Pre-Exposure Prophylaxis (PrEP) Training for Providers in Clinical Settings

_Version 3.0_
Welcome!

- Please sign the registration sheet.
- Please make a name tag for yourself.
- Please take a participant manual, notebook, and pen.

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Introductions

Take a minute (and only one, please!) to tell us:

• Your name

• The name of your organization

• Your position there
PrEP-Specific Competencies

After completing this training, participants will be able to:

• Identify candidates eligible for PrEP.
• Assess individual risk for HIV.
• Educate and counsel PrEP candidates and users.
• Assess medical eligibility for PrEP.
• Prescribe PrEP.
• Conduct clinical and laboratory assessments during follow-up visits.
• Determine how PrEP monitoring and evaluation tools may be used locally.
• Provide adherence education, counseling, and support to PrEP candidates and users.
Training Overview

1. PrEP Basics
2. PrEP Screening and Eligibility
3. Initial and Follow-Up PrEP Visits
5 PrEP Monitoring and Evaluation Tools

6 Post-Training Assessment, Evaluation, and Closing
Ground Rules

• Be punctual.
• Keep client stories confidential.
• Respect differing opinions.
• Be an active participant in all training activities.
• Stick to our agreement on cellphone use.
• Ask questions—ask, ask, ask.
• Let others finish speaking before responding or commenting.
Pre-Training Assessment

• The purpose of this assessment is to find out what you know about implementing PrEP. Your answers will help adjust the training.

• We assume that you know little about PrEP, so do not worry if you do not know all of the answers.

• Please hand your assessment forms to me when you are finished.

• You will have approximately 20 minutes to complete the assessment.
Pre-Training Assessment Debrief

• How did you feel about the questions in the pre-training assessment?
• Were the questions easy or difficult? Why or why not?
• Why did you answer the way you did?

We will review the answers to the questions after you complete the post-training assessment at the end of the training.
This training is for professional and lay HIV providers and other health care team members in clinical settings and is based on these approved HIV training resources:

[Insert country-specific approved HIV national training curriculum citation/web address.]
Integrating facts about PrEP into current HIV prevention training and other relevant curricula supports the introduction of PrEP in a range of settings such as primary health, sexually transmitted infections (STIs), and reproductive health services.
Module 1

1. PrEP Basics
Module 1 Learning Objectives

After completing Module 1, participants will be able to:

• Define PrEP.

• Differentiate PrEP from post-exposure prophylaxis (PEP) and antiretroviral therapy (ART).

• Describe the need for PrEP.

• Identify people at risk and people at substantial risk for HIV infection.

• Identify key populations (KPs) for PrEP at local level.
• Explain the relationship between PrEP effectiveness and adherence.

• State the key reasons why PrEP is needed.

• Specify the PrEP regimens approved by the World Health Organization and within your own country.

• Identify concerns regarding PrEP implementation.

• Explain the risks and benefits of PrEP.
Introduction to Module 1

• HIV prevention needs change over a lifetime.

• **Combination prevention is a mix** of biomedical, behavioral, and structural interventions that decrease risk of HIV acquisition.

• **Greater impact may come from combining approaches** than from using single interventions alone.

• An important **additional** prevention tool is provided by PrEP: using antiretroviral drugs (ARVs) for prevention.
## Combination Prevention

<table>
<thead>
<tr>
<th>Structural</th>
<th>Behavioral</th>
<th>Biomedical</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Policies</td>
<td>• Education</td>
<td>• HIV testing</td>
</tr>
<tr>
<td>• Laws</td>
<td>• Counseling</td>
<td>• Condoms</td>
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<tr>
<td>• Regulatory</td>
<td>• Stigma reduction</td>
<td>• VMMC</td>
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<tr>
<td>environment</td>
<td>• Harm reduction</td>
<td>• PMTCT</td>
</tr>
<tr>
<td>• Culture</td>
<td>• Adherence interventions</td>
<td>• STI treatment</td>
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<tr>
<td>• Cash transfers</td>
<td></td>
<td>• Antiretroviral therapy for</td>
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<tr>
<td></td>
<td></td>
<td>prevention (ART)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PEP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PrEP</td>
</tr>
</tbody>
</table>
• What is pre-exposure prophylaxis (PrEP)?
PrEP is the use of ARVs by people who are HIV negative to prevent the acquisition of HIV *before* exposure to the virus.

<table>
<thead>
<tr>
<th>Pre</th>
<th>Before</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure</td>
<td>Activity that can lead to HIV infection</td>
</tr>
<tr>
<td>Prophylaxis</td>
<td>Prevention</td>
</tr>
</tbody>
</table>
Global Progress of PrEP

- **2012**: FDA approval in the United States
- **2015**: WHO recommendation
- **2016**: Southern African guidelines on PrEP for persons at risk, including adolescents
- **2018**: Adolescents included in PrEP recommendations in the United States
- Regulatory approval in dozens of countries
- Access through programs and research in several other countries
• What is PEP?
PEP is short-term antiretroviral treatment to reduce the likelihood of HIV infection after potential exposure, either occupationally or nonoccupationally—for instance, through sexual intercourse.
Questions

• 1) What are some similarities and differences between PrEP and PEP?
• 2) What are the main differences between ART and PrEP?
### Comparing PrEP and PEP

#### What is the same?

<table>
<thead>
<tr>
<th>What is the same?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both are used by HIV-negative persons.</td>
</tr>
<tr>
<td>Both use ARVs to prevent HIV acquisition.</td>
</tr>
<tr>
<td>Both are available from clinical providers by prescription.</td>
</tr>
<tr>
<td>Both are effective when taken correctly and consistently.</td>
</tr>
</tbody>
</table>

#### What is different?

<table>
<thead>
<tr>
<th>What is different?</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrEP is started before potential exposure. PEP is taken after exposure.</td>
</tr>
<tr>
<td>PEP is taken for 28 days only. PrEP requires ongoing use as long as HIV risk exists.</td>
</tr>
</tbody>
</table>
Questions

• 1) What are some similarities and differences between PrEP and PEP?

• 2) What are the main differences between ART and PrEP?
Differences Between ART and PrEP

Treatment for HIV infection requires lifelong ART and consistently high adherence to achieve viral suppression.

PrEP is needed during periods of substantial HIV risk.

• Individuals taking PrEP receive regular risk assessment. Discontinuing PrEP is appropriate when they:
  ▪ Are no longer at substantial risk for HIV infection.
  ▪ Decide to use other effective prevention methods.

Motivation for adherence is different.

▪ ART is taken regularly by HIV-positive persons to remain healthy and keep from infecting others.

▪ PrEP is taken by HIV-negative persons who are largely healthy to avoid acquiring HIV infection.
Why We Need PrEP

• Several effective HIV prevention interventions already exist, including condoms and harm reduction for people who inject drugs (PWID).

• Global annual HIV infections have remained consistently close to 2 million for several years, declining in recent years.

• HIV incidence remains high among key and vulnerable populations: PWID, sex workers (SWs), transgender persons (TG), men who have sex with men (MSM).

• PrEP provides an additional prevention intervention to be used together with existing interventions like condoms.

• PrEP is not meant to replace or be a substitute for existing prevention interventions.
Local HIV Epidemiology

• Most new infections are happening amongst [insert populations]. These populations are an appropriate target for PrEP.

• In [insert country name], there are [insert most recent incidence data] new infections annually.
“Key populations” are groups of people most at risk for contracting HIV.

- Who are the KPs and other populations targeted for PrEP in the communities you serve?
Key Populations, Priority Populations

Key Populations

- SWs
- TG
- MSM
- PWID
- People in prisons and other closed settings

Other Priority Populations

- Clients of SWs
- Migrant workers
- Fisher folk
- Adolescent girls and young women (AGYW)
Small Group Activity

Read this information in your participant manuals:
Do not read beyond this point.

<table>
<thead>
<tr>
<th>ARVs Used in PrEP Trials</th>
<th>Partners PrEP Demonstration project</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx Study</td>
<td>Key HIV PrEP Trials Table</td>
</tr>
<tr>
<td>PROUD: Immediate vs.</td>
<td>Effectiveness and Adherence in Trials</td>
</tr>
<tr>
<td>Deferred PrEP</td>
<td>ANRS IPERGAY</td>
</tr>
</tbody>
</table>

With your group, discuss these questions:

- From these studies, what can you conclude about PrEP’s effectiveness?
- In what circumstances was PrEP most effective?

You will have 10 minutes to work.
Evidence PrEP Works

• PrEP efficacy was measured in:
  ▪ 11 randomized control trials (RCTs) comparing PrEP with placebo.
  ▪ 3 RCTs comparing PrEP with no PrEP (e.g., delayed PrEP or “no pill”).
  ▪ 3 observational studies.

• Multiple demonstration projects worldwide

• PrEP was effective in reducing HIV acquisition—most effective in studies with high adherence.

• Quantifiable drug in plasma increased efficacy estimates to 74–92%.
Global Expansion of PrEP

• By late 2018, estimated 380,000 individuals prescribed PrEP, across nearly 70 countries.¹

• Over 20% of WHO member states had adopted guidelines for PrEP or were poised to do so.²

• National guidelines in low- and middle-income countries as well as high-income countries.

• Regional guidelines from:
  ▪ European AIDS Clinical Society
  ▪ Southern African HIV Clinicians Society
  ▪ Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine

PrEP Use in a Routine Setting

• In San Francisco, USA, a large health care system assessed PrEP uptake and outcomes from July 2012 to February 2015.

• Among 801 individuals evaluated for PrEP:
  ▪ 82% initiated PrEP.
  ▪ Mean duration on PrEP during the observation period was 7.2 months.
  ▪ No HIV infections occurred.

• 30% of PrEP users were diagnosed with an STI in the 6 months following PrEP initiation.

• Among a small subset asked about behavior change during PrEP use, 56% reported no change in condom use; 41% reported a decrease in use; 17% reported increase in use.
PrEP Efficacy Depends on Adherence

• Taken as prescribed, PrEP works! Both ART and PrEP must be taken correctly and consistently.

• Highest PrEP effectiveness was in trials with PrEP use of more than 70% (risk ratio = 0.30, 95% confidence interval: 0.21–0.45, P<0.001) compared with placebo).*

• As you can see in “Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention” in Module 1 of the PrEP Participant Manual, the higher the percentage of participant samples with detectable PrEP drug levels, the greater the efficacy.

• How would you define adherence?
**Defining Adherence**

**Adherence to drugs** means that an individual is taking prescribed medications *correctly* and *consistently*. It involves taking the correct drug in the correct dose:

- With consistent frequency (the same number of times per day).
- At a consistent time of day.

**Adherence with follow-up** means that clients attend *all* scheduled clinic visits and observe all required protocols, including:

- Clinic and lab assessments.
- Prescription refills.
Planned, Ongoing and Completed PrEP Evaluation Studies (June 2015)

Data from demonstration projects and open-label extension studies are beginning to come in. So far, the findings suggest that people want and will take daily oral PrEP correctly outside of a clinical trial setting. Expanded and faster rollout is key.

For the latest on these studies, visit [www.avac.org/prep/track-research](http://www.avac.org/prep/track-research).
PrEP Evaluation Studies

- [Insert most recent studies or updates on the studies in the previous slide. You may use these links to obtain updated study information.]

- http://www.prepwatch.org
- https://www.avac.org
When taken **CORRECTLY** and **CONSISTENTLY**—
PrEP works!
ARVs Recommended for Oral PrEP

- The World Health Organization (WHO) recommends oral PrEP regimens containing tenofovir disoproxil fumarate (TDF).

- Per WHO, consider these regimens for PrEP:

  1. Combined tablet of emtricitabine (FTC) 200 mg/TDF 300 mg PO daily.
  2. Combined tablet of lamivudine (3TC) 300 mg/TDF 300 mg PO daily.
  3. Single-agent TDF 300 mg PO daily.

