

Pre-Exposure Prophylaxis (PrEP) Training of Trainers



Welcome!

Welcome!

- Please sign the registration sheet.
- Please make a name tag for yourself.
- Please take a participant manual, a notebook, and a pen.
- You will use your manuals during Day 1 and Day 2 of this training and will take them home at the end of Day 2.

Introductions

Take 1 minute (and only 1 minute, please!) to state:

- Your name.
- The name of your organization.
- Your position there.

Training of Trainers Goals

During this training, you will:

- Review key PrEP information and skills.
- Learn the concepts and principles behind effective training for adults and how you can implement them.
- Practice delivering various types of participatory training sessions and receive feedback on your delivery.

Training of Trainers Overview

- 1 Review of Key PrEP Training Content
- 2 Participatory Training Principles and Techniques
- 3 Practice Delivering Participatory Training

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.

Module 1

1

Review of Key PrEP Training Content

Module 1 Learning Objectives

After completing this module, you will be able to:

- Identify key content from the *Pre-Exposure Prophylaxis (PrEP) Training for Providers in Clinical Settings*.
- Experience sample PrEP training sessions that you will deliver as trainers.



Pre-Exposure Prophylaxis (PrEP)

Training for Providers

in Clinical Settings

For Training of Trainers Day 1

(Version 3.0)



Module 1

1

PrEP Basics

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

Structural

- Policies
- Laws
- Regulatory environment
- Culture
- Cash transfers

Behavioral

- Education
- Counseling
- Stigma reduction
- Harm reduction
- Adherence interventions

Biomedical

- HIV testing
- Condoms
- VMMC
- PMTCT
- STI treatment
- Antiretroviral therapy for prevention (ART)
- PEP
- PrEP

Question

- What is pre-exposure prophylaxis (PrEP)?



Pre-Exposure Prophylaxis

PrEP is the use of ARVs by people who are HIV negative to prevent the acquisition of HIV *before* exposure to the virus.



Pre

Before

Exposure

Activity that can lead to HIV infection

Prophylaxis

Prevention

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

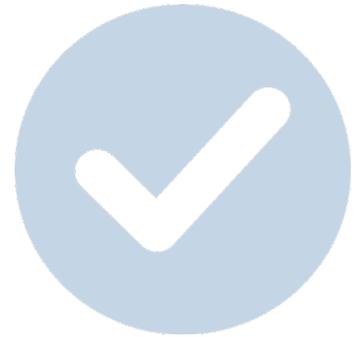
Question

- What is PEP?



Post-Exposure Prophylaxis

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?

Both are used by HIV-negative persons.

Both use ARVs to prevent HIV acquisition.

Both are available from clinical providers by prescription.

Both are effective when taken correctly and consistently.

What is different?

PrEP is started before potential exposure. PEP is taken after exposure.

PEP is taken for 28 days only. PrEP requires ongoing use as long as HIV risk exists.

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.

Question

“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)

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*

¹ Fitch L, Clancy J, Donaldson E, Gardiner E, Warren M. Tracking global oral PrEP provision: the who, what, and where of oral PrEP. Paper presented at: HIV Research for Prevention Conference (HIVR4P 2018); October 23, 2018, Madrid. Abstract OA04.01.

² Hodges-Mameletzis A, Dalal S, Msimanga-Radebe B, et al. Going global: the adoption of the World Health Organization's enabling recommendation on oral pre-exposure prophylaxis for HIV. *Sexual Health*. 2018; 15(6):489-500.

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.**

* Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV pre-exposure prophylaxis (PrEP) for all populations: A systematic review and meta-analysis. *AIDS* 2016(30):1973-1983. doi:10.1097/QAD.0000000000001145.

Question

- 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)



KEY  Ongoing  Planned  Completed

For the latest on these studies, visit www.avac.org/prep/track-research.

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.

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>

Summary

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.

Key Initial Visit Counseling Messaging: PrEP and Substance Use

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.

Module 2

2

PrEP Screening and 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.

OR

OR

*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.

General Screening Questions

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?

Serodiscordant Couples

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.

For a Person Who Has a Partner with HIV

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?

Additional Factors to Ask About

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?

