be done by taking a recent-risk history, with focus on risks in the HIV test window period in addition to asking about the symptoms of acute infection listed below. If unsure after the assessment, do a so-called NAT test, if available. Only if acute HIV infection is suspected should PrEP be withheld and client referred to a clinician. In all other cases PrEP should be provided while repeat HIV tests are being monitored. The symptoms of acute HIV infection generally occur during the first two weeks after exposure to HIV (estimated peak at 11-13 days after infection). This is a period when the body has a very high VL, although the infection may still not be detected by third and fourth generation test kits. Acute HIV infection can produce the following symptoms based on a cohort of volunteers with acute HIV infection at IHRI¹²:

- Fever (80% chance)
- Fatigue (65% chance)
- Pharyngitis (55% chance)
- Headache (53% chance)
- Muscle aches (47% chance)
- Loss of appetite (43% chance)
- Weight loss (35% chance)
- Diarrhea (35% chance)
- Skin rash (33% chance)
- Joint pains (24% chance)
- Oral ulcers (24% chance)
- Nausea/vomiting (22% chance)
- Enlarged lymph nodes (15% chance)



2.3 Check creatinine clearance (CrCl, kidney function) after one to three months on PrEP in all users who are 30 years old or older, and in users who are less than 30 years old if they have known kidney disease, high blood pressure, or diabetes. No creatine clearance test is done for healthy clients less than 30 years of age.

Creatine clearance testing is repeated every 6-12 months only if a) the value at the prior test was < 90 milliliters/minute, b) in all recipients who are older than 50 years of age, and c) in anyone with known kidney disease, high blood pressure or diabetes. If creatinine clearance remains greater than 60 milliliters/min, PrEP may be continued.

If creatinine clearance is <60 milliliters/min, the test should be repeated on a different day. If still <60 milliliters/min, PrEP should be discontinued and a doctor should be consulted. Creatinine clearance will usually return to normal levels after stopping PrEP, and PrEP can be restarted if creatinine clearance is greater than 60 milliliters/min after 1-3 months of stopping PrEP.

The creatinine clearance value may be provided by your laboratory. If not, it should be calculated with the following equation: $[(140 - \text{age}(\text{yr})) * \text{weight}(\text{kg})] / [72 * \text{serum Cr}(\text{mg/dL})]$ (multiply by 0.85 for women). For convenience, [online calculation tools](#) can be used. In case the CrCl value is <60 milliliters/min, it is recommended to consult a doctor before starting or continuing PrEP.

2.4 Check for hepatitis B infection. If the blood test indicates hepatitis B infection, daily PrEP or on-demand PrEP (for those who are eligible for on-demand PrEP) may be started. The client should be advised to consult with a gastroenterologist for treatment considerations. Availability of hepatitis B virus testing should not be a barrier to PrEP initiation or use. PrEP can be initiated before hepatitis B test results are available.⁸

3. Optional but highly recommended STI screening tests.

STI testing for syphilis, gonorrhea, and chlamydia is not essential to start PrEP but is highly recommended as people with an STI have increased risk of becoming infected with HIV if exposed through sexual contact. If STI testing cannot be provided at the PrEP provision site, a referral system should be in place.

If there is an STI, PrEP can still be provided. Advise all clients about reducing risk for STI, recommend an STI test every three to six months, and review the history of the client every time they come for service.

4. PrEP dispensing:

Once a negative result of the HIV test is available and there is no indication of acute HIV infection and the client is deemed ready to take PrEP, PrEP providers should proceed to discuss adherence and follow-up. Strategies to optimize PrEP adherence should be discussed including reducing obstacles to taking PrEP properly. Then 1 month (1 bottle of 30 tablets) of PrEP is dispensed to the client. If results of the blood tests to assess kidney function and/or hepatitis B infection may not be available on the day of the blood draw but other criteria for starting PrEP have been met, providers should still dispense one bottle of PrEP to not delay PrEP initiation. A medical doctor will have had to issue a signed prescription in advance as only then the clinic staff can access and dispense medication.