  (Note the limited evidence on the use of TDF alone for PrEP for MSM.)

- In [insert country name] the available recommended PrEP regimens include: [insert available regimen]

PrEP Side Effects: Reports from RCTs

Approximately 10% of participants in randomized controlled trials (RCTs) trials experienced side effects:

• They were mild.

• They usually did not persist beyond the first month.

Side effects may include:

• Gastrointestinal (GI) side effects: nausea, vomiting, abdominal pain.

• Creatinine elevation: typically reversible.

• Loss of bone mineral density: recovers after stopping PrEP.
Side Effects: Reported in iPrEx OLE

Reported in Multisite iPrEx Open-Label Extension (iPrEx OLE) Observational Study of a PrEP Cohort Taking Daily Oral TDF/FTC

- 39% of participants reported any PrEP-related side effects (mainly mild).
- A “start-up syndrome” has been reported.
- GI symptoms included: nausea, flatulence, diarrhea, abdominal pain, vomiting, headaches, and skin problems or itching.
- The start-up syndrome is transient but can influence adherence.
- Side effects among PrEP users peaked around Month 1, and symptoms resolved by Month 3.
- Adherence counseling should focus on the transient nature of a start-up syndrome.
Will PrEP Users Engage in More Risk Behaviors?

Will PrEP Encourage People to Use Condoms Less Often or to Have More Sexual Partners (i.e., “Risk Compensation”)?

• There was no evidence of this in clinical trials, where participants received regular counseling, screening, and access to condoms and lubricants.

• Evidence from real-world PrEP implementation shows declines in self-reported condom use and increases in STI diagnoses among some PrEP users.

• Combination prevention should include quality counseling and access to condoms and lubricants.
Will PrEP Lead to More HIV Drug Resistance?

- Drug resistance (HIVDR) in PrEP users was rare in clinical trials.

- HIVDR occurred mostly in cases where the person had undiagnosed HIV infection when starting PrEP.

- HIVDR will not occur when adherence to PrEP is high and HIV seroconversion does not occur.

- There can be risk of HIVDR if adherence is suboptimal and HIV infection occurs while the individual is on PrEP.

- Optimal PrEP adherence is crucial.

- Health providers must support and monitor adherence and teach PrEP users to recognize signs and symptoms of AHI.
Questions

• Does PrEP protect against other STIs?

• What can people do to protect themselves against STIs while they are taking PrEP?

• What should the package of prevention services include?
Does PrEP Protect Against Other STIs?

- PrEP does *not* protect against syphilis, gonorrhea, chlamydia, or human papilloma virus (HPV).

- Only condoms protect against STIs and pregnancy.

- PrEP protects against HIV.

- PrEP also provides modest protection against herpes simplex virus type 2 in heterosexual populations.

- PrEP should be provided within a package of prevention services, including STI screening and management, risk reduction counseling, condoms, and contraceptives.
Can PrEP Be Used with Drugs or Alcohol?

- Yes. Using drugs or drinking alcohol will not affect the safety or effectiveness of PrEP.
- However, drugs and alcohol could make you forget to take the PrEP tablets.
Module 1 Summary

What We Know about PrEP

• PrEP can be used by HIV-negative persons to reduce the risk of HIV acquisition.

• Daily oral PrEP with TDF-containing regimens is currently recommended.

• PrEP should be taken as an additional prevention intervention.

• PrEP is effective if taken correctly and consistently.

• PrEP can be used by at-risk populations, including heterosexual men and women, MSM, SWs, PWIDs, and transgender women, among others.

• PrEP is safe and has minimal side effects.
MORNING BREAK
After completing Module 2, participants will be able to:

• Name the 5 main eligibility criteria for PrEP.

• Use the standard medical screening form for PrEP eligibility and substantial risk.

• Name the contraindications for PrEP.

• Explain how to exclude AHI.
WHO Recommendations

Oral PrEP containing TDF should be offered as an additional prevention choice for people at substantial risk for HIV infection as part of combination HIV prevention approaches.*

Questions

• Who should receive PrEP?
• What are the eligibility criteria for initiating PrEP?
Eligibility for PrEP

Criteria

<table>
<thead>
<tr>
<th>• HIV seronegative.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No suspicion of AHI.</td>
</tr>
<tr>
<td>• At substantial risk for HIV infection.</td>
</tr>
<tr>
<td>• Creatinine clearance (eGFR) &gt;60ml/min.*</td>
</tr>
<tr>
<td>• Willingness to use PrEP as prescribed.</td>
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</tbody>
</table>

* eGFR: estimated glomerular filtration rate. Waiting for creatinine result should not delay initiation of PrEP
Exclude HIV Infection Before Starting PrEP

• PrEP is a prevention intervention for people who are HIV negative.

• All persons at substantial risk for HIV and who may be eligible for PrEP should be offered HIV testing prior to PrEP initiation.

• HIV testing must be done using national guidelines and algorithms.
  ▪ Ideally, use rapid HIV tests at point of care.
  ▪ Promptly link clients who test HIV positive to HIV treatment and care services.
National HIV Testing Algorithm

• [Add country-specific text here.]
• What is acute HIV infection?
Acute HIV Infection

• Acute HIV infection (AHI) is the early phase of HIV disease characterized by an initial burst of viremia.

• AHI infection develops within 2 to 4 weeks after someone is infected with HIV.

• Approximately 40–90% of AHI clients experience “flu-like” symptoms.
  ▪ These symptoms are not specific to HIV but occur in many other viral infections.
  ▪ Clients with AHI can be asymptomatic.

• The figure on the next slide depicts some of the presenting signs and symptoms of AHI.

• Never start PrEP if AHI is suspected.
Main symptoms of Acute HIV infection

**Systemic:**
- Fever
- Weight loss

**Central:**
- Malaise
- Headache
- Neuropathy

**Pharyngitis**

**Mouth:**
- Sores
- Thrush

**Esophagus:**
- Sores

**Muscles:**
- Myalgia

**Liver and spleen:**
- Enlargement

**Lymph nodes:**
- Lymphadenopathy

**Skin:**
- Rash

**Gastric:**
- Nausea
- Vomiting

Question

• Why must you assess for acute HIV infection before prescribing PrEP?
Diagnosis of Acute HIV Infection

• During AHI, antibodies might be absent or be below the level of detection.
  ▪ Serological testing using rapid tests might be negative.

• AHI can be diagnosed using “direct” viral tests like HIV RNA or HIV antigen testing.

• In the absence of HIV RNA and antigen testing, defer PrEP for 4 weeks if AHI is suspected.
  ▪ Repeat the HIV serological test after 4 weeks to reassess eligibility.
Question

- Who is at substantial risk for HIV infection?
Substantial Risk for HIV Infection
(based on history in the past 6 months)

- The client is sexually active in a high HIV prevalence population (either in the general population or a key population group) and reports any one of the following in the past 6 months:
  - Vaginal or anal intercourse without condoms with more than one partner.
  - Sex partner with one or more HIV risk.
  - History of an STI (based on lab test, syndromic STI treatment, or self-report).
  - History of use of PEP.

- The client reports a history of sharing of injection material and/or equipment with another person in the past 6 months.

- The client reports having a sexual partner in the past 6 months who is HIV positive and who has not been on effective* HIV treatment.

*On ART for less than 6 months, or has inconsistent or unknown adherence.
Potential Signs of Risk

Situations That May Prompt a Person to Consider Starting PrEP

• Alcohol and recreational drug use before sex.
• Leaving a long-term monogamous relationship.
• Leaving school or home at an early age.
Small Group Brainstorm

• Close your participant manuals.

• With your small group, brainstorm a list of questions to screen for substantial risk.

• Keep in mind that you must ask about clients’ sexual behaviors, their partners’ sexual behaviors, issues with serodiscordant couples, and other aspects of their situation—for example, their current life circumstances.

• Choose one group member to record your questions on a sheet of notebook paper.
Small Group Brainstorm
(continued)

• When you have finished your brainstorm, find the list of sample screening questions in your manuals.

• Compare your brainstormed questions to this list.

• Make a note of any questions you missed and any questions on your list that do not appear in the manual.

• You will have 15 minutes to work.
Screening for Substantial Risk

• Frame screening questions in terms of people’s behavior rather than their sexual identity.

• In your screening questions, refer to a defined time period (e.g., 6 months).

• As a PrEP provider, remember to be sensitive, inclusive, nonjudgmental, and supportive.

• Be careful not to develop a screening process that might discourage PrEP use.
Consider PrEP if a client from a high-prevalence setting or a high-prevalence population answers “yes” to any of the following questions.

**Over the past 6 months:**

- Have you had sex with more than one partner?
- Have you had sex without a condom?
- Have you had sex with people whose HIV status you do not know?
- Are any of your partners at risk for HIV infection?
- Have you had sex with a person who has HIV?
PrEP Can Protect the HIV-Negative Partner in a Heterosexual Serodiscordant Relationship

- If the partner with HIV has been on ART for less than 6 months.
  - It takes 3 to 6 months on ART to suppress viral load.
  - In studies of serodiscordant couples, PrEP has provided a useful bridge to full viral suppression during this time.

- If the HIV-negative partner is not confident of the HIV-positive partner’s adherence to treatment or has other sexual partners besides the partner on treatment.

- If the HIV-negative partner is aware of gaps in the HIV-positive partner’s treatment adherence.

- If the couple is not communicating openly about treatment adherence and viral load test results.
Questions to Help Identify Good Candidates for PrEP

• Is your partner taking ART for HIV?

• Has your partner been on ART for more than 6 months?

• Do you regularly discuss your partner’s adherence to HIV treatment (i.e., at least monthly)?

• Do you know your partner’s last viral load? What was the result? And when was the testing done?

• Do you wish to have a child with your partner?

• Are you and your partner consistently using condoms?
Do any aspects of your situation indicate higher HIV risk? Have you…

- Received money, housing, food, or gifts in exchange for sex?
- Been forced to have sex against your will?
- Been physically assaulted by anyone, including a sex partner?
- Taken PEP to prevent HIV infection?
- Had an STI?
- Injected drugs or hormones using shared equipment?
- Used recreational or psychoactive drugs?
- Been required to leave your home?
- Moved to a new place?
- Lost your job?
- Had fewer than 12 years of schooling or left school early?
Creatinine and Estimated Creatinine Clearance

• TDF can be associated with a small decrease in estimated creatinine clearance (eGFR) early during PrEP use. Usually this does not progress.

• PrEP is not indicated if eGFR* is < 60ml/min.

* eGFR: estimated glomerular filtration rate using Cockcroft-Gault equation:
  Estimated CrCl = [140-age (years)] x weight (kg) x f
  where f=1.23 for men and 1.04 for women / [72 x serum creatinine (μmol/L)]
Online Cockcroft-Gault Calculator

Creatinine Clearance Estimate by Cockcroft-Gault Equation

Input:
- Sex: Male (1)
- Age: yr
- Serum Creat: mg/dL
- Weight: kg

Result:
- Creat Clear: mL/min
- Decimal Precision: 2

CreatClear = Sex * ((140 - Age) / (SerumCreat)) * (Weight / 72)

• Is PrEP safe during pregnancy?
PrEP Use During Pregnancy

• In settings with high-prevalence, generalized epidemics, women acquire HIV during pregnancy and breastfeeding.

• Existing safety data support the use of PrEP in pregnant and breastfeeding women who are at continuing substantial risk for HIV infection.

• WHO guidelines state that there is no safety-related rationale for disallowing or discontinuing PrEP use during pregnancy and breastfeeding for HIV-negative women who are receiving PrEP and who remain at risk for HIV acquisition.

• Surveillance of maternal, pregnancy, and infant outcomes is ongoing to identify any safety concerns.

