

PRE-EXPOSURE PROPHYLAXIS (PREP)
TRAINING FOR PROVIDERS
IN CLINICAL SETTINGS

Facilitator Manual (Version 2.0) 2017





These training materials were made possible by the U.S. President's Emergency Plan for AIDS Relief through the Centers for Disease Control and Prevention under the terms of cooperative agreement number U2GGH000994. Its contents are the sole responsibility of ICAP at Columbia University and do not necessarily represent the views of the U.S. Government.

#### **Recommended Citation:**

Pre-Exposure Prophylaxis (PrEP) Training for Providers in Clinical Settings. New York: ICAP at Columbia University; 2016.

#### Acknowledgment:

The *Pre-exposure Prophylaxis (PrEP) Training for Providers in Clinical Settings* was developed by ICAP at Columbia University in collaboration with the Centers for Disease Control and Prevention, with funding from PEPFAR. The training was developed as a set of tools that are adaptable to each county's local context and guidelines. The use of PrEP is an evolving area and it is therefore expected that these documents will require updating over time as recommendations change.

Organizations and entities that choose to adapt these documents for their own use should credit ICAP at Columbia University and note that their work is an adaptation.

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#### **Foreword**

Despite remarkable progress in HIV treatment, there were still an estimated 2.1 million new HIV infections globally in 2015. Thus, a large number of individuals remain at substantial risk for acquisition of HIV infection. Key populations at substantial risk include sex workers (SW), men who have sex with men (MSM), transgender persons (TG), and people who inject drugs (PWID), as well as other priority populations such as young women in southern Africa. These realities compel the need for continued efforts to expand access to effective HIV prevention interventions while at the same time continuing the scale-up of access to HIV treatment programs for individuals living with HIV.

Pre-Exposure prophylaxis (PrEP) is a new, efficacious HIV prevention intervention. It involves the use of antiretroviral drugs (ARVs) by HIV un-infected persons to prevent acquisition of HIV. Several clinical trials have demonstrated the efficacy of PrEP in MSM and transgender women, serodiscordant couples, heterosexual men and women, and PWIDs. The efficacy of PrEP has varied widely across trials, largely based on the level of adherence achieved with the daily doses of tenofovir/emtricitabine (TDF-FTC). 'Real world' effectiveness of PrEP, particularly given concerns about adherence and risk compensation, was demonstrated in the PROUD study and also in several demonstration projects. Ultimately, PrEP works when it is taken as prescribed.

It is important to note that across all clinical trials and demonstration projects, PrEP was provided as a component of a package of HIV prevention interventions, including repeat HIV testing, promotion and provision of condoms, screening and management of sexually transmitted infections (STIs), adherence support, risk-reduction counseling, and harm reduction interventions. Thus, there is global consensus that PrEP is an important tool in the package and that it should be offered to people at substantial risk of HIV infection as part of a combination HIV prevention approach.

This training manual for PrEP implementation was developed specifically for the use of PrEP for health workers in clinical settings. The goal is to enable clinical providers to attain the skills required to provide PrEP to appropriate candidates in an effective and safe manner. The training provides information regarding the evidence for PrEP effectiveness, PrEP procedures, and monitoring. It also includes a set of job aids. It is anticipated that facilities will need to adapt this training material to reflect specific contexts and include evidence from new research and experience in the use of PrEP.

PrEP offers a unique opportunity to confront the HIV epidemic, prevent HIV acquisition by individuals at risk for HIV, and reach global targets.

We welcome feedback regarding this training.

ICAP at Columbia University New York, December 2016 Web: <a href="http://icap.columbia.edu">http://icap.columbia.edu</a>

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## Acronyms

**AHI** Acute HIV Infection **ART** Antiretroviral Therapy

**ARV** Antiretroviral

US Centers for Disease Control and Prevention CDC

**FSW** Female Sex Worker **FTC** Emtricitabine Antibody/Antigen Ab/Ag

**HBsAg** Hepatitis B Surface Antigen

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

HIV Human Immunodeficiency Virus

**HIV-DR** HIV Drug Resistance

HIV Testing Services or HIV Testing Strategy HTS

**iNSC** Integrated Next Step Counselling **MSM** Men who have Sex with Men **NSC** Next Step Counselling Post-Exposure Prophylaxis **PEP** 

Preventing Mother To Child Transmission **PMTCT** 

**PrEP** Pre-Exposure Prophylaxis **PWID** People Who Inject Drugs Randomized Controlled Trial **RCT** 

**RNA** Ribonucleic Acid

**RPR** Rapid Plasma Regain test (syphilis) Sexually Transmitted Infection STI **TasP** Treatment as Prevention

**TDF** Tenofovir Disoproxil Fumarate

**UNAID** Joint United Nations Programme on HIV/AIDS

**VMMC** Voluntary Male Medical Circumcision

WHO World Health Organization

3TC Lamivudine

#### Introduction

## **Section 1: Training Overview**

#### **Training Goals and Development**

The goal of the *Pre-exposure Prophylaxis* (*PrEP*) *Training for Providers in Clinical Settings* is to equip HIV care providers with the knowledge and skills necessary to provide PrEP to appropriate candidates and with high quality in order to decrease the risk of HIV infection.