Daily PrEP: Dispense 1 bottle (30 pills) of PrEP at the first visit, 2 bottles (60 pills) at the month 1 follow-up visit, and 3 bottles (90 pills) at any subsequent visits. We recommend to not dispense more than 3 months (90 pills or 3 bottles) at a single visit as the client is to return for HIV testing every 3 months. Instruct the client to take 1 pill per day, and to choose one time of day to take PrEP and adhere to that schedule throughout. Reiterate that among MSM and TGW who do not use hormone therapy, PrEP can be started with a double dose 2-24 hours before exposure, and a daily dose should be continued for two days after last potential exposure. For all other clients, including TGW who use hormone therapy, PrEP must be started 7 days before risk exposure and continued for 7 days after last risk exposure.

On-demand PrEP for MSM: Dispense one bottle (30 pills) to be taken according to the pattern of need. The first 2 PrEP pills must be started within 2-24 hours before having first risky sex followed by one tablet daily thereafter. Before stopping on-demand PrEP, one pill must be taken per day for 2 days after last HIV risk exposure.

- 5. Make an appointment for a follow-up visit after one month of PrEP** to assess side effects, any outstanding labs, re-test for HIV (if needed), and treatment adherence. Resupply PrEP at month 1 (60 tablets), month 3 (90 tablets), and every three months thereafter. Follow-up appointments follow this schedule, as per table below, detailing assessments per visit. If outstanding labs at any time reveal impaired kidney function (defined as diminished creatinine clearance less than 60 ml/min), PrEP should be discontinued and client referred for physician consultation. If labs at any time show hepatitis B infection, reiterate that client should not stop PrEP abruptly and also refer for physician consultation.

6. Stopping PrEP

Before stopping daily PrEP, clients should preferably come to see the provider who asks the client about the last risk of HIV exposure. An HIV test is done. Among MSM and TGW who do not use hormone therapy, PrEP is continued daily for 2 days after last potential exposure, and can then be stopped. For all other clients, including TGW who use hormone therapy, PrEP is continued for 7 days after the last HIV risk exposure, then stopped. If found to be infected, immediate referral to a physician is warranted to transition to ART as treatment. Make sure clients know that PrEP is to be continued for 2 or 7 days, depending on the client, after last HIV risk exposure.

Before stopping on-demand PrEP, one pill per day must be taken for 2 days after last HIV risk exposure. Periodic HIV testing is to continue.

Clients should be encouraged to return to services regularly, even when they wish to stop PrEP. When stopping PrEP for any reason, relevant information should be recorded in the client's file, including the status of HIV infection at the time of PrEP discontinuation, reasons for stopping PrEP, recent adherence to PrEP, sex risk behavior, and use of drugs, both injectable and non-injectable.

7. Additional advise and instructions to be given to clients:

- Keep PrEP pills at room temperature.
- PrEP pills may be transferred to another container not indicating ARV contents, provided it's a secure bottle or medicine container kept at room temperature.
- Return to the clinic immediately for the following to prepare for stopping PrEP:
 - » There are clear side effects from taking PrEP.
 - » After starting PrEP, the client has no risk behavior for HIV, either from sex and/or injection.
 - » HIV infection occurs while taking PrEP.
- If a client has stopped using PrEP, it is highly recommended that they return for HIV testing one month after stopping and every three months thereafter.
- Advise clients to come back to consult regarding PrEP again if their risk changes.