PrEP Screening for Substantial Risk and Eligibility

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

1. Facility Information	
Facility Name	
Date of Initial Client Visit (<i>dd/mm/yyyy</i>) ____/____/____	Person Completing Form
2. Client Information	
First Name	Middle Name
Surname	
Address	Telephone #
Client ID Number	
3. Client Demographics	
What was your sex at birth?	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other (<i>specify</i>): _____ <input type="checkbox"/> No response
What is your current gender?	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender (<i>male to female</i>) <input type="checkbox"/> Transgender (<i>female to male</i>) <input type="checkbox"/> Other (<i>specify</i>): _____ <input type="checkbox"/> No response
What is your age? (<i>Specify number of years.</i>)	_____
4. Screening for Substantial Risk for HIV Infection	
Client is at substantial risk if he/she belongs to categories 1 , 2 , or 3 below	Question Prompts for Providers
1 If client is sexually active in a high HIV prevalence population PLUS reports ANY one of the below in the last 6 months	Have you been sexually active in the last 6 months?
<input type="checkbox"/> Reports vaginal or anal intercourse without condoms with more than one partner	In the last 6 months, how many people did you have vaginal or anal sex with?

PrEP Screening for Substantial Risk and Eligibility *(continued)*

- 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.*



Clinical Scenario 1

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?

Clinical Scenario 2

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?

Module 3

3

Initial and Follow-Up PrEP Visits

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.
- Details in: *Guidance for Providing Informed-Choice Counseling on Sexual Health for Women Interested in Pre-Exposure Prophylaxis (PrEP)*, from www.fhi360.org.

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.

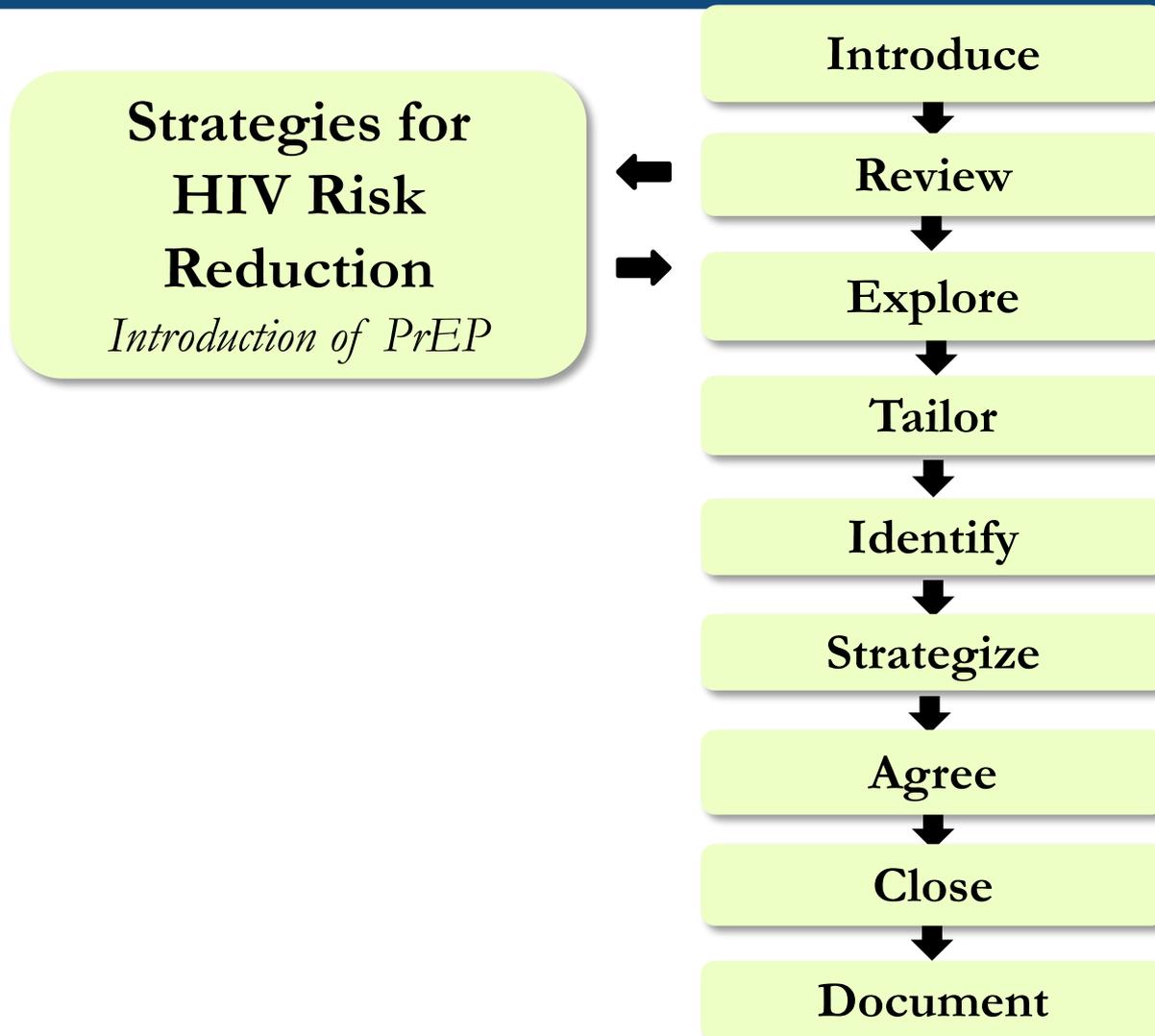
PrEP Counseling Is About Problem Solving