Women and PrEP

Additional Information for Women

• PrEP does not affect the efficacy of hormonal contraceptives.
  - Taking PrEP and hormonal contraceptives together does not make them less effective.

• PrEP does not protect against pregnancy.

• PrEP is safe and can be continued during pregnancy and breastfeeding.
Willingness to Use PrEP As Prescribed

• Education and counseling are provided to support clients to make an informed choice about PrEP.

• Clients must not be coerced into using PrEP.

• Research indicates that adherence is higher among people who are aware that they are at risk for HIV infection and are motivated to take PrEP.
Eligibility Criteria Recap

- HIV seronegative.
- No suspicion of AHI.
- Substantial risk for HIV infection.
- Creatinine clearance (eGFR) >60ml/min.
- Willingness to use PrEP as prescribed.
LUNCH
# PrEP Screening for Substantial Risk and Eligibility

## Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility

### 1. Facility Information

<table>
<thead>
<tr>
<th>Facility Name</th>
</tr>
</thead>
<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Date of Initial Visit (dd/mm/yyyy)</th>
<th>Person Completing Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>__ / __ / ________</td>
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### 2. Client Information

<table>
<thead>
<tr>
<th>First Name</th>
<th>Middle Name</th>
<th>Surname</th>
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<table>
<thead>
<tr>
<th>Address</th>
<th>Telephone #</th>
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<table>
<thead>
<tr>
<th>Client ID Number</th>
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</table>

### 3. Client Demographics

**What was your sex at birth?**
- [ ] Male
- [ ] Female
- [ ] Other (specify): _________
- [ ] No response

**What is your current gender?**
- [ ] Male
- [ ] Female
- [ ] Transgender (male to female)
- [ ] Transgender (female to male)
- [ ] Other (specify): _________
- [ ] No response

**What is your age? (Specify number of years):**
_______

### 4. Screening for Substantial Risk for HIV Infection

<table>
<thead>
<tr>
<th>Client is at substantial risk if he/she belongs to categories 1, 2, or 3 below</th>
<th>Question Prompts for Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> If client is sexually active in a high HIV prevalence population PLUS reports ANY one of the below in the last 6 months</td>
<td>Have you been sexually active in the last 6 months?</td>
</tr>
<tr>
<td>[ ] Reports vaginal or anal intercourse without condoms with more than one partner</td>
<td>In the last 6 months, how many people did you have vaginal or anal sex with?</td>
</tr>
</tbody>
</table>
• In the brainstorming session, we identified types of questions you must ask in order to screen for PrEP eligibility.

• Using a standard form can ensure that screening is consistent and well documented.

• Source to complete this form: Complete this screening form with the client.

• Let us review the screening form section by section.
Small Group Clinical Scenarios

• Read the clinical scenario assigned to your group.
• Then discuss the scenario questions.
• Refer to the PrEP screening tool during your discussion as needed.
• You will have 10 minutes to work.
Joseph, a 22-year-old man, presents at the clinic because he is interested in starting PrEP. He reports using condoms sometimes during sex with his HIV-positive male partner. His partner is healthy and has been on ART for 4 years. His most recent viral load from “a few months ago” was reported as 1200 copies/mL. Their last unprotected intercourse was last week. Joseph is in good health and takes no medications. His rapid HIV antibody test today is negative.

• Is Joseph a candidate for PrEP?

• If so, what did you consider in order to determine eligibility?
Marie, an 18-year-old woman, comes to the clinic because she feels sick and is afraid she might have HIV. She reluctantly explains that, during the past year, she has been having sex for money or gifts in order to support her 2 children. Some of her partners have used condoms and others have not. She does not know whether her partners have HIV. Marie reports that she has been feeling run-down and sick for the past few weeks. Her rapid HIV antibody test today is negative.

• Is Marie a candidate for PrEP?
• If so, why?
• What other information would you need in order to determine eligibility?
Clinical Scenario 3

Geraldine, a 30-year-old wife and mother, presents at the clinic because she has heard that she can get drugs that will prevent her from getting HIV. She suspects that her husband has been injecting drugs, as he has needle marks on his arms. Geraldine is afraid that her husband might have HIV and that he will infect her. She reports that her husband has not been tested. Geraldine’s rapid HIV antibody test today is negative.

• Is Geraldine a candidate for PrEP?
• If so, why?
• What other information might you need in order to determine eligibility?
Clinical Scenario 4

Daniel is a 25-year-old man who presents at the clinic seeking treatment for “blisters.” He reports that, during the past several days, he has had a few painful blisters around his mouth and on his genitals. He declines to report his sexual activity; he says he is a married man and faithful to his wife. He asks if he can take just one pill for the blisters here at the clinic, so that his wife or neighbors do not find out that he is taking pills. Daniel does not want to take any medications ongoing, as his neighbors or church might find out and conclude that he has HIV. He declines to take an HIV test.

• Is Daniel a candidate for PrEP?
• Why?
AFTERNOON BREAK
Trainer Role-Play Debrief

• Based on the role-play, how would you complete Section 5 of the screening tool?

• To determine eligibility, what other information would you need to gather?

• What was most challenging about this screening?

• How did the provider handle the challenges?

• What other questions or comments do you have about the role-play?
Screening Role-Play 1

- Find Screening Role-Play Scenario 1 in your manuals.
- Decide who will play the provider and who will play the client.
- Practice a brief role-play.
- The client should answer using the information in Screening Role-Play Scenario 1 in your participant manual.
- The provider should use the screening tool and complete it as if he or she were interviewing a real client.
- Start with Section 3 of the form.
- After the practice, one pair will perform for the group.
- You will have 15 minutes to work.
Screening Role-Play 1 Debrief

• Based on the role-play, how would you complete Section 5 of the form?

• To determine eligibility, what other information would you need?

• What did you learn by doing these role-plays?

• What worked best? Why?

• What was most challenging? Why?

• How could you address the challenges? What strategies would you use?
Screening Role-Play Performance Debrief

• What challenges did the provider encounter and how did she or he handle them?

• What did the provider do well?

• What could the provider improve the next time around?
Screening Role-Play 2

- Find Screening Role-Play Scenario 2 in your manuals.
- Participants who played the provider for Role-Play Scenario 1 should play the client; those who previously played the client should play the provider.
- Practice a brief role-play.
- The client should answer using the information in Screening Role-Play Scenario 2 in the participant manual.
- The provider should use the screening tool and complete it as if he or she were interviewing a real client.
- Start with Section 3 of the form.
- After the practice, one pair will perform for the group.
- You will have 15 minutes to work.
Screening Role-Play 2 Debrief

• Based on the role-play, how would you complete Section 5 of the form?
• To determine eligibility, what other information would you need?
• What did you learn by doing these role-plays?
• What worked best? Why?
• What was most challenging? Why?
• How could you address the challenges? What strategies would you use?
Module 2 Summary

• Providers should inform and counsel potential PrEP users and conduct an individualized risk assessment.

• **Eligibility for PrEP**
  - At substantial risk for HIV infection.
  - HIV seronegative.
  - No suspicion of AHI.
  - No contraindications to the ARVs used in the PrEP regimen.
  - Willingness to use PrEP as prescribed.

• **PrEP screening questions** should be framed in terms of a person’s behavior.

• **Side effects** in clinical trials were rare and when they occurred they were mild.

• **Contraindications for PrEP**
  - Current or suspected HIV infection.
  - Renal impairment as defined by estimated creatinine clearance of <60 ml/min.
Module 3

Initial and Follow-Up PrEP Visits
Module 3 Learning Objectives

After completing Module 3, participants will be able to:

• Specify the procedures for the initial PrEP visit.

• Demonstrate knowledge of national guidelines for HIV testing services (HTS) and local algorithms for HIV testing.

• Describe the rationale for and content of brief counseling during the initial PrEP visit.

• Follow the Integrated Next Step Counseling (iNSC) process to counsel clients on sexual health and PrEP adherence.
• Specify the suggested procedures for follow-up PrEP visits.

• Describe the rationale for and content of follow-up counseling at each visit.

• Name typical challenges that facilities and providers may face when implementing PrEP, and strategies for addressing those challenges.
## Initial PrEP Visit: Suggested Procedures

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV test using national HTS guidelines algorithm</td>
<td>• Assessment of HIV infection status.</td>
</tr>
<tr>
<td>Acute HIV infection symptom checklist</td>
<td>• To assess for AHI.</td>
</tr>
<tr>
<td>Serum creatinine</td>
<td>• To identify pre-existing renal impairment.</td>
</tr>
<tr>
<td>Hepatitis B surface antigen (HBsAg)</td>
<td>• To identify undiagnosed hepatitis B (HBV) infection.</td>
</tr>
<tr>
<td></td>
<td>• To identify those eligible for HBV vaccination.</td>
</tr>
<tr>
<td>RPR</td>
<td>• To diagnose and treat syphilis infection.</td>
</tr>
<tr>
<td>STI screening</td>
<td>• To diagnose and treat STI.</td>
</tr>
<tr>
<td></td>
<td>• Syndromic or diagnostic STI testing, depending on local guidelines.</td>
</tr>
<tr>
<td>Pregnancy testing</td>
<td>• To ascertain pregnancy.</td>
</tr>
<tr>
<td>Brief counseling</td>
<td>• To assess substantial risk for HIV.</td>
</tr>
<tr>
<td></td>
<td>• To assess HIV prevention options and provide condoms and lubricants.</td>
</tr>
<tr>
<td></td>
<td>• To discuss desire for PrEP and willingness to take PrEP.</td>
</tr>
<tr>
<td></td>
<td>• To plan for effective PrEP use and sexual and reproductive health.</td>
</tr>
</tbody>
</table>
Provider Checklist for Initial PrEP Visit

- **Conduct HIV testing (using the algorithm in the national HIV testing guidelines).**
  
  Assess on HIV infection status.

- **Exclude acute HIV infection.**
  - Ask about the last potential exposure to HIV.
  - Ask about and look for flu-like symptoms.

- **Screen for substantial risk for HIV.**

- **Screen for signs and symptoms of kidney disease.**
  
  To identify potential pre-existing renal impairment if lab results are not available on the day of testing.

- **Conduct serum creatinine testing (calculate eGFR).**
  
  Absence of creatinine results should not delay PrEP initiation. Providers should do same-day initiation of PrEP, then discontinue PrEP if a patient’s eGFR is not within the appropriate range.

- **Screen for hepatitis B (HBsAg).**
  - To identify undiagnosed hepatitis B (HBV) infection.
  - To identify those eligible for vaccination against hepatitis B.

- **Screen for sexually transmitted infections (STI).**
  - Perform syndromic and etiological STI testing (depending on local guidelines).
  - Rapid plasma reagin test (RPR) for syphilis (if available).

- **Conduct risk reduction counseling.**
  - Refer clients based on needs (i.e., for social support, harm reduction, gender-based violence programs, etc.).
Initial PrEP Counseling

What Initial Prep Counseling Should Do

• Increase awareness of PrEP as a choice.
• Explain how PrEP works.
• Cover sexual health and PrEP as part of combination HIV prevention.
• Help clients decide whether PrEP is right for them.
• Educate about the importance of adherence and follow-up visits.
• Explain the symptoms of AHI.
• Review common adherence strategies.
• Describe common PrEP side effects and side-effects management.
PrEP works when taken regularly!
*PrEP is effective when taken every day.*

PrEP reaches maximum effectiveness after 7 daily doses.

PrEP does not prevent STIs other than HIV.
*Using condoms with every act of sexual intercourse provides some protection against many of these infections.*

PrEP does not prevent pregnancy.
*Use effective contraception unless you want pregnancy.*

PrEP is safe.
During the counseling session, assess client understanding that the protection provided by PrEP is not complete and does not prevent other STIs or unwanted pregnancies, and that therefore PrEP should be used as part of a package of HIV prevention services that also includes condoms, lubrication, contraception, risk reduction counseling, and STI management.