| | Baseline | Follow up | Before stopping PrEP | Remarks |
|--|----------|--|----------------------|--|
| Mandatory procedures: | | | | |
| HIV test | ✓ | ✓ | ✓ | And every 3 months thereafter |
| Baseline Creatinine clearance (CrCl) | | | | |
| Age < 30 without kidney disease, diabetes, or high blood pressure | Optional | Optional (Once within 3 months if kidney-related comorbidities present at initiation) | Optional | Until age 30 or kidney-related comorbidities develop |
| Age < 30 with kidney disease, diabetes, or high blood pressure | | Once within 3 months after oral PrEP initiation | | |
| Age ≥ 30 | | Once within 3 months after oral PrEP initiation | | |
| Repeat creatinine clearance for anyone with value <90 ml/min, age > 50, or history of kidney disease, diabetes or high blood pressure | | ✓ | ✓ | Every 6–12 months. If CrCl <60 ml/min, repeat test on another day. If still <60 ml/min, discontinue PrEP and consult a doctor. CrCl can be retested 1–3 months after stopping, if > 60 ml/min, PrEP can be restarted. |
| Hepatitis B (HBsAg) test | | Once within 3 months after oral PrEP initiation | | |
| Verbal assessment of PrEP side effects | | ✓ | | If the results are abnormal, refer to a physician for consideration of stopping PrEP |
| Optional but highly recommended: | | | | |
| Screen for STI, especially syphilis | ✓ | ✓ | | Every 6 months |
| Hepatitis C test | | Once within 3 months after oral PrEP initiation | | |

Post-exposure Prophylaxis (PEP)

PEP is used to prevent HIV infection after potential exposure to HIV through risk behavior.¹³ PEP should be started within 72 hours after potential HIV exposure for the best chance of stopping replication of the virus. PEP is estimated to reduce the chance of HIV infection establishing itself by more than 80%. Three antiretroviral drugs are used for PEP, taken every day continuously for 28 days.

Healthcare providers must closely monitor side effects and provide support throughout the 28 days of taking the drugs to optimize the chance that the client takes PEP continuously and consistently, and that the client returns for HIV testing after PEP completion. See the table at the end of this paragraph for follow-up assessments up to 6 months after the risk exposure.

One, three and six months after completion of PEP, the client should be tested to verify HIV infection and ideally should not engage in risk behavior for HIV (i.e. use a condom for every sex act) for correct interpretation of test results. If the hepatitis B or C test indicates a liver infection, PEP can still be taken but the client should be referred to a liver doctor for hepatitis treatment and monitoring.

PEP usually consists of two so-called nucleoside reverse transcriptase inhibitors (often tenofovir and lamivudine or emtricitabine) and a third HIV drug. The actual three drugs combination will depend on local recommendations, any known ART use by the source individual, and institutional availability. A clear guideline or SOP should be accessible for all providers on how to access PrEP as fast as possible for eligible clients, especially over weekends and holidays, and how to refer for clinical expert input. For reasons of tolerability and cost, rilpivirine is the most commonly used third drug in many settings, while dolutegravir also has good tolerability and is becoming more affordable in many countries in the region. For clients with creatinine clearance < 60 ml/min or newly found hepatitis B or C we recommend immediate referral to a clinician.

General tips for provision of PEP

- Check what PEP regimen is recommended and available in your country/clinic and make sure a clear guideline or SOP is in place, accessible at all times and by all your team members on how to start PEP, also on weekends and holidays, and whom to contact for clinical expert input.
- If the client has a history of risk behavior with a partner with a known history of ART use, the client should be urgently referred for assessment to a qualified physician to evaluate the PEP formula.
- Dispensing of PEP is the same as PrEP. Thus, a doctor will have had to issue a signed prescription in advance. Then the clinic staff can access dispense medication.
- Medical staff must help address any possible drug interactions, such as risk of ergotamine (a migraine painkiller) with protease inhibitor or efavirenz.
- Care and support personnel must closely monitor clients for drug intolerance. In the initial period, there should be daily contact with the client to monitor symptoms.
- PEP is more demanding for client and providers because it is, by definition, an urgent problem requiring a intervention with greater likelihood of side effects. A client potentially exposed to HIV yesterday, has only 48 hours left for PEP to be effectively started, so every hour counts.