- 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



Steps in iNSC

iNSC Step	Critical Components	Example Prompts
Introduce the counseling session	Explain what you are talking about and why. Get permission to proceed.	<i>I would like to take a few minutes to check in with you about your goals and how to meet them. Is that okay?</i>
Review the client's experiences	Ask about what the client already knows about PrEP and how he or she learned it.	<i>Thank you. Can you tell me a little about what you have heard about PrEP and about your experiences with PrEP?</i>
Explore 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.	<i>What seems to make PrEP easy to take or harder to take?</i>
Tailor the discussion to focus on making pill taking easier	This pause allows the provider or counselor to consider how to tailor the next question based on information gathered in earlier steps.	<i>Let me think for a moment about what you have said.</i>

Steps in iNSC

(continued)

iNSC Step	Critical Components	Example Prompts
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	<i>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?</i>
Strategize with the client on the next step	Work with the client to identify one or more viable strategies for increasing effective PrEP use.	<i>How could that happen? What are some ideas for how you could approach that?</i>
Agree on which strategy will be tried next	Ask which strategy (or strategies) the client is willing to try or continue using.	<i>Of the things that we have talked about, which might you be willing to try between now and the next time we meet?</i>
Close and document the session	Summarize the discussion and thank the client.	<i>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.</i>

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?



iNSC Role-Play Performance 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 could the provider improve the next time around?



iNSC Role-Play 2

- 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 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?



Module 4

4

**Monitoring and Managing PrEP Side Effects,
Seroconversion, and Stigma**

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.

Question

- 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”

Situation	Recommendation
Hormonal contraception	<ul style="list-style-type: none">• PrEP does not affect the efficacy of hormonal contraceptives and hormonal contraceptives do not affect PrEP efficacy.
Pregnancy and breastfeeding	<ul style="list-style-type: none">• Safety data support the use of PrEP in pregnant and breastfeeding women who are at continued substantial risk for HIV infection.
Hepatitis B infection	<ul style="list-style-type: none">• HBV vaccination is appropriate for people at substantial risk for HBV or HIV infection.
Management of recent HIV exposure with PEP	<ul style="list-style-type: none">• 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.