ICAP at Columbia University (ICAP) used a backward design approach to develop this training. First, content and training experts were identified. Together these experts developed a series of competency statements (tasks or skills) that HIV care providers would need in order to provide PrEP to appropriate candidates with the required level of proficiency. Next, the team created learning objectives and assessment measures to describe what HIV care providers should be able to achieve at the end of the training program. These learning objectives were then sequenced and grouped into six learning modules. Finally, the team created learning activities and training tools for all learning objectives. Training tools include a facilitator manual, participant manual, job aids, monitoring and evaluation tools, and a comprehensive slide set with essential content, visuals, and talking points.

## **Competencies and Content Areas**

The core competencies health providers will develop during the training are:

- 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 laboratory assessments during follow-up PrEP visits.
- Assess PrEP Monitoring and Evaluation tools for local use.
- Provide adherence education, counseling and support to PrEP candidates and users.

This is a classroom-based training. Content areas are:

- PrEP basics
- PrEP screening and eligibility
- Initial and follow-up PrEP visits
- Monitoring and managing PrEP side effects, seroconversion, and stigma
- Monitoring and evaluation tools for local use

The target population for this training is providers with **existing** knowledge and experience in HIV prevention, care, and treatment, including:

- Physicians
- Medical officers
- Clinical officers
- Nurses
- Nurse midwives
- Prevention and treatment counselors

#### **Training Adaptation**

This training program is generic. It was developed for adaption at the country, state/provincial, or facility-level, based on the local epidemiology of the HIV epidemic and populations at risk. The recommendations that form the technical content in this program are based primarily on those from global organizations such as WHO and CDC. All of the training tools, whether clinical or educational, need local review and adaptation to ensure that they meet local needs, have the support of key stakeholders and health providers, and reflect national guidelines and policies.

#### Components of this Training Package

You should familiarize yourself with all components of this training package well in advance of the training. The package includes the facilitator manual, participant manual, PowerPoint slides, job aids, and sample monitoring and evaluation tools.

#### **Facilitator Manual**

The facilitator manual contains six modules, each divided into training sessions of varying length. Each training session contains the time, materials, and advance preparation needed to complete the session; step-by-step instructions for how to deliver the session; and any scenarios or role-play guidance needed. You may use the manual as a step-by-step guide while you deliver the training sessions.

Please review the full training manual before leading the training, including this introduction, all training sessions, clinical and role-play scenarios, job aids, and monitoring and evaluation tools. Take note of any advance preparation needed. For example, for some training sessions you must prepare a few additional slides or find a colleague to practice and perform a role-play with you.

#### Participant Manual

The participant manual is divided into six modules, each containing the learning objectives, all content to be delivered (from the slides), scenarios, role-plays, and pair or small group activity instructions. Participants will use the manuals throughout the training. In some training sessions, participants will close their manuals in order to attend to an interactive trainer presentation. In other sessions, participants will have their manuals open in order to read content or follow activity instructions. Participants should take home their manuals after the training's end. Please review the entire participant manual before leading the training.

#### **PowerPoint Slides**

The PowerPoint slides contain each module's learning objectives, key content to be delivered, scenarios, small group or pair activity instructions, and break and lunch notices. You should use the slides hand in hand with the facilitator manual. The facilitator manual session steps list all slides for each session, and in some cases, key points to emphasize when showing a slide. Please review all slides before leading the training.

#### Adapting to Specific Context

There are a variety of reasons to adapt the clinical scenarios and exercises included in the facilitator manual. For example:

- If you have simplified a session to suit the target group (possibly based on results of the preprogram assessment), the clinical scenarios or other exercises may also have to be changed.
- You may want to substitute clinical scenarios or exercises with ones more relevant to a specific context. If you do, make sure that all the points that the original scenario or exercise was designed to illustrate are included in the replacement scenario or exercise.

If you do choose to adapt, amend, or replace a clinical scenario or exercise, ask yourself the following questions:

- 1. Is the task in the new scenario or exercise clearly defined?
- 2. Is the new scenario or exercise consistent with the content of the module?
- 3. Does the new scenario or exercise achieve the same objective(s) as the original?
- 4. Does the new scenario or exercise fit in the time allotted?
- 5. Does the new scenario or exercise contribute to the variety of activities offered?
- 6. Will the new scenario or exercise engage participants in active thinking and learning?
- 7. What advantages does the replacement scenario or exercise have over the original?
- 8. What materials will be needed?
- 9. Do new PowerPoint slides need to be created for the new scenario or exercise?

## **Training Program Schedule**

The PrEP Training for Providers in Clinical Settings was developed as a five-to-six module face-to-face training that will take two or two-and-a-half days to complete.