Assessments for PEP dispensing and follow-up

| Lab tests | During taking PEP | | Monitoring after completing PEP | | |
|--|--|--|---------------------------------|---------|---------|
| | Baseline | When indicated | Month 1 | Month 3 | Month 6 |
| Same-day HIV test | ✓ | ✓ | ✓ | ✓ | ✓ |
| Complete tests for blood (CBC), kidneys (Creatinine), and liver (SGPT/ALT) | ✓ | ✓ | | | |
| HIV NAT or VL, if available | | ✓ In case of suspicion of acute HIV infection | | | |
| Hepatitis B virus antigen screening (HBsAg) | ✓ | ✓ | | | |
| Hepatitis B virus antibody test (Anti-HBs) | ✓ If both HBsAg and Anti-HBs negative, recommend or proceed with HBV vaccination series | | | | |
| Hepatitis C antibody test (Anti-HCV) | ✓ | | | | ✓ |
| STIs, especially syphilis test (VDRL or RPR) | | ✓ | | | ✓ |

Checklist for PrEP and PEP dispensing readiness

- Monitor PrEP drug stock (TDF/FTC 300 mg/200 mg).
- Monitor PEP drug stock based on local guideline regarding the 3 drugs to use.
- HIV test kit/HIV testing service for acute HIV testing, if affordable (NAT or VL).
- Access to creatine, hepatitis B, and hepatitis C testing on site or at referral lab.
- Personnel in place: manager, counselor, medical technicians, medical consultants to write prescriptions in advance as needed, and care and support staff as needed.
- Standard operating procedures Manual (SOP) regarding service flow, interventions and drugs to be dispensed.
- Client files: client history form (first visit), client follow-up visit form, PrEP or PEP dosage record, etc. Forms can be paper or computerized.
- PrEP information for clients to read at home; provide case manager phone number.
- Service facilities such as counseling rooms, blood collection room, laboratory room, medicine storage room, client data file storage.
- Referral clinic or hospital for receiving other necessary services such as liver disease treatment, kidney disease management, STI diagnosis and treatment, etc.

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Chapter 3

Assessing Client
Readiness

We assess client readiness so that the contents of our health messages correspond to an individual's prevailing concerns and are communicated in a manner that maximizes their impact on a client's thoughts and behavior.

Only exceptional circumstances should lead to same-day PrEP being denied to a client at risk or interested in PrEP, such as suspicion of acute HIV infection. Any other criteria discussed below should NOT lead to PrEP being denied to interested clients but to education and optimization of external factors to meet the criteria as much as possible.

Ideally clients meet the following criteria in addition to any applicable clinical criteria before starting PrEP

- The client has risk behavior for becoming infected with HIV
- The client acknowledges their risk behavior independently or after counseling
- The client is ready and willing to take PrEP, and can come to regular appointments
- The client has a correct understanding about PrEP

Readiness assessment

The following table can be used to assess client eligibility and readiness. When identifying barriers or concerns, the intent should be to explore and to overcome barriers with the client through gains based counseling (see Chapter 4) rather than denying PrEP to any client who is either at risk, interested or both. Even if the client has low risk or declines to identify risk, if they are interested in PrEP and are otherwise eligible they should receive PrEP.

| Check | Criteria for starting PrEP in MSM and TGW | Eligible | To be explored further during counseling |
|-------|---|---------------------------|---|
| | <p>Meeting one or more of the following:</p> <ol style="list-style-type: none"> 1. Has inconsistent condom use with a partner living with HIV who is either waiting to start ARV or still has a detectable viral load. 2. Had sex without a condom with partner of unknown serostatus within the last 6 months. 3. Used PEP within the last 6 months. 4. Is a sex worker. 5. Has now or has had an STI during the past 6 months, in particular syphilis, anal chlamydia, anal gonorrhea, or purulent anal discharge. 6. Used stimulant drugs (oral, inhalation or injection) within the last 6 months before or during sex. 7. Unwilling or unable to discuss risk behavior but interested in PrEP. | <p>Meets one or more.</p> | <ol style="list-style-type: none"> 1. No sex and not sharing needle/ syringes with anyone. 2. Having sex but not including any of the risk behaviors. |