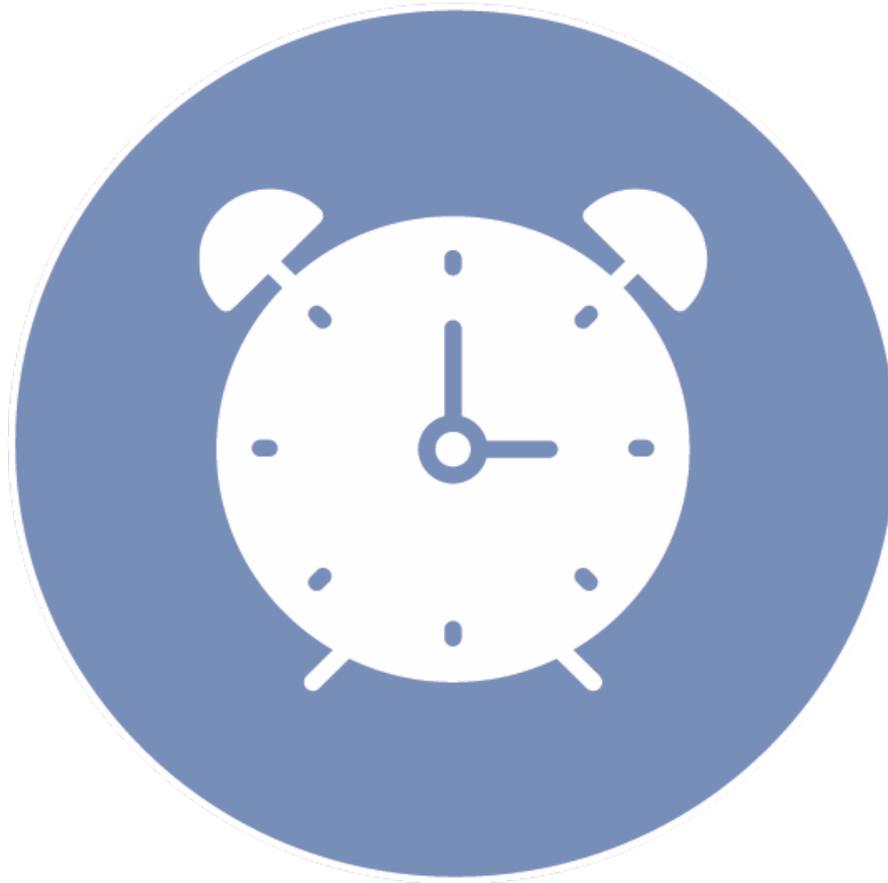
MORNING BREAK



LUNCH



AFTERNOON BREAK



Day 2 Overview

- On Day 2 you will learn the principles and methods behind participatory trainings such as the *PrEP Training for Providers in Clinical Settings*.
- Then you will prepare to deliver participatory training sessions from the *PrEP Training for Providers in Clinical Settings* trainer manual.
- You will do so in pairs (or small groups). Each pair (or small group) will deliver a different session.

Module 2

2

Participatory Training Principles and Techniques

Module 2 Learning Objectives

After completing this module, you will be able to:

- Describe an effective training experience you had as an adult.
- Name key characteristics and components of effective training.
- Describe what a discussion is and give tips on leading one.
- Name the main principles of adult learning.
- Give examples of how trainers can put principles of adult learning into practice when delivering trainings.



Module 2 Learning Objectives

(continued, 2)

- Describe what a brainstorm is and give tips on leading one.
- Identify examples of how principles of adult learning have been put into practice during a particular training.
- Demonstrate how to give constructive feedback to a colleague.
- Describe what a role-play is and give tips on leading one.
- Describe what a scenario is and how it may be used in participatory training.

Small Group Discussion

- Think back to an effective learning experience you have had as an adult—from university or a professional training, or simply on the job.
- Then discuss with your small group:
 - Why was the course or training effective?
 - How did the trainer engage you and help you learn?
- Choose one group member to record responses on a sheet of notebook paper. There may be many different responses.
- *You will have 15 minutes to work.*



Discussion

A discussion is a dialogue between participants and the trainer, with participants responding to discussion questions and one another's ideas, and the new questions that surface. In leading a large group discussion, trainers must keep participants focused, actively elicit responses, and limit participants who like to talk a lot. Participants having small group discussions must take on these roles themselves.

Methodology Debrief: Discussion

- What was your experience participating in the discussion (both in small groups and as part of the whole group)?
- What did I (the trainer) do to introduce and facilitate the discussions?
- What are some benefits of using discussion during training?
- What are some challenges to using discussion during training?



Introduction to Principles of Adult Learning

A large body of research and writing exists on adult learning, and there are various theories about how adults learn best. Most academics and practitioners, however, agree that certain basic principles should guide the design and implementation of any adult learning experience.

Principles of Adult Learning

- **Respect**—Adult learners must feel respected and feel like equals.
- **Affirmation**—Adult learners need constructive feedback and praise.
- **Experience**—Adult students learn best by drawing on their own knowledge and experience.

Principles of Adult Learning

(continued, 2)

- **Relevance**—Learning must meet adults' real-life needs.
- **Dialogue**—Trainers and learners must enter into dialogue and learn from one another.
- **Engagement**—Adult learners must engage with the material to be learned through dialogue, discussion, and learning from peers.