Source: Southern African Clinicians Society Guidelines for Provision of PrEP
Health Care Worker Discussion Prompts for Initial PrEP Visits

Sexual Behavior

• What has been going on for you sexually over the past couple of months?

• How much of the time did you use condoms?

• What has made it easier to use condoms during sex? What has made it more difficult?

• What concerns do you have about your sexual activities?

• How might taking PrEP impact your sexual activity?

Drug Use

• Did you use any drugs in the last 12 months?
• If so, which drugs (e.g., alcohol, opioids, stimulants, cannabis)?
• And how did you use them (smoking, orally, injecting)?
• When did you last use drugs (and which ones)?
• How often do you use drugs (once a year, once a month, once a week, once a day—or more frequently)?
• Has your drug use ever been a problem for you? [Note: Referral to drug services may be appropriate if locally available.]
• Do you think your drug use may put you at risk for becoming infected with HIV or transmitting HIV?

Plan for Staying HIV and STI Negative

• In what ways are you reducing your risk of getting HIV and other STIs now?

• What steps have you considered for the future?

• You are reducing your risk for HIV by deciding to take PrEP. Let’s talk about how PrEP fits into your risk reduction efforts. [Emphasize that PrEP will reduce the risk of acquiring HIV, but it will NOT reduce the risk of acquiring other STIs.]

• What other ideas or plans, if any, do you have for staying HIV and STI negative?

Preparing for Effective PrEP Use

- Do you have any experience taking a medicine daily?
- What is your experience taking a medicine daily?
- Are you now taking any medication on a daily, long-term basis? [If so, you may need to refer the client to a pharmacist or other health care provider.]
- When you have taken medicines in the past, how did you remember to take them? What helps you remember to take your pills?
- What is your plan for taking your PrEP pill daily?
- What will you do if you are away from home for a night or more?
- What will you do if you miss a dose of your PrEP pill?
- What is your understanding of possible PrEP side effects? How will you cope with side effects if you have them?

Understanding Social and Cultural Context Is Critically Important

- People at risk of acquiring HIV infection often experience stigma from multiple sources.
  - MSM, SWs, and PWID are criminalized in many places, making them reluctant to seek HIV care.
  - Transgender individuals often face stigma, discrimination and violence.
- In health care settings, addressing barriers may also mean acknowledging and redressing the imbalance in power between the providers of services and those seeking services.
Taking PrEP each day is easiest if you make taking the pills a daily habit, linked to something else you do daily without fail.

If you forget to take a pill or miss a dose, take it as soon as you remember. For example, if you usually take PrEP in the morning but realize at 10 one night that you forgot, it is okay to take your pill then and resume your usual schedule the following morning.

PrEP pills can be taken any time of day, with or without food.

PrEP is safe and effective even if you are taking hormonal contraceptives, sex hormones, or nonprescription drugs.
Adherence Strategies

• Link PrEP to daily routine or event like brushing teeth or eating breakfast.

• Take your pill at the same time every day.

• Identify what to do if a dose is missed.

• Use a pillbox.

• Identify significant others who can support PrEP adherence.

• Use reminder alarms, text messages, or a calendar.

• Have a back-up supply of pills in your bag or purse.
  - In case your routines are disrupted (i.e., if you stay out overnight, go on holiday, or skip meals), consider carrying extra pills.
Small Group Brainstorm

• Close your participant manuals.

• With your small group, brainstorm one of these questions:
  ▪ 1) What are some common reasons for low adherence? Include both reasons associated with the individual and the medication, and reasons related to the health system.
  ▪ 2) What can providers do to promote and support adherence? Include counseling, reminder calls, and other activities.

• Choose one group member to record your questions on a sheet of notebook paper.

• You will have 10 minutes to work.
# Understanding Adherence

## Common Reasons for Low Adherence to ART

<table>
<thead>
<tr>
<th>Individual Factors</th>
<th>Medication-Related Factors</th>
<th>Facility-Related Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Forgetting doses</td>
<td>• Adverse events</td>
<td>• Distance to health services</td>
</tr>
<tr>
<td>• Being away from home</td>
<td>• Pill burden</td>
<td>• Access to pharmacies</td>
</tr>
<tr>
<td>• Changes in daily routines</td>
<td>• Complexity of dosing regimens</td>
<td>• Long waiting times to receive care and obtain refills</td>
</tr>
<tr>
<td>• Depression or other illness</td>
<td>• Dietary restrictions</td>
<td>• Burden of direct and indirect costs of care</td>
</tr>
<tr>
<td>• Limited understanding of treatment benefits</td>
<td>• In contrast to ART, PrEP requires taking just one tablet daily and does not mandate any dietary restrictions</td>
<td></td>
</tr>
<tr>
<td>• Lack of interest in or desire to take the medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Substance or alcohol use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Absence of supportive environment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Fear of stigma and discrimination</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Understanding Nonadherence: Voluntary vs. Involuntary

<table>
<thead>
<tr>
<th>Voluntary Nonadherence</th>
<th>Involuntary Nonadherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>(intentionally by a client)</td>
<td>(not intentionally by a client)</td>
</tr>
<tr>
<td>• Not convinced PrEP is needed.</td>
<td>• Forgot to take pill.</td>
</tr>
<tr>
<td>• Does not believe PrEP works or is working.</td>
<td>• Forgot to refill prescription.</td>
</tr>
<tr>
<td>• Does not like taking pills.</td>
<td>• Has competing priorities (e.g., employment, child care).</td>
</tr>
<tr>
<td>• Has experienced side effects; wishes to avoid side effects.</td>
<td>• Has difficulty with personal organization and scheduling.</td>
</tr>
<tr>
<td>• Has experienced stigma while taking PrEP.</td>
<td>• Affected by depression or other unaddressed mental illness.</td>
</tr>
<tr>
<td></td>
<td>• Cannot afford PrEP medication, laboratory tests, or other costs.</td>
</tr>
</tbody>
</table>
### Understanding Nonadherence: Voluntary vs. Involuntary (continued)

<table>
<thead>
<tr>
<th>Voluntary Nonadherence</th>
<th>Involuntary Nonadherence</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(intentionally by a client)</em></td>
<td><em>(not intentionally by a client)</em></td>
</tr>
<tr>
<td>• Does not believe it is necessary to take every day.</td>
<td>• Does not want to come to the health care facility (or cannot afford to do so).</td>
</tr>
<tr>
<td>• Does not want to take with alcohol or other drugs.</td>
<td>• Dissatisfaction with health care provider interactions.</td>
</tr>
<tr>
<td>• Wishes to avoid others witnessing pill taking.</td>
<td>• No place to store medication.</td>
</tr>
<tr>
<td></td>
<td>• Unaddressed substance use issues, especially dependence on alcohol or other drugs.</td>
</tr>
<tr>
<td></td>
<td>• Insufficient food to take pills.</td>
</tr>
</tbody>
</table>
Adherence: Lessons from ART Programs

How Health Providers Can Positively Influence Adherence

- Facilitate accurate knowledge and understanding of medication benefits and requirements.
- Express confidence in the effectiveness of PrEP.
- Prepare for and manage side effects.
- Identify social support.
- Build self-efficacy for adherence.
- Develop a routinized daily schedule that includes regular pill taking.
- Maintain an open line of communication with PrEP clients.
- Monitor adherence.
## Approaches to PrEP Medication Adherence Support

<table>
<thead>
<tr>
<th>Support Issue</th>
<th>Provider Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understand PrEP—have adequate, accurate knowledge</td>
<td>• Briefly explain or provide materials about:</td>
</tr>
<tr>
<td></td>
<td>- Indications for medication.</td>
</tr>
<tr>
<td></td>
<td>- The anticipated risks and benefits of taking medication.</td>
</tr>
<tr>
<td></td>
<td>- How to take it (one pill per day).</td>
</tr>
<tr>
<td></td>
<td>- What to do if one or more doses are missed.</td>
</tr>
<tr>
<td></td>
<td>• Assess for misinformation.</td>
</tr>
<tr>
<td>Prepare for and manage side effects</td>
<td>• Educate on side effects to expect, for how long, how to manage them.</td>
</tr>
<tr>
<td></td>
<td>• Educate on AHI signs and symptoms and how to obtain prompt evaluation and care.</td>
</tr>
<tr>
<td>Foster self-efficacy</td>
<td>• Provide PrEP role models via on-on-one peer supporters or champions</td>
</tr>
<tr>
<td></td>
<td>• Establish PrEP support groups.</td>
</tr>
<tr>
<td>Routinized daily schedule</td>
<td>• Discuss how to integrate daily dose with other daily events and what to do when away from home.</td>
</tr>
<tr>
<td></td>
<td>• Recommend or provide medication-adherence tools:</td>
</tr>
<tr>
<td></td>
<td>- Pill boxes.</td>
</tr>
<tr>
<td></td>
<td>- Phone apps, pager, or SMS reminder services.</td>
</tr>
</tbody>
</table>
## Approaches to PrEP Medication Adherence Support (continued)

<table>
<thead>
<tr>
<th>Support Issue</th>
<th>Provider Options</th>
</tr>
</thead>
</table>
| Provider support                       | • Regularly assess adherence.  
• Ask for a client self-report.  
• Use technology (SMS reminders, smart phone apps).  
• Various providers or health care workers can support adherence (pharmacist, peer workers). |
| Social support                         | • Discuss privacy issues for PrEP user.  
• Offer to meet with partners or family members if they are supportive.                                                                         |
| Mental health and substance abuse      | • Consider screening for depression or substance abuse problems.  
• Provide or refer to mental health or substance abuse treatment and relapse prevention services when appropriate.          |
| Population-specific challenges         | • Consider tailored medication adherence support for:  
  - Adolescents.  
  - People with unstable housing.  
  - Transgender women.  
  - Others with specific stressors that may interfere with medication adherence.                                                                 |
Adherence Assessments

• Discuss adherence at each visit.
  ▪ To encourage realistic, honest discussion about challenges or issues a client may be facing, avoid putting your own judgment on him or her.
  ▪ Encourage PrEP clients to self-report pill taking in order to understand their experience with adherence.
  ▪ Ask about adherence over the last 3 days. (Short-term recall tends to be better than long-term recall.)

• Additional methods to monitor adherence
  ▪ Pharmacy refill history.
  ▪ Pill count.
Drug Supply

Clients who have some medication supply in reserve tend to show better adherence.

- Providing an **extra week’s supply of medication at the first visit** will ensure an adequate supply for daily dosing until the next visit.

- This is important in case the follow-up visit is delayed for any reason.

- If you cannot give an extra week’s supply, schedule the client’s next visit a week before the pill supply will run out.
Promoting PrEP

Key Approaches

Motivational Interviewing
• Helps PrEP users explore their feelings, motivations for PrEP use, reasons for nonuse of medicines, and negative experiences with medicines.

Informed Choice Counseling (ICC)
• Adapted from family planning to address the challenges of informing the choice of PrEP and developing a plan for adherence.

Integrated Next Step Counseling
• iNSC is discussed later in the training.

And there are others
Essential Features of PrEP Adherence Counseling

Shared among These Approaches

• It is context specific.
  ▪ Valuing each client’s context, situation, and decisions.

• It is client centered.
  ▪ Attentive to unmet needs that may challenge PrEP use or adherence.

• It is focused on problem solving, with an emphasis on the client’s choice.

PrEP Counseling Is Client Centered

• The term “client centered” refers to seeing clients as the expert on their own lives. The counselor serves as a guide to assist in setting and reaching goals.

• Client-centered counseling emphasizes respecting an individual’s experiences and choices.