| Check | Criteria for starting PrEP in MSM and TGW | Eligible | To be explored further during counseling |
|-------|---|--|--|
| | <p>Willing to use PrEP and seeing the importance of PrEP.</p> | <p>The client is motivated to take PrEP, has a clear reason to take it, and is ready to start right away – there is no hesitation.</p> | <p>The client seems indifferent, or not motivated or doesn't feel they are at risk. Maybe hesitant that they can comply with the regimen.</p> |
| | <p>Conducive environment to treatment compliance.</p> | <p>Has a clear plan when and where to take PrEP.</p> <p>Does not have any inhibiting factors, does not have to hide the PrEP from family, partner or room mates; has a private space where others cannot pry; is not at risk of being questioned or pressured by others.</p> | <ol style="list-style-type: none"> 1. Does not know where to store medicine. 2. Has to conceal their sexual identify at home (i.e., gay/transgender). 3. No private space and cannot hide things; at risk of being searched or asked what medicine they are taking. 4. Partner has a tendency to use violence/or not be understanding. |

| Check | Criteria for starting PrEP in MSM and TGW | Eligible | To be explored further during counseling |
|-------|---|--|--|
| | <p>Has correct understanding of how to take PrEP.</p> | <p>Correctly describes what PrEP is, how it is taken, and when the next appointment is plus knows symptoms of acute HIV infection.</p> | <p>Not fully clear on what PrEP is, how it is taken, what is expected of PrEP user, or what symptoms of acute HIV infection are.</p> |
| | <p>Is physically ready in terms of HIV status and HBV status.</p> | <p>HIV test is negative and no symptoms of possible acute HIV infection.</p> <p>Tests negative for hepatitis B.</p> | <p>Possible acute HIV infection.</p> <p>Tests positive for hepatitis B.</p> |

Correct understanding of PrEP

Ideally, the client is able to answer the following questions as applicable to his/her situation correctly and the table below can be used as a checklist and education tool with clients in this context.

Questions to (re-)check understanding of PrEP

How is PrEP taken?

- Daily PrEP: Take one pill each day at the same time every day.
- On-demand PrEP: Take 2 pills before having sex and then 1 pill daily at 24 hours intervals from the first 2 pills until 2 days after last sex.

Is the preventive effect immediate?

- Daily PrEP: MSM and TGW not using hormone therapy can start with a double dose 2 - 24 hours before sex, and can then be continued daily. For all other clients, PrEP must be taken for 7 consecutive days before first risk exposure to be effective against acquiring HIV
- On-demand PrEP: Take the first (double) dose 2 - 24 hours before sex, and then continued as prescribed.

When should you contact the clinic immediately?

- Call the clinic immediately when there is a suspicion of acute HIV infection or when there are side effects from PrEP.

What are the symptoms of acute HIV infection?

- The symptoms of acute HIV infection may include fever, fatigue, pharyngitis, headache, muscle aches, loss of appetite, weight loss, diarrhea, skin rash, joint pains, oral ulcers, nausea and/or vomiting, and lymph node enlargement.

If you forget to take PrEP as scheduled, what should you do?

- Daily PrEP - Take the forgotten pill as soon as you remember if within 12 hours of usual time. If more than 12 hours have passed, take the pill together with the next dose, so 2 pills, at your regular time.
- On-demand PrEP - This depends on how many pills are forgotten; mostly, the first two pills are not often forgotten. For subsequent pills, take the pill as soon as you remember and at the same time of day you took the first 2 pills before having the next sex.

If you want to stop PrEP is that OK? How to stop using PrEP?

- Yes, you can. For daily PrEP, contact your provider for evaluation prior to stopping. MSM and TGW not using hormone therapy should continue a daily pill until 2 days after the last HIV risk. For all other clients, including TGW who use hormone therapy, continue to take pills until 7 days after the last HIV risk
- On-demand PrEP: Stop immediately after taking one pill per day for two days after the last episode of sex.

What are the side effects of PrEP and are they common?

- Only a minority of users will have side effects, such as headache, abdominal pain or weight loss in the first few days. Usually, the symptoms will disappear after that.
- With longer-term use, kidney function may decline and bones may become thinner.

When do I have to visit the clinic the next time?

- If my HIV test is negative, I can start PrEP immediately, and make an appointment for follow-up after 1 month, 3 months and every 3 months thereafter.
- If kidney function is abnormal within the first three months on PrEP, the team will discuss with me how to proceed.