Principles of Adult Learning

(continued, 3)

- **Immediacy**—Adult learners must be able to apply the new learning immediately.
- **20–40–80 Rule**—Adult learners typically remember 20% of what they hear, 40% of what they hear and see, and 80% of what they hear, see, and do.

Principles of Adult Learning

(continued, 4)

- **Thinking, Feeling, and Acting**—Teaching is more effective when learners think, feel (emotions), and act (do something with new knowledge).
- **Safety and Comfort**—Adult learners need to feel safe and comfortable in order to participate and learn. They need to know that their ideas and contributions will not be ignored or belittled.

Questions

- Which of these principles have you used in your practice as an instructor?
- What has been your experience using them?
- Do any of the principles seem challenging to put into practice? Why?
- What questions or thoughts do you have about these principles?



Questions

Look back to the list of effective teaching and training from the previous session.

- What similarities to the principles do you see?
- Any differences?



Traditional Training

Traditional training focuses on the transfer of knowledge and expertise from the trainer to the learners, often using didactic lectures, where the trainer speaks and the learners listen. Learners are often passive, absorbing and repeating back information that the trainer imparts.

Traditional Training

(continued, 2)

Traditional education and training can be effective.

Many of the effective learning experiences that you have described may have been courses or training delivered in the traditional way.

In many cases, though, traditional training does not promote learning, retention, and skill building as effectively as participatory training.

Participatory Training

In participatory training, learners are active participants. Participatory trainers use methodologies that elicit and build on participants' experience and knowledge; that promote analysis, discussion, and strategizing; and that engage participants in practicing new skills.

Participatory Training

(continued, 2)

Participatory training methodologies include discussion, brainstorming, analysis of scenarios and case studies, role-play, and others.

Participatory training puts into practice all of the principles of adult learning.

Principles into Practice

As trainers, we are responsible for putting these principles of adult learning into practice when we plan and deliver training. Putting the principles into practice will promote learning and retention of what is learned. Participants are also responsible, but trainers play the most important role.

Small Group Brainstorm

- With your small group, brainstorm a list of ways that trainers can put the principles assigned to your group into practice.
- You may draw from your own experience as a trainer, the experiences shared during the previous session, your experiences during this training of trainers, and any other ideas.
- Choose a group member to record your ideas on the sheet of flip chart paper.
- *You will have 15 minutes to work.*



Questions

- What questions or comments do you have about these ideas?
- What ideas would you add to other groups' work, if any?



Questions

You have shared valuable ideas for putting the principles of adult learning into practice. Now compare your ideas to the ideas in your manual.



- Which ideas are the same? Which are new?
- Take a few minutes to write in your manuals any brainstormed ideas that do not appear there. Note any new ideas in the manual.

Brainstorm

In brainstorming, the trainer asks a question or poses a problem and asks participants to respond with as many ideas as they can think of. Brainstorming may be used with both large and small groups. The purpose is to produce as many ideas as possible.

Methodology Debrief: Brainstorm

- What was your experience participating in the brainstorm?
- What did I (the trainer) do to introduce and facilitate the brainstorm?
- What are some benefits of using brainstorms during training?
- What are some challenges to using brainstorms during training?



MORNING BREAK



Pair Discussion

- With your pair partner, discuss these questions and write your responses in your notebook:
 - What has the trainer done well to uphold the principles of adult learning during this training?
 - How could the trainer improve the next time around?
- *You will have 10 minutes to work.*



Question

- What is constructive feedback?



What Is Constructive Feedback?

Constructive feedback means giving a person concrete observations and advice about how he or she has performed—observations and advice that the person can use to construct an improved performance the next time around. Constructive feedback is given in a positive way that is not overly critical.

Question

- Why should you give constructive feedback?



Why Give Constructive Feedback?

- Giving concrete observations and advice that help someone to improve her or his performance, in a positive tone, is part of creating an effective learning environment.
- Constructive feedback upholds the principles of adult learning—by affirming and respecting participants, encouraging dialogue, using participants' own experiences, and creating a safe and comfortable environment for learning.

Why Give Constructive Feedback?

(continued, 2)

- Nonconstructive feedback—feedback that is too negative and harsh, and that does not contain concrete suggestions for improvement—violates principles of adult learning (safety and comfort, respect, affirmation).
- If a critique is too negative or harsh, people may dismiss the feedback or take offense—and be less likely to use the feedback to learn and improve.