• The approach can increase a client’s motivation to use PrEP correctly, because it addresses clients’ perceptions about the consequences of nonadherence vs. adherence.
PrEP Counseling Is About Problem Solving

• Problem solving is not counselor driven, with health care workers telling clients what their problems are or what they must do to fix those problems.

• PrEP counseling helps clients identify factors that either facilitate accessing PrEP, or are barriers to it.

• PrEP counseling helps clients identify the factors that influence their behaviors and develop strategies to reduce any barriers.
Integrated Next Step Counseling

• iNSC was used in the iPrEx OLE study to counsel individuals on sexual health promotion more generally, with specific emphasis on PrEP adherence for individuals on PrEP.

• The model is client centered and focused on problem solving, starting with the client’s identification of personal goals and of barriers and facilitators to achieving those goals.

• This counseling is a conversation about all the things someone is doing or considering doing to protect his or her sexual health.

• iNSC is used to deliver negative HIV test results and serves both as post-test HIV counseling and as counseling on the decision to use PrEP in a single brief, targeted, tailored conversation.
Integrated Next Step Counseling: Flow

Strategies for HIV Risk Reduction
Introduction of PrEP

Introduce
Review
Explore
Tailor
Identify
Strategize
Agree
Close
Document
## Steps in iNSC

<table>
<thead>
<tr>
<th>iNSC Step</th>
<th>Critical Components</th>
<th>Example Prompts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introduce</strong> the counseling session</td>
<td>Explain what you are talking about and why. Get permission to proceed.</td>
<td><em>I would like to take a few minutes to check in with you about your goals and how to meet them. Is that okay?</em></td>
</tr>
<tr>
<td><strong>Review the</strong> client’s experiences</td>
<td>Ask about what the client already knows about PrEP and how he or she learned it.</td>
<td><em>Thank you. Can you tell me a little about what you have heard about PrEP and about your experiences with PrEP?</em></td>
</tr>
<tr>
<td><strong>Explore</strong> context of client-specific facilitators and barriers</td>
<td>Use open-ended questions to explore factors or situations that help make pill taking a little easier; and those that make it harder or a little more difficult.</td>
<td><em>What seems to make PrEP easy to take or harder to take?</em></td>
</tr>
<tr>
<td><strong>Tailor</strong> the discussion to focus on making pill taking easier</td>
<td>This pause allows the provider or counselor to consider how to tailor the next question based on information gathered in earlier steps.</td>
<td><em>Let me think for a moment about what you have said.</em></td>
</tr>
<tr>
<td>iNSC Step</td>
<td>Critical Components</td>
<td>Example Prompts</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Identify adherence-related needs</td>
<td>Guide the conversation toward identifying the client’s perceptions of what would help to best integrate PrEP use into daily life</td>
<td>Given everything going on right now, what would need to happen for it to feel a little easier to work this regimen into your daily life?</td>
</tr>
</tbody>
</table>
| Strategize with the client on the next step | Work with the client to identify one or more viable strategies for increasing effective PrEP use. | How could that happen?  
What are some ideas for how you could approach that?                                                                                      |
| Agree on which strategy will be tried next | Ask which strategy (or strategies) the client is willing to try or continue using. | Of the things that we have talked about, which might you be willing to try between now and the next time we meet?                          |
| Close and document the session        | Summarize the discussion and thank the client.                                       | What I’m hearing is that _______ would really make it feel easier to work PrEP into your life and that you’ll give it a try between now and the next time we meet. Thank you for talking with me and I look forward to talking again. |
Introduce the Counseling Session

• Explain what you’re talking about and why.

• Get permission to proceed.

• *I would like to take a few minutes to check in with you about your goals and how to meet them. Is that okay?*
Review the Client’s Experiences

- Ask about what the client already knows about PrEP and how he (or she) learned it.

- Thank you. Can you tell me a little about what you have heard about PrEP and about your experiences with PrEP?
HIV Risk Reduction Strategies to Explore with the Client

• PrEP is one of several options that can help decrease risk of HIV infection. Others include:
  ▪ Consistent use of male or female condoms.
  ▪ Diagnosis and treatment of STIs.
  ▪ Mutual monogamy.
  ▪ PEP.
  ▪ Needle and syringe access programs, opioid substitution therapy, and other harm reduction strategies.

• PrEP is more effective when used in combination with other prevention options.
Explore the Context of Client-Specific Facilitators and Barriers

• Use open-ended questions to explore factors or situations that help make pill taking a little easier—and those that make it harder or a little more difficult.

• *What seems to make PrEP easy to take or harder to take?*
Tailor the Discussion to Focus on Pill Taking

• This pause allows the provider or counselor to consider how to tailor the next question based on information gathered in earlier steps.

• *Let me think for a moment about what you have said.*
Identify Adherence-Related Needs

• Guide the conversation toward identifying the client’s perceptions of what would help to best integrate PrEP use into daily life.

• Given everything going on right now, what would need to happen for it to feel a little easier to work this regimen into your daily life?
Strategize with the Client on the Next Step

• Work with the client to identify one or more viable strategies for increasing effective PrEP use.

• How could that happen?

• What are some ideas for how you could approach that?
Agree on Which Strategy to Try Next

• Ask which strategy (or strategies) the client is willing to try or continue using. Refer to HIV Risk Reduction Strategies to Explore with the Client.

• Of the things that we have talked about, which might you be willing to try between now and the next time we meet?
Close and Document

• Summarize the discussion and thank the client.

• What I’m hearing is that ______ would really make it feel easier to work PrEP into your life and that you’ll give it a try between now and the next time we meet.

• Thank you for talking with me and I look forward to talking again.
Peer Workers for PrEP

- Outreach workers, including lay or peer workers, are uniquely able to engage people who may benefit from PrEP but do not routinely access health care.

- Lay and peer workers can provide nonjudgmental, respectful support.
  - Peers with PrEP experience can be effective role models.

- PrEP services that include lay providers from KP groups can help reduce client concerns about stigma and increase PrEP uptake.
Role of Peers in Promoting PrEP

• Peers play an important role in promoting PrEP, delivering accurate messaging, and supporting adherence.

• Peer workers are an effective “first line” in introducing PrEP to clients at community events and outreach activities and in clinic waiting rooms.

• Include peers in PrEP discussions and trainings.
Clinical Scenario for Role-Play

Anne, a sex worker, is interested in starting PrEP. She uses condoms during sex with commercial clients but not with her long-term partner, whose HIV status is unknown. She had a negative HIV test 6 months ago and wants to avoid HIV infection, because she would like to have a baby with her partner. She is using an injectable hormonal contraceptive as she used to forget to take oral contraceptives every day.

• We will now role-play this scenario. Please observe the role-play and follow along with the table of iNSC steps in your manuals.

• As you observe, think about how you might use iNSC yourself in this scenario.
Role-Play Debrief

• How well did the provider follow the iNSC steps?

• What types of prompts or strategies worked best? Why?

• What were the most challenging aspects of the counseling?

• How did the provider handle the challenges?

• What other questions or comments do you have about iNSC so far?
iNSC Role-Play 1

• Find iNSC Role-Play Scenario 1 in your manuals.
• Decide who will play the provider and who will play the client.
• Practice a brief role-play.
• The client should answer using the information in iNSC Role-Play Scenario 1 in your participant manual.
• The provider should use the iNSC steps and sample prompts as if he or she were counselling a real client.
• As you are practicing, I will observe and choose a pair to perform. I will not tell you which pair in advance, so everyone must be prepared to perform.
• You will have 15 minutes to work.
iNSC Role-Play 1 Debrief

• What did you learn by doing these role-plays?
• What types of prompts or strategies worked best? Why?
• What were the most challenging aspects of the counseling? Why?
• How could you address the challenges?
• What strategies would you use?
• How well did the provider follow the iNSC steps?

• What types of prompts or strategies worked best? Why?

• What were the most challenging aspects of the counseling?

• How did the provider handle the challenges?

• What could the provider improve the next time around?
MORNING BREAK
Find iNSC Role-Play Scenario 2 in your manuals.

Participants who played the provider for iNSC Role-Play Scenario 1 should play the client; those who previously played the client should play the provider.

Practice a brief role-play.

The client should answer using the information in iNSC Role-Play Scenario 2 in the participant manual.

The provider should use the iNSC steps and sample prompts as if he or she were counselling a real client.

As you practice, I will observe and choose a pair to perform. I will not tell you which pair I choose, so you must all be prepared to perform.

You will have 15 minutes to work.
iNSC Role-Play 2 Debrief

• What did you learn by doing these role-plays?
• What types of prompts or strategies worked best? Why?
• What were the most challenging aspects of the counseling? Why?
• How could you address the challenges?
• What strategies would you use?
PrEP Follow-Up Visits

• Clients on PrEP require regular visits with the health provider.

• Programs should decide on the optimal frequency of visits for monitoring PrEP use. The suggested follow-up visit schedule is:
  ▪ A month after initiating PrEP.
  ▪ Every 3 months thereafter.

• Outside of regular monitoring visits, clients should also consult their providers if they experience adverse events, side effects, or signs or symptoms of AHI.
Follow-Up PrEP Counseling

What to Discuss During Sessions

• Current context of sexual health (e.g., sexual health and drug use behaviors).

• Non-PrEP sexual health protection strategies (e.g., condom use).

• Assessment of continued risk of HIV and continuing need for PrEP.

• Intention to remain on PrEP.

• Facilitators and barriers to PrEP use.

• Adherence problems.

• Common adherence strategies.

• Challenges connected with disclosure.
What to Discuss During Sessions

• Reasons for ongoing monitoring while on PrEP.
• Dosing requirements for highest protection.
• What to do if a dose is missed.
• How to recognize symptoms of AHI.
• Side effects and side-effects management.
• How to safely discontinue and restart PrEP (if appropriate).
## Follow-Up PrEP Visit Procedures

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Schedule Following PrEP Initiation</th>
</tr>
</thead>
</table>
| Confirmation of HIV-negative status               | • At one month follow-up  
• Every 3 months.                                           |
| Review the client’s HIV risk                      | • Every visit                                                                                   |
| Address side effects                              | • Every visit                                                                                   |
| Brief adherence counseling                        | • Every visit                                                                                   |
| Estimated creatinine clearance                    | • At least every 6 months, or more frequently if there is a history of conditions affecting the kidney, such as diabetes or hypertension |

• Provide STI screening, condoms, contraception as needed.

• Counsel clients on AHI symptoms and advise them to come back as soon as possible for evaluation if these symptoms occur.
Provider Checklist for Follow-Up PrEP Visits

- **Brief PrEP Counseling**
  - Ask about signs and symptoms of acute HIV infection.
  - Assess for substantial ongoing risk for HIV.
  - Confirm the client wishes to remain on PrEP.
  - Review facilitators and barriers to PrEP use.

- **Adherence Counseling**
  - Assess adherence and adherence challenges.
  - Provide adherence counseling.
  - Discuss the importance of effective use of PrEP.

- **Assessment and Management of Side Effects**
  - Ask about and manage side effects.

- **Confirmation of HIV-Negative Status**
  - Repeat HIV test 1 month after starting PrEP, then every 3 months thereafter.

- **Calculation of Estimated Creatinine Clearance (eGFR): Recommended Frequencies**
  - At least every 6 months—more frequently if there is a history of conditions affecting the kidney (e.g., diabetes, hypertension, any chronic nephropathy).
  - Check creatinine test results, calculate creatinine clearance, and add the results to the appropriate forms.

- **Screening for Sexually Transmitted Infections (STIs)**

- **Risk Reduction Counseling**
  - Refer clients based on their specific needs (i.e., for social support, harm reduction, gender-based violence programs, etc.).
Repeat HIV Testing

• Repeat HIV testing is needed to inform decisions on whether to continue or discontinue PrEP.

• Repeat HIV testing using national guidelines
  ▪ 1 month after starting PrEP.
  ▪ Every 3 months thereafter.