Provide a PrEP information sheet or user guide for clients to take back home, preferably with the counselor's contact number. Create opportunity for clients to ask questions on a widely used app in your area (LINE, WhatsApp) at any time. At the beginning, clients tend to have more questions or concerns; addressing them timely is much preferred to losing clients to follow-up. However, if the clinic loses contact with a client, then staff should follow up by app or cell phone, or according to any agreed channels.





Chapter 4

PrEP Counseling

Studies have shown gain-framed health messages to be the most effective when targeting prevention behaviors such as PrEP.¹⁴ For this reason we recommend gain-framing counseling for PrEP clients, meaning that our counseling promotes the benefits of PrEP, with the core message being


“If you take PrEP, you’re protected from HIV”.









Our counseling should correspond to an individual’s prevailing concerns regarding PrEP and our messages should be communicated in a manner that maximizes the impact on our clients’ thoughts and behavior. The identification of a client’s concerns regarding PrEP can be done by using the the so-called Stages of Change Model.¹⁵ This model teaches us that clients must not only recognize the personal relevance of PrEP but also act either to initiate or to maintain healthy behavioral practices.

The Stages of Change as related to PrEP



1. **Precontemplation** – client either does not acknowledge or understand HIV acquisition risk or does not want to use PrEP
2. **Contemplation** – client thinks PrEP may be good but is still undecided / uncommitted
3. **Determination/Preparation** – Client commits to PrEP, develops a plan to use PrEP and prepares information, skills, strategies and tools to help
4. **Action** – Client starts PrEP but may start with a provisional try
5. **Maintenance** – Client continues PrEP and identifies “triggers” that may cause non-adherence and develops management skills to avoid missed doses or discontinuation
6. **Relapse** – PrEP non-adherence or discontinuation and return to earlier stages of change

We assess the stage the client is in by listening to the client carefully and matching the client's words to one of the stages and tailor our response and strategies accordingly as illustrated per stage below. Text in *"quotation marks in italics"* are potential cues by clients for us as providers. Text with a  *tickmark in italics* are questions and advice we as providers can ask or recommend.

| STAGE OF CHANGE | STAGE SPECIFIC BEHAVIOR CHANGE STRATEGIES | | |
|--|--|---|---|
| PRE-CONTEMPLATIVE STAGE | Tell a story | Provide information | Discuss benefits of PrEP: |
| <p>Service recipients do not see the importance of starting PrEP.</p> <p><i>"I have not heard of PrEP."</i></p> <p><i>"I don't think I need to take PrEP."</i></p> <p><i>"I am concerned about the HIV test results every time I come here because it is difficult to use condoms all the time."</i></p> | <p>Tell the client of a similar situation to introduce PrEP.</p> <p> <i>Another one of my clients was able to reduce his worry about test results by taking PrEP to prevent infection. What have you heard about PrEP?</i></p> <p>Offer alternatives:</p> <p> <i>Condoms and PrEP prevent STI and HIV. In situations where it may be difficult to use condoms, PrEP alone provides assurance that you are protected from HIV.</i></p> | <p>Specific to the client's situation.</p> <p> <i>What do you know about PrEP?</i></p> <p> <i>Would you like to know how to prevent HIV in addition to using condoms?</i></p> <p> <i>Although we detected gonorrhea / chlamydia today, we can help you prevent HIV in the future by taking PrEP. This will give you confidence that you are protected from HIV when you have sex. Would you be interested to know more?</i></p> | <p>Adopting this new preventative behavior can benefit both physical and mental health of client.</p> <p> <i>How do you think PrEP might reduce your anxiety about HIV testing?</i></p> <p> <i>How do you think PrEP can help you maintain your health?</i></p> <p> <i>Taking PrEP is an effective way to prevent HIV infection.</i></p> |