Trainer Role-Play Debrief

- What feedback did Marie give Beatrice?
- How did she give the feedback constructively? What did she do first? Next?
- What effect did the feedback have?



How to Give Constructive Feedback

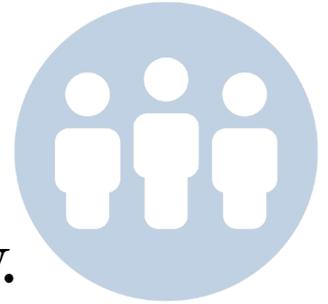
- First, tell the person what she or he did well. (This will make the person more receptive to hearing what she or he needs to do in order to improve.)
- Next, tell the person what she or he can do to improve:
 - Be brief.
 - Be honest.
 - Be specific.
 - Be respectful.
 - Be positive and encouraging.

How to Receive Constructive Feedback

- Do not defend or explain your performance; simply listen and accept the feedback.
- If you do not understand a suggestion, ask for clarification.
- Ask for specific suggestions for improvement.
- Reflect on the feedback, and use relevant suggestions to improve your performance going forward.

Constructive Feedback Role-Play

- Read only your own scenario (not your partner's).
- Using the scenarios, practice a brief role-play.
- Follow the guidance in your manual for giving and receiving constructive feedback.
- As you are practicing, I will observe and choose a pair to perform. I will not tell you which pair I choose, so everyone must be prepared to perform.
- *You will have 10 minutes to work.*



Constructive Feedback Role-Play Debrief

- 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?



Role-Play

A role-play is a brief informal performance where participants act out roles in order to practice handling a particular problem or situation and to experience what it is like to be in those roles. Role-playing is informal; participants do not need to memorize dialogue or perform perfectly—the point is to experience the situation and learn from that experience.

Methodology Debrief: Role-Play

- What was your experience participating in the role-plays?
- What did I (the trainer) do to introduce and facilitate the role-playing?
- What are some benefits of using role-play during training?
- What are some challenges to using role-play during training?



Module 3

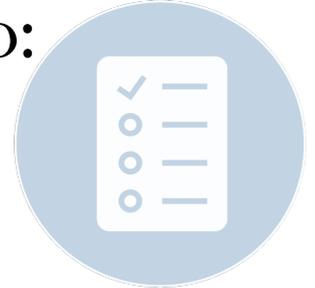
3

Practice Delivering Participatory Training

Module 3 Learning Objectives

After completing Module 3, you will be able to:

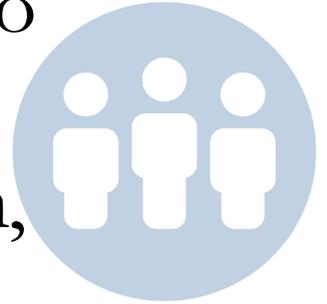
- Prepare to deliver a participatory training session with a co-trainer.
- Deliver a practice training session using participatory techniques that uphold the principles of adult learning.
- Give constructive feedback to colleagues on their training delivery.
- Name potential challenges to delivering the *PrEP Training for Providers in Clinical Settings* at your facilities, and describe strategies for addressing the challenges.



Preparation

With your pair partner or small group, prepare to deliver an assigned training session. To prepare:

- Read session objectives, materials, preparation, and steps.
- Decide who will facilitate which part of the session (each participant must facilitate 1 part).
- Familiarize yourself with session steps and materials (slides, forms).
- Review relevant information from this TOT training.
- *You will have 45 minutes to prepare.*



If you have time, practice delivering key parts of the session (in a corner or hallway).

LUNCH



Training Delivery Practice

- Each pair (or small group) will deliver their assigned training session. The rest of you will be participants.
- I will give 10-, 5-, and 1-minute time checks.
- After 20 minutes, I will ask presenters to stop (even if they have not finished) and to comment on their performance—what they think they did well and what they would improve.
- Then, I will ask everyone to give the presenters constructive feedback (*about 5 minutes*).

AFTERNOON BREAK



Questions

- What challenges might you face when delivering the *PrEP Training for Providers in Clinical Settings* at your facilities?
- How might you address those challenges?



Training Evaluation

- Please take a few minutes to complete this Training Evaluation Form.
- We welcome your honest feedback in order to improve future trainings.
- Your evaluation will be confidential. You do not need to include your name.
- You may leave your evaluation form inside the envelope at the front of the room.

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Thank You for Your Participation!