• Remember the limitation of serological tests during AHI in the “window” period from HIV infection to detection of antibodies.

• Don’t forget that exposure to ARVs can decrease sensitivity of serological tests.

• Stop PrEP if you suspect AHI.
Providers should assess for a client’s substantial risk at each PrEP follow-up visit by asking the questions below. *If at least one item is ticked, the client is at substantial risk.*

Have you...

- Had vaginal sexual intercourse with more than one partner of unknown HIV status in the past 6 months?
  
  Y □ N □ *(If yes, tick substantial risk.)*

- Had vaginal sex without a condom in the past 6 months?
  
  Y □ N □ *(If yes, tick substantial risk.)*

- Had anal sexual intercourse in the past 6 months?
  
  Y □ N □ *(If yes, tick substantial risk.)*

- Had sex in exchange for money, goods or a service in the last 6 months?
  
  Y □ N □ *(If yes, tick substantial risk.)*

- Injected drugs in the past 6 months?
  
  Y □ N □ *(If yes, tick substantial risk.)*

- Been diagnosed with a sexual transmitted infection (STI) more than once in the past 12 months?
  
  Y □ N □ *(If yes, tick substantial risk.)*

You will use this checklist during every follow-up visit to assess for substantial risk of HIV infection.
Assessing PrEP Adherence

• Monitoring PrEP use and adherence is important.

• It is essential that the monitoring be done in an open-ended and nonjudgmental manner.

• A neutral assessment of adherence allows for a constructive discussion that can support the client in finding solutions to adherence challenges.
Assessing PrEP Adherence

(continued)

• Take a neutral approach to adherence behavior to support the client in finding solutions to adherence challenges

• Normalize adherence challenges:

  “Many people have trouble remembering to take a daily pill, especially when starting a new medication. Has this happened to you?”

• Ask about difficulties adhering, not nonadherence

  “Tell me about any difficulties you have had in taking your daily pill.”

Instead of:

  “Have you missed doses of your medication?”
Sample Open-Ended Questions about Adherence

• How has it been for you to take PrEP?
• What side effects have you had, if any?
• What helps you remember to take your pill?
• What challenges do you experience in taking the pills? When are you more likely to forget?
• What are your concerns about missing PrEP pills?
• What have been your experiences with missing PrEP doses?
• What helps or might help you to take your pills regularly? Helpful strategies may include the following (next slide).
“Here are some strategies you could try to help with PrEP adherence.”

- Use a pill box.
- Take PrEP pills with other daily medicines.
- Use a phone alarm.
- Mark doses taken on a calendar.
- Have more support from your partner, a family member, or a friend.
- What keeps you motivated to take the PrEP pills?
- What might help make taking PrEP even easier?
Behavior and Activity

• Has taking PrEP changed what else you do to protect yourself from getting HIV and STIs (for example, topping versus bottoming, using condoms, discussing HIV and STI status and/or testing with partners)?

• Has PrEP made you feel safer about sex?

• Has PrEP made it easier for you to take charge of your health?

• In addition to taking PrEP, what are your plans to stay HIV negative?

Plan for Staying HIV and STI Negative

• What I hear you saying is that you currently reduce your risk for HIV by [fill in protective behaviors] and also you talked about your desire or plan with [fill in name of person(s)]. Have I understood you correctly?

• What other ideas or plans, if any, do you have for staying HIV and STI negative?
PrEP Discontinuation

Starting PrEP Does Not Mean Staying on PrEP for Life

- People often move in and out of substantial risk for HIV.
- Education and support for safe stops and restarts of PrEP use are essential.
- A variety of life changes may prompt a person to stop PrEP, including:
  - A partner with HIV achieves viral suppression on ART.
  - A relationship becomes mutually monogamous.
  - Sex work or injection drug use stops.
  - Other risks change.
PrEP Discontinuation

(continued)

• Clients who decide to stop PrEP should:
  ▪ Contact their health care providers.
  ▪ Continue to take PrEP for 28 days after their last potential exposure to HIV.
PrEP Clinical Pathway

Confirm HIV Negative Status

- Perform rapid HIV test according to national guidelines/algorithms.
- Link HIV-positive persons promptly to care and treatment services.

Screen for Substantial Risk for HIV

- Client who is sexually active in a high-HIV-prevalence population (either in the general population or key population group) plus reports any of the following in the past 6 months:
  - Vaginal or anal intercourse without condoms with more than one partner, OR
  - Sex partner with one or more HIV risk, OR
  - History of a sexually transmitted infection (STI), based on lab test, syndromic STI treatment, or self-report, OR
  - History of use of post-exposure prophylaxis (PEP)
- OR
- Client who reports history of sharing of injection material/equipment with another person in the past 6 months
- OR
- Client who reports having a sexual partner in the past 6 months* who is HIV positive AND who has not been on effective HIV treatment
  - *On ART for less than 6 months, or has inconsistent or unknown adherence

Establish Eligibility

Clients are eligible if they fulfill ALL the criteria below:

- HIV negative.
- Are at substantial risk for HIV.
- Have no signs or symptoms of acute HIV infection.
- Have creatinine clearance (eGFR) >60 ml/min.*

*Awaiting treatment results should not delay PrEP initiation. Providers should do same-day initiation of PrEP, then discontinue PrEP later if the patient’s eGFR is not within the appropriate range.

PrEP Initiation

- Provide information on PrEP, the importance of adherence, the potential side effects, and a follow-up schedule.
- Screen and manage for STIs.
- Do risk-reduction counseling and provide condoms and lubricants.
- Do PrEP adherence counseling.
- Provide PrEP.
Facilities may use information, education, and communication (IEC) materials and activities to address challenges around PrEP acceptance and adherence.

- What questions or concerns might clients have about PrEP that IEC materials could help to answer?
Frequently Asked Questions about PrEP

What is PrEP?
PrEP stands for pre-exposure prophylaxis. It is a single daily pill that protects you from getting infected with HIV. It works when you take it before you are exposed to HIV.

Who should use PrEP?
PrEP is for anyone (both men and women) who is at substantial risk of becoming infected with HIV. It is for situations and times in your life when you may have a high risk of HIV infection.

Is PrEP a new drug?
No. PrEP is not a new drug. PrEP is made of antiretroviral drugs (HIV medication) that are used to help treat people who are HIV positive, as well as to prevent mother-to-child transmission of HIV.

When and how do I use PrEP?
- See a health care provider to find out if you are eligible for PrEP.
- If you are prescribed PrEP, you must take 1 pill every day.
- You can take PrEP at any time during the day and at different times on different days, as long as you take 1 pill every day.
- You can take PrEP with or without food.
- When starting or re-starting PrEP, you must take it every day for at least 7 days before you are protected.
- You must go back to your health care provider for regular follow-up visits while you are taking PrEP.
- While you are taking PrEP, you will need to be tested for HIV every 3 months to be sure that you are not infected.
• You may use this job aid during PrEP visits to ensure that all appropriate PrEP information has been given to a client.

• Clinics should add any questions and adapt this job aid to local contexts.
  ▪ You may want to add to this job aid any frequently asked questions and answers that surfaced during our discussion, and that you think would be helpful for clients to know.
Examples of IEC Materials

IEC Materials from CDC

• “PrEP.” https://www.cdc.gov/hiv/basics/prep.html
• “PrEP 101” [fact sheet].
• “Are You Ready for PrEP?” [poster].
  https://www.cdc.gov/actagainstaids/pdf/campaigns/starttalking/sts
  h-prep-infographic-basics.pdf
  https://www.cdc.gov/actagainstaids/pdf/campaigns/starttalking/sts
  h-prep-infographic-access.pdf
  https://www.cdc.gov/actagainstaids/pdf/campaigns/starttalking/sts
  h-prep-infographic-right2.pdf
Examples of IEC Materials

(continued)

IEC Materials from the New York City Government

• http://www1.nyc.gov/site/doh/health/health-topics/prep-pep.page

IEC Materials from South Africa


Demand Generation Resources

from the OPTIONS Consortium’s PrEP Communications Accelerator

• http://accelerator.prepwatch.org/about/

These are a few examples. There are many others online that may better fit your local context.
PrEP Fact Sheet

PrEP - before exposure to coming into contact with HIV
Pre prophylaxis: a medicine to prevent infection

• ART for partners living with HIV
1. PrEP is a new pill you take once a day to prevent HIV

2. If you have sex with someone with HIV and there is enough PrEP in your blood, it will stop HIV from spreading

3. PrEP works best if you take it every day

4. PrEP doesn’t protect against other STIs or pregnancy

5. PrEP is private - you don’t need to tell anyone you’re using it, if you don’t want to…

6. PrEP is safe - a few people may experience mild side effects, which go away after a couple weeks
GET TESTED FOR OTHER STIs

- STIs (sexually transmitted infections) can make it easier to get HIV or to pass it to others.
- You may not know if you have an STI. Most infections do not cause symptoms.
- If you are a man or transgender person who has sex with men, your medical provider should test your blood and any parts of your body that you use during sex. If you use it, check it!
- Get tested at least annually; some people may need to get tested every three to six months. Talk to your provider to see what’s best for you.

THE ONLY WAY TO BE HIV AND STI SURE IS TO GET TESTED
Jonathan has been on PrEP (TDF/FTC) for the last 9 months. At the follow-up visit, he is in good health, and his repeat HIV test is negative. Jonathan reports recently starting a monogamous relationship with a man who tested HIV negative last year and feels he might no longer need PrEP.

*How would you manage this case?*
Peer Outreach for Follow-Up

• Trained peer supporters can play an important role in outreach to PrEP clients.

• Peer outreach workers may be better able than other clinic staff to reach clients in community settings.

• Clients may feel more able to discuss adherence and retention challenges with peer supporters than with health professionals.
Small Group Brainstorm

• With your small group, brainstorm responses to these questions:
  ▪ 1) What challenges you will face when implementing PrEP?
  ▪ 2) What strategies might you use to address these challenges?

• Choose one group member to record your responses on a sheet of notebook paper.

• You will have 15 minutes to work.
Module 3 Summary

• Prescribe PrEP as part of a comprehensive HIV prevention strategy.
• Confirm a negative HIV test immediately prior to initiating PrEP.
• Ensure there are no contraindications to PrEP.
• Ensure that clients have correct information about PrEP.
• Develop an adherence support plan with the client and monitor adherence at each visit.
• Conduct risk reduction counseling at each visit.
AFTERNOON BREAK
Training Overview

Monitoring and Managing PrEP Side Effects, Seroconversion, and Stigma
After completing Module 4, participants will be able to:

• Explain how to manage creatinine elevation.
• List additional causes of creatinine elevation.
• Explain how to manage seroconversion.
• Develop strategies to minimize PrEP stigma.
• Give examples of gaps in knowledge about PrEP.
• Describe how M&E tools might be adapted for local use.
Monitoring Creatinine Elevation

• Approximately 1 in every 200 PrEP users may develop an elevation of serum creatinine.
  
  ▪ Defined as a 50% increase above baseline or an elevation above the normal range.
  
  ▪ Reminder: Renal impairment is defined as having an estimated creatinine clearance of <60 ml/min.

• Creatinine elevations have usually reversed after stopping PrEP.

• It is important to monitor transient creatinine elevation and be alert for signs of chronic or severe renal insufficiency.
Question

• How would you manage an increase in creatinine clearance?
Managing Creatinine Elevation

- Stop PrEP if creatinine elevation is confirmed on a separate specimen and if estimated creatinine clearance decreases to <60 ml/min.

- After PrEP is stopped, creatinine should be checked for another 1 to 3 months and PrEP restarted if eGFR returns to > 60 ml/min.

- Consider additional causes and management of creatinine elevations if:
  - Creatinine elevation reaches more than 3 times the baseline.
  - Renal function or creatinine elevations do not return to normal levels within 3 months after stopping PrEP.