| STAGE OF CHANGE | STAGE SPECIFIC BEHAVIOR CHANGE STRATEGIES | | |
|---|---|---|--|
| <p>CONTEMPLATIVE STAGE</p> | <p>Explore ambivalence</p> | <p>Identify and reinforce motivations</p> | <p>Discuss behavior in relation to self-image and self-efficacy</p> |
| <p>The client sees the benefits of starting PrEP but also recognizes possible costs, leading to hesitation to start.</p> <p><i>"I am always worried what my HIV test results will be. I haven't started PrEP yet, but ..."</i></p> <p><i>"I think PrEP might be a good choice in prevention, but I am not ready to start taking medicine."</i></p> <p><i>"Yes, I think PrEP may be helpful, but I worry that other people will think that I have HIV if I take it."</i></p> | <p>Help the client to see why he or she is hesitant to take PrEP.</p> <p>Provide choices based on the client's concerns, such as when to take PrEP.</p> <ul style="list-style-type: none"> ✔ What are some of your concerns about taking PrEP? | <p>Find out what will help the client make a decision more easily.</p> <ul style="list-style-type: none"> ✔ What do you think you can do to reduce your worries? ✔ Most people do not experience side effects with PrEP and we provide support if you do. ✔ What would be some of the good things about taking PrEP for you? ✔ Follow-up monitoring is provided every six months to keep you healthy. | <ul style="list-style-type: none"> ✔ You told me you are very safe, but you also said you always worry about your HIV test result. What are the behaviors that have you worried about your test? ✔ Taking hormones, vitamins or nutritional supplements shows that you can take PrEP daily. ✔ If you dislike taking pills, think of PrEP as a vitamin that will prevent HIV infection. ✔ Continue the story about the client who reduced both his worry and his risk about HIV infection by taking PrEP. |

| STAGE OF CHANGE | STAGE SPECIFIC BEHAVIOR CHANGE STRATEGIES | | |
|---|---|---|--|
| DETERMINATION / PREPARATION STAGE | Getting started / Planning | Build self-efficacy, confidence, practice skills and establish a first step | Support |
| <p>The client is ready to start PrEP.</p> <p><i>"I want to prevent HIV by taking PrEP."</i></p> | <p>Inform the client of the steps in preparing to take PrEP and follow-up monitoring.</p> <ul style="list-style-type: none"> ✔ <i>We monitor your body periodically by checking HIV status and your liver and kidney function if indicated.</i> ✔ <i>How do you think you will include PrEP into your daily routine?</i> ✔ <i>What method of PrEP, daily or on demand, do you think would suit your lifestyle?</i> <p>Help the client adjust their plan for taking PrEP as appropriate.</p> <ul style="list-style-type: none"> ✔ <i>You can choose a time of day to take PrEP that is convenient for you.</i> | <p>Show the client that there are applications that provide reminders on when to take PrEP. Assess client's confidence in taking PrEP and identify gaps where assistance may be needed.</p> <p>Show the client that there are applications that provide reminders on when to take PrEP.</p> <ul style="list-style-type: none"> ✔ <i>You can carry doses of PrEP in a pill box so that you can take it at the appointed time if not at home.</i> <p>Remind the client to pack a supply of PrEP when traveling.</p> <p>Role-play giving reasons for taking PrEP in different situations. (if the client will not disclose taking PrEP)</p> | <ul style="list-style-type: none"> ✔ <i>PrEP side effects are easy to manage but rare. If you experience a side effect, contact us by telephone or through LINE. We are here to help.</i> ✔ <i>If you need treatment for STI, you can be treated while taking PrEP.</i> ✔ <i>If you have already started PrEP but feel that you are no longer at risk, you may stop PrEP with a cessation plan.</i> |