- Common causes of chronic or severe renal insufficiency include: diabetes mellitus, uncontrolled systemic hypertension, hepatitis C infection, liver failure, and pre-eclampsia during pregnancy.
Seroconversion on PrEP

• In clinical trials, the level of protection was strongly correlated with adherence.

• HIV infection can be prevented with consistent use of PrEP.

• HIV seroconversion after prescribing PrEP can occur if PrEP is not used correctly or consistently, or if HIV infection was undiagnosed at the time of PrEP initiation.

• Counseling should include information to help PrEP users recognize AHI signs and symptoms, which should prompt a clinic visit without delay.
How would you manage seroconversion on PrEP?
Managing Seroconversion

- If a person using PrEP tests positive for HIV, PrEP should be stopped immediately and the person referred for prompt initiation of HIV treatment.

- Transition from PrEP to HIV treatment without a gap avoid the risk of resurgence in viral load, immunological injury, and secondary transmissions.

- The PrEP M&E Tools package includes a Seroconversion Tracker. Tracking seroconversion is important in informing gaps in care and in identifying needs for increased outreach to PrEP clients if adherence is an issue.
# PrEP “Special Situations”

<table>
<thead>
<tr>
<th>Situation</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormonal contraception</td>
<td>• PrEP does not affect the efficacy of hormonal contraceptives and hormonal contraceptives do not affect PrEP efficacy.</td>
</tr>
<tr>
<td>Pregnancy and breastfeeding</td>
<td>• Safety data support the use of PrEP in pregnant and breastfeeding women who are at continued substantial risk for HIV infection.</td>
</tr>
<tr>
<td>Hepatitis B infection</td>
<td>• HBV vaccination is appropriate for people at substantial risk for HBV or HIV infection.</td>
</tr>
</tbody>
</table>
| Management of recent HIV exposure with PEP | • People who have been exposed to HIV in the past 72 hours should be offered PEP.  
  • WHO recommends PEP consisting of TDF/3TC (or FTC), preferably combined with a boosted protease inhibitor, for 28 days (per national guidelines).  
  • PEP may be transitioned to PrEP after 28 days if the HIV test remains negative and there is substantial ongoing risk of HIV acquisition. |
Minimizing PrEP Stigma

• Confidentiality is essential in PrEP services.

• People may face stigma if their PrEP use becomes known.

• PrEP use can exacerbate stigma if others mistakenly consider PrEP use to be evidence of irresponsible behavior or if they mistakenly think that PrEP is HIV treatment.
  ▪ Such stigma will decrease PrEP uptake and adherence among people who would otherwise benefit from it.

Presenting PrEP to your communities as a responsible choice that protects both partners will increase the impact of PrEP, will prevent more HIV infections, and can help reduce stigma.
Small Group Brainstorm

• With your small group, brainstorm a list of possible strategies to minimize the stigma that your PrEP clients may face.

• Choose one group member to record your ideas on the sheet of flip chart paper.

• You will have 20 minutes to work.
Current Gaps in Knowledge and Need for Continued Surveillance

Not Studied

• Renal safety of FTC/TDF PrEP in people with diabetes mellitus and uncontrolled systemic hypertension.
• 3TC use in combination with TDF for PrEP (although for HIV treatment 3TC is equivalent to FTC).
• Comparison of daily vs. on-demand PrEP regimens.
• Effectiveness of on-demand oral PrEP regimens for women.
• Clinical HBV rebound when stopping FTC/TDF PrEP: Not identified in clinical trials, though most excluded people with HBV infection.

Need for Continued Surveillance

• Maternal, pregnancy, and infant outcomes in women of reproductive age.
• WHO recommends offering PrEP as part of a comprehensive HIV prevention package integrated with PMTCT, antenatal, and postnatal care settings with high HIV incidence.

Module 4 Summary

• PrEP users should be informed about how to recognize signs and symptoms of AHI.

• If someone using PrEP tests positive for HIV, stop PrEP immediately and start ART as soon as possible, without a gap after PrEP is discontinued.

• If confirmation of a positive HIV test result is delayed for more than a few hours, transition to fully suppressive ART (3 ARVs, per national treatment guidelines).

• Ideally, blood creatinine (eGFR) should be measured before starting PrEP and at least every 6 months after PrEP is started.
  ▪ Initiation of PrEP should not be delayed while waiting for creatinine results.
Module 5

PrEP Monitoring and Evaluation Tools
Module 5 Learning Objectives

After completing this session, participants will be able to:

• Correctly complete the PrEP Screening Log, PrEP Facility Record, Seroconversion Tracker, and PrEP Client Register.

• Use the Provider Checklist for Substantial Risk during PrEP follow-up visits.

• Correctly complete the PrEP Monthly Summary Form and PrEP Quarterly Cohort Report.

• Describe how PrEP M&E tools might be adapted for local use.

• Identify the correct order of the steps that health care workers should take during an initial PrEP visit.
Module 5 Learning Objectives (continued)

• Identify at which steps of the initial PrEP visit the health care worker should complete or refer to the PrEP Screening Log, PrEP Screening for Substantial Risk and Eligibility Form, Integrated Next Step Counseling Flow, PrEP Client Register, and PrEP Facility Record.

• Identify the correct order of the steps that health care workers should take during a follow-up PrEP visit.

• Identify at which steps of the follow-up PrEP visit the health care worker should complete or refer to the Provider Checklist for Substantial Risk, Integrated Next Step Counseling Flow, PrEP Client Register, and PrEP Facility Record.

You will find these PrEP M&E tools in your participant folders. We will review and practice using these in Module 5.

- PrEP Screening for Substantial Risk and Eligibility
- PrEP Screening Log
- PrEP Facility Record
- PrEP Client Register
- Seroconversion Tracker
- PrEP Monthly Summary Form
- PrEP Quarterly Cohort Report
PrEP Screening for Substantial Risk and Eligibility

<table>
<thead>
<tr>
<th>Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility</th>
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</table>

**1. Facility Information**

<table>
<thead>
<tr>
<th>Facility Name</th>
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<table>
<thead>
<tr>
<th>Date of Initial Client Visit (dd/mm/yyyy)</th>
<th>Person Completing Form</th>
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<table>
<thead>
<tr>
<th>First Name</th>
<th>Middle Name</th>
<th>Surname</th>
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<table>
<thead>
<tr>
<th>Address</th>
<th>Telephone #</th>
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<table>
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<tr>
<th>Client ID Number</th>
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</table>

**2. Client Information**

**3. Client Demographics**

What was your sex at birth?

- [ ] Male
- [ ] Female
- [ ] Other (specify): ___________
- [ ] No response

What is your current gender?

- [ ] Male
- [ ] Female
- [ ] Transgender (male to female)
- [ ] Transgender (female to male)
- [ ] Other (specify): ___________
- [ ] No response

What is your age? (Specify number of years.)

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<th>_______</th>
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**4. Screening for Substantial Risk for HIV Infection**

Client is at substantial risk if he/she belongs to categories 1, 2, or 3 below

<table>
<thead>
<tr>
<th>Question Prompts for Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>If client is sexually active in a high HIV prevalence population PLUS reports ANY one of the below in the last 6 months</td>
</tr>
</tbody>
</table>

1. Have you been sexually active in the last 6 months?

2. Are you using a condom consistently?
PrEP Screening for Substantial Risk and Eligibility (continued)

• We practiced using this form in Module 3.

• Source to complete this form: This screening form is completed with the client.
# Pre-Exposure Prophylaxis (PrEP) Screening Log

<table>
<thead>
<tr>
<th>DATE</th>
<th>CLIENT NUMBER</th>
<th>GIVEN NAME</th>
<th>SURNAME</th>
<th>GENDER</th>
<th>AGE (years)</th>
<th>DATE TESTED</th>
<th>RESULT</th>
<th>COMPLETED THE PrEP SCREENING FOR SUBSTANTIAL RISK AND ELIGIBILITY FORM</th>
<th>TEENAGE FOR PR EP</th>
<th>SERVICES (Risk Log)</th>
<th>PEP ACCEPTED OR DECLINED (why PEP was offered)</th>
<th>REASON FOR DECLINING PR EP</th>
<th>PEP CLIENT NUMBER (if accepted)</th>
</tr>
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<tr>
<td></td>
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<td></td>
<td>Yes</td>
<td>Yes</td>
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<td>PEP Accepted</td>
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<td>Yes</td>
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<td>Yes</td>
<td></td>
<td>PEP Accepted</td>
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</tbody>
</table>

* REASONS FOR DECLINING PR EP:  
  1. No need for PR EP  
  2. Missed several clinic visits  
  3. Missed recent clinic visits  
  4. Missed recent clinic visits  
  5. Missed recent clinic visits  
  6. Missed recent clinic visits  
  7. Missed recent clinic visits  
  8. Missed recent clinic visits  
  9. Missed recent clinic visits  
  10. Other (please specify)
• The PrEP Screening Log is completed after the initial PrEP Screening.

• It should include *everyone* screened for PrEP, regardless of whether they are eligible for PrEP or decline it.

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

• Source document to complete this form: Consult the PrEP Screening for Substantial Risk and Eligibility form.

• Let us review the form section by section.
• Why is it important to collect the data in the PrEP Screening Log?
Importance of the PrEP Screening Log

• The data help to inform clinics and ministries of health of the PrEP eligibility and acceptability rate and the main reasons that individuals are ineligible for or decline PrEP.

• The data can inform increased outreach and education efforts and IEC materials.

• The fact that a large number of people screened are ineligible can inform how the screening form might be revised—for example, by adding additional KP or vulnerable groups.
# PrEP Facility Record

## Pre-Exposure Prophylaxis (PrEP) Facility Record

<table>
<thead>
<tr>
<th>Date (dd/mm/yyyy)</th>
<th>Person Completing Form</th>
</tr>
</thead>
</table>

### A. Facility Information

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>District</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Date of Initial PrEP Client Screening Visit</th>
<th>PrEP Client Number (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(dd/mm/yyyy): / /</td>
<td>/ /</td>
</tr>
</tbody>
</table>

### B. Client Demographics

<table>
<thead>
<tr>
<th>First/Given Name:</th>
<th>Middle Name:</th>
<th>Surname:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>Telephone:</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Telephone (alternative):</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Date of Birth (dd/mm/yyyy)</th>
<th>Age (years):</th>
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</table>

<table>
<thead>
<tr>
<th>Client ID Number:</th>
<th>Marital Status:</th>
<th>Single</th>
<th>Married</th>
<th>Divorced</th>
<th>Widowed</th>
<th>Separated</th>
<th>Refused</th>
</tr>
</thead>
</table>

### C. Sexual and Drug Injection Core Risk Classification

1. Do you consider yourself: male, female, transgender, or other? | 2. What was your sex at birth? |
<table>
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</thead>
<tbody>
<tr>
<td>Yes</td>
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</tbody>
</table>

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*Note: Fill in the blanks with appropriate information.*
• This form is completed after the initial PrEP screening, for clients who agree to start PrEP.

• The provider must ask questions of the client in order to complete some sections of the form.

• Other sections are completed using test results and information obtained during PrEP screening.

• Source to complete this form: Complete this form with the client and consult the PrEP Screening for Substantial Risk and Eligibility form.

• PrEP Follow-Up Visits section of this form will be completed at each follow-up visit.

• Let us review the form section by section.
Practice:
PrEP Facility Record

• Find the M&E Practice Scenarios in your manuals.

• Choose one scenario. Decide who will play the provider and who will play the client.

• Participants playing a client should review the synopsis of their characters in order to respond appropriately.

• Conduct a brief role-play in which the provider completes the PrEP Facility Form with the client (as if with a real client).

• Use today’s date or other appropriate dates for test dates on the form.