| STAGE OF CHANGE | STAGE SPECIFIC BEHAVIOR CHANGE STRATEGIES | | |
|--|---|--|---|
| ACTION STAGE | Continued support | Offer alternatives | Follow-up |
| <p>The client is taking PrEP.</p> <p><i>"I have started taking PrEP - so far no side effects."</i></p> | <p>Remind clients of the physical and mental health benefits of taking PrEP.</p> <p>Provide reminders on when to take PrEP.</p> | <p>Promote PrEP together with condoms.</p> <ul style="list-style-type: none"> ✔ PrEP will prevent HIV infection. But PrEP + condoms will prevent both HIV, STI and hepatitis. <p>If client's partner refuses to use condoms the client still has the power to prevent HIV infection.</p> <ul style="list-style-type: none"> ✔ PrEP will provide you reassurance that you will be protected from HIV. | <p>Affirm the client's efforts in taking PrEP.</p> <ul style="list-style-type: none"> ✔ The way you are sticking to your PrEP regimen shows you really take your health seriously. Provide Counseling to find barriers to PrEP and identify solutions. ✔ What will help you to continue to take PrEP? |

| STAGE OF CHANGE | STAGE SPECIFIC BEHAVIOR CHANGE STRATEGIES | | |
|---|--|---|--|
| MAINTENANCE STAGE | Recognizing relapse as part of the change process | Offer alternatives | Identify support |
| <p>Client anticipates triggers for relapse and coping strategies.</p> <p><i>"I can anticipate what may happen and prepare myself accordingly."</i></p> | <p>Assist client in identifying possible "triggers," which may lead to a lapse in taking PrEP and how they may cope with these. Triggers may include, traveling to another province or country, or forgetting follow-up appointments to get refills.</p> <p>Help the client identify a reward system for taking PrEP and keeping appointments.</p> | <p>Provide choices in taking PrEP, e.g. PrEP daily or PrEP on demand. Also provide the client with choice on where they can get PrEP.</p> <p>☑ <i>For MSM: As your sexual behavior changes, you may change the way you take PrEP - from PrEP daily to PrEP on demand and back again.</i></p> | <p>Help client identify peer support.</p> <p>☑ <i>Who has experience in taking PrEP and can remind and encourage you to take PrEP?</i></p> <p>Help the client become a role model for taking PrEP for peers.</p> |

| STAGE OF CHANGE | STAGE SPECIFIC BEHAVIOR CHANGE STRATEGIES | | |
|---|--|--|--|
| RELAPSE | Recognizing what leads to relapse: | Highlight triggers/ barriers | Review and modify plan |
| <p>The client may have had a time when they didn't take PrEP.</p> <p><i>"I forgot to take PrEP this time, but I still want to take it."</i></p> <p><i>"I don't want to continue taking PrEP."</i></p> | <p>Help client identify and understand circumstances that led to the missed dose(s) and/or wanting to stop taking PrEP.</p> <ul style="list-style-type: none"> ✔ A missed dose doesn't mean failure, it means that we have to review how you are taking PrEP. ✔ Missing one dose will not likely affect the level of protection PrEP offers from HIV, but let's see what can help you not to miss too many. ✔ If you feel you need to stop PrEP, PrEP provides the flexibility to start and stop taking PrEP as your lifestyle changes. What has changed for you? | <p>Review plan and encourage confidence that client is able to continue taking PrEP as recommended.</p> <ul style="list-style-type: none"> ✔ Some clients carry PrEP with them in a pill fob when they are out of the house. How would this work for you? ✔ Others need not know you are taking PrEP. Let's review your plan on when you take it. ✔ When in situations where it may be difficult to take PrEP, condoms are effective in preventing HIV too and they protect against STIs as well. | <p>Identify what has worked and what has not.</p> <ul style="list-style-type: none"> ✔ You may have missed a dose, but all the doses you took before show how committed you are to protecting yourself. What might help you avoid missed doses in the future? ... What worked for you in the past? ✔ It's possible to switch between PrEP daily and PrEP on demand as your lifestyle changes. <p>In the event the client decided to discontinue PrEP.</p> <ul style="list-style-type: none"> ✔ The effort you made to start PrEP shows how much you care – please make sure you come back for your final monitoring visit so you can continue to protect your health. ✔ Condoms are effective in preventing HIV too and they protect against STIs as well. We can provide you with some. ✔ Using a personal, new needle and syringe when you inject helps prevent HIV infection. We can provide you with some. ✔ If PrEP should fit your lifestyle again in the future, we can help you start again. |

References