• Repeat this process for another scenario, with roles reversed.

• You will have approximately 15 minutes to work.
# Pre-Exposure Prophylaxis (PrEP) Client Register

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
<th>M</th>
<th>N</th>
<th>O</th>
<th>P</th>
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</table>

**Legend:**
- TDF/FTC: Tenofovir DF and Emtricitabine
- NVP: Nevirapine
- DRV/r: Darunavir with cobicistat
- E: Efavirenz
- Other: Other antiretroviral

**Notes:**
- Follow-up on 1 month or 1 month after the last dose of PrEP.
- PrEP adherence: 100% adherence is recommended.
- PrEP effectiveness: 90% effectiveness within 1 month of PrEP.

**Key:**
- PrEP adherence: 100% adherence is recommended.
- PrEP effectiveness: 90% effectiveness within 1 month of PrEP.
• As each new client starts PrEP, the relevant information is added to this register, and the client’s follow-up visits are recorded.

• Source document to complete this form: Use the PrEP Facility Record.

• Let us review the form section by section.
Practice: PrEP Follow-Up Visits and Client Register

- Choose one of the same scenarios from your previous role-play (PrEP Facility Record).

- Decide who will play the provider and who will play the client.

- Role-play a brief initial PrEP follow-up visit.

- Providers should use the Provider Checklist for Follow-Up PrEP Visits as a guide as well as the Provider Checklist for Substantial Risk.

- Clients should invent appropriate answers for questions about adherence—for example, about side effects and signs and symptoms of AHI.
• Use a date 1 month from today for the visit date, plus other appropriate dates as needed.

• Repeat this process for another scenario, with roles reversed.

• Then complete the PrEP Visits section of the Facility Record and the PrEP Client Register for the “client” that you interviewed.

• You will each complete your own form.

• You will have approximately 20 minutes to work.
• If a client is overdue for a return visit and the outcome is not recorded (e.g., died, lost to follow-up, or transferred out), what should you do?
When Seroconversion Occurs

Seroconversion can occur when:

• The client had AHI before starting PrEP.
• The client has had poor adherence and has been exposed to HIV.
# Seroconversion Tracker

<table>
<thead>
<tr>
<th>PrEP SEROCONVERSION TRACKER</th>
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<tbody>
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<td><strong>Sex at Birth (see codes)</strong></td>
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</table>
Importance of the Seroconversion Tracker

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

• Source documents to complete this form: PrEP Client Register and ART records.

• Refer to the variable and code definitions as needed when completing the tracker.

• The tracker will help ensure appropriate linking and follow-up of clients diagnosed with HIV and can facilitate reporting of seroconversions for surveillance.
• How might you adapt and use these forms at your facilities?
MORNING BREAK
### PrEP Monthly Summary Form

### Pre-Exposure Prophylaxis (PrEP) Monthly Summary Form

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>Level of Facility</th>
<th>Facility Code</th>
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<tbody>
<tr>
<td>District</td>
<td>Province/Region</td>
<td></td>
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<tr>
<td>Month of Report</td>
<td>Year of Report</td>
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</table>

#### SECTION 1: ALL New PrEP Candidates

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

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age Group (years)</th>
<th>15-19</th>
<th>20-24</th>
<th>25-29</th>
<th>30-34</th>
<th>35-39</th>
<th>40-44</th>
<th>45-49</th>
<th>50+</th>
<th>Total</th>
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<td>Female</td>
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Optimally, all data from all HIV testing points referring for PrEP within a facility should be combined and reported here.

The number of clients testing HIV negative is the “denominator” for assessing coverage of who is eligible for PrEP screening. Data for the HIV testing and results table should be taken from clinic HIV testing services registers.

Source documents to complete this form: Use the PrEP Screening Log and PrEP Client Register.

Let us review the form section by section.
Practice: PrEP Monthly Summary Form

• Find the Sample Data for PrEP Monthly Summary Form in your manuals.

• With your small group, complete the PrEP Monthly Summary Form using this data.

• Discuss as a group how to complete each section.

• Then each participant should complete her or his own form.

• *You will have 15 minutes to work.*
Pre-Exposure Prophylaxis (PrEP) Quarterly Cohort Report

Instructions: Complete each of the tables below for the full PrEP client population and each subpopulation as specified. Client cohorts should be defined based on the month clients first started PrEP (for example, clients starting PrEP between June 1–June 30, 2019 should be assigned to the June 2019 cohort). The client cohorts to include can be identified via the “Months ago started on PrEP” column, as well as the specific year and month of PrEP initiation to be documented in the subsequent column. For example, if the current month is June 2019, cohorts 1–5 would be defined and recorded as shown below. Note: 1) Individuals newly testing HIV+ (Column 7) will not receive PrEP at the current visit, so the # tested for HIV (Column 6) may exceed the # newly tested HIV+ (Column 5); and 2) Results in the # stopped, lost to follow-up, and died columns (Columns 8–12) after the Cohort 1 time point are cumulative and must incorporate any results from previous time points for the cohort. Illustrative data are shown in the tables below to demonstrate how data are to be recorded and indicators calculated.

**EXAMPLE: ALL PrEP CLIENTS**

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Baseline</th>
<th>Follow-Up</th>
<th>Cumulative for Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Months ago started on PrEP</td>
<td>Calendar year/month started PrEP (yyy/mm)</td>
<td># started PrEP at this clinic</td>
</tr>
<tr>
<td>1</td>
<td>1 mos.</td>
<td>2019/05</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>3 mos.</td>
<td>2019/03</td>
<td>25</td>
</tr>
<tr>
<td>3</td>
<td>6 mos.</td>
<td>2018/12</td>
<td>21</td>
</tr>
<tr>
<td>4</td>
<td>9 mos.</td>
<td>2018/09</td>
<td>8</td>
</tr>
<tr>
<td>5</td>
<td>12 mos.</td>
<td>2018/06</td>
<td>10</td>
</tr>
</tbody>
</table>

**EXAMPLE: Summary of ALL Cohort Outcomes**

| Cohort | Percent receiving HIV+ test Percent testing HIV+ this visit Percent stopped: HIV+ test Percent no longer at substantial risk Percent lost to follow-up |
|--------|-----------------------------------------------|-------------------------------------------------|-----------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| 1      | 96% | 0 | 0 | 0 | 0 | 4% |
| 2      | 3% | 0 | 0 | 0 | 0 | 4% |
| 3      | 3% | 0 | 0 | 0 | 0 | 4% |
| 4      | 3% | 0 | 0 | 0 | 0 | 4% |
| 5      | 3% | 0 | 0 | 0 | 0 | 4% |
• This form is used to collect and track data per quarter and PrEP cohort.

• Source to complete this document: Use the PrEP Client Register.

• Let us review the form section by section.
Practice:
PrEP Quarterly Cohort Report

• Find the instructions for PrEP Quarterly Cohort Report in your manuals.

• With your small group, complete the PrEP Quarterly Cohort Report using this information.

• Discuss as a group how to complete each section.

• Then each participant should complete his or her own form.

• You will have 15 minutes to work.
Question

- How might you adapt and use these M&E forms for your facilities?
Question

• What are the possible entry points or ways a client could be referred to or introduced to PrEP?
Entry Points for PrEP

• Outpatient clinic or facility
  ▪ HIV testing (the most common)
  ▪ Testing for STIs
  ▪ Sexual and gender-based violence services
  ▪ Harm reduction and other drug treatment services
  ▪ Antenatal services

• Gynecology and reproductive services

• Inpatient
  ▪ Referred from emergency room or hospital staff
• Community-based and outreach HIV testing—Clients tested in community outreach settings may be referred for PrEP.

• PMTCT—HIV-negative partners of HIV-positive pregnant women may be referred for PrEP.

• PEP services—Clients completing PEP services may be referred for PrEP.
PEP to PrEP Transition

- Clients who present more than once for PEP may be candidates for PrEP.

- PEP encounters should be viewed as a prevention opportunity to help at-risk persons engage in sustained risk reduction and HIV prevention services, including PrEP.

- PrEP offers more consistent protection against HIV than repeated courses of PEP.
Entry Points for PrEP for M&E Use

• If your facility has multiple points of entry, consider adapting the PrEP M&E tools to capture these points.

• This will provide very useful information about where PrEP clients come from, which will help to inform national prevention and demand creation strategies.
The PrEP Client Flow describes the sequence of PrEP services that new and returning clients receive.

The client flow should be adapted to fit clinic structure and existing procedures.
Small Group Activity

• Each step of the PrEP Client and Clinic Flow for the initial visit is written on a sheet of paper.

• Each group will receive a set of the steps.

• With your group, tape the steps onto the wall in the correct order, horizontally.

• Everyone should discuss and, working together, put them in order, revising along the way as needed.

• Do not number the steps, just tape them to the wall in the correct order.

• You will have 15 minutes to work.
PrEP Client and Clinic Flow Follow-Up Visit

- Please find the PrEP Client and Clinic Flow Follow-Up Steps in your manuals.
- Let us review the steps one by one.
PrEP Outreach for Follow-Up

• Please find the PrEP Outreach for Follow-Up in your manuals.
• Let us review the information step by step.
PrEP Client Definitions

- **PrEP-Initiated Client:** Has completed the PrEP eligibility screening form and initiated PrEP.

- **PrEP-Declined Client:** Has completed the PrEP eligibility screening form and was determined to be eligible, but declined the offer of PrEP.

- **PrEP-Discontinued Client:** Has initiated PrEP but has been documented as declining to continue taking PrEP for any reason.

- **Missed PrEP Appointment:** Has initiated PrEP and missed a PrEP follow-up appointment *within the last 90 days*.

- **Lost to Follow-Up:** Has initiated PrEP and missed a PrEP follow-up appointment *by more than 90 days*. 
Questions

• When a client misses a PrEP follow-up appointment, what procedures are followed at your facilities? How are they similar to or different from this information?

• Now that you have reviewed client flow and the M&E tools, what challenges can you see for PrEP follow-up at your facilities?

• What strategies might be used to address the challenges?
Question

• What final questions or concerns do you have about implementing PrEP?
Module 5 Summary

• Tracking PrEP screening data can inform increased outreach and education efforts and IEC materials.

• Tracking PrEP seroconversion data will help ensure appropriate linking and follow-up on clients diagnosed with HIV and can facilitate reporting of seroconversions for surveillance.

• Clients who present more than once for PEP may be candidates for PrEP. Engage these clients in sustained risk reduction and HIV prevention services, including PrEP.

• If your facility has multiple points of entry, consider adapting the PrEP M&E tools to capture these points.
Module 6

Post-Training Assessment, Evaluation, and Closing
Post-Training Assessment

• The objective of this post-training assessment is to find out what you know about implementing PrEP and how much your knowledge and skills have improved since the pre-training assessment.

• Results of the pre-training and post-training assessments will help improve future trainings.

• Remember to write your name on your assessment.

• You will receive a copy of the correct answers as you leave the training.

• You have 15 minutes to complete the assessment.
PrEP Specific Competencies

After completing this training program, participants will be able to:

• Identify eligible candidates for PrEP.
• Assess individual risk for HIV.
• Educate and counsel PrEP candidates and users.
• Assess medical eligibility for PrEP.
• Prescribe PrEP.
• Conduct clinical and lab assessments during follow-up PrEP visits.
• Determine how PrEP M&E tools may be used locally.
• Provide adherence education, counseling, and support to PrEP candidates and users.
Training Evaluation

• Please take a few minutes to complete this Training Evaluation Form.

• We welcome your honest feedback to help us improve future trainings.

• Your evaluation will be confidential. You do not need to include your name.
Other PrEP Resources for Providers


PrEP Resources for PrEP Users


Local PrEP Resources

[Insert local PrEP resources, organizations, clinics, studies, etc.]
Thank You for Your Participation!