The modules should be taught sequentially. A sample training agenda is provided here.

DAY 1	
8:00-8:30	Participant registration
8:30-10:30	Module 1: Pre-assessment and PrEP Basics
10:30-10:45	MORNING BREAK
10:45-12:00	Module 2: PrEP Screening and Eligibility
12:00-13:00	LUNCH
13:00-14:00	Module 2: PrEP Screening and Eligibility, cont.
14:00-14:15	AFTERNOON BREAK
14:15-16:15	Module 2: PrEP Screening and Eligibility, cont.

DAY 2	
8:30-10:00	Module 3: Initial and Follow-up PrEP Visits
10:00-10:15	MORNING BREAK
10:15-12:00	Module 3: Initial and Follow-up PrEP Visits, cont.
12:00-13:00	LUNCH
13:00-14:15	Module 3: Initial and Follow-up PrEP Visits, cont.
14:15-14:30	AFTERNOON BREAK
14:30-16:45	Module 4: Monitoring and Managing PrEP Side Effects, Seroconversion, and Stigma
16:45-17:15	Module 5: Post-test, Evaluation, and Closing (if not covering Module 6)

DAY 3	
8:30-10:00	Module 6: PrEP Monitoring and Evaluation Tools
10:00-10:15	MORNING BREAK
10:15-11:45	Module 6: PrEP Monitoring and Evaluation Tools, cont.
11:45-12:15	Module 5: Post-test, Evaluation, and Closing

Set up a registration table at least 30 minutes before the training program is scheduled to start. The registration table is where participants will stop before they enter the training room for the first time. This is where they will:

- Register for the training, or sign in if already registered. The sign-in sheet may include spaces
  for name, job title, place of employment, address of employer, work phone number, cell
  phone number, and e-mail address.
- Fill in their nametags. Trainers and participants should wear their nametags throughout the training to facilitate the learning of names and future networking.

One trainer and one support person may staff the registration table for most training group sizes. However, the other trainers should be available at this time to meet and greet participants troubleshoot any problems. Their presence will help ensure a positive first impression and learning environment.

#### Starting the Day

Begin the training day by answering any questions and reviewing the agenda for the day. You may also use this time to orient participants to the training facility (location of bathrooms, where breaks and meals will be served) and any other logistics. This should take no more than 5–10 minutes.

#### **Training Evaluation**

#### **Pre-Program Assessment**

The training package includes a pre-assessment consisting of open-ended questions intended to measure participants' pre-training knowledge of key content and skills related to PrEP implementation. The pre-program assessment is also designed to give participants a sense of what they need to know and be able to do by the training's end. The open-ended questions eliminate guessing by participants. The completed pre-assessments will therefore give trainers a quick but fairly accurate snapshot of what participants know and don't know. You should review the completed pre-assessments in order to identify any content areas that you may need to adapt during the training, but you will not formally grade the pre-assessments or return them to participants.

#### Post-Test

The training package includes a multiple-choice post-test (in Module 5). Post-test questions are the same as those asked in the pre-assessment (but with multiple choice answers), and are designed to measure learning of key content and skills related to PrEP implementation. You will grade and return the post-tests to participants. If your training will include Module 6, you may choose to have participants complete the post-test after Module 6.

#### **Training Evaluation Form**

The Training Evaluation Form is an important source of feedback and provides information on how the training program should be improved in the future so as to better meet participant training needs. Please distribute program completion certificates to participants after they have handed in their completed post-tests and evaluation forms.

#### Introduction

# Section 2: Trainer Roles and Responsibilities and Training Tips<sup>1</sup>

#### Roles and Responsibilities of the Trainer

- 1. **Trainers are the standard-setters for the discussion**. As the trainer, you must stay focused, alert, and interested in the discussion and learning that is taking place. You create the standards of communication by looking around the room at all participants, listening closely, and encouraging contributions from everyone.
- 2. Trainers make the training environment a priority. You are in charge of deciding everything, from how the tables and chairs are set up to where small group exercises will take place, and all other logistical issues. You are also responsible for judging how the physical environment of the training affects participants' engagement and learning, and for making changes as needed.
- 3. **Trainers keep track of time.** It is easy to over-schedule activities and not incorporate enough "down time" for participants. Always allow for activities to take longer than expected.
- 4. Trainers are responsible for explaining the purpose of each learning activity and its significance to participants. Also, let participants know the expected time that will be spent on each activity.
- 5. Trainers make use of various techniques and tools to keep the discussion moving when tension arises or discussion comes to a halt. You must be prepared with strategies to keep participants engaged and learning.
- 6. **Trainers must pay attention to participants' behavior.** You should observe verbal and non-verbal cues from participants and take appropriate actions to meet both spoken and unspoken needs.
- 7. Trainers are responsible for ensuring confidentiality in the learning environment. During the training, participants will share clinical scenarios as well as stories of how they, their colleagues, or managers have handled different scenarios in the workplace. They may also share stories about themselves or their friends stories that are personal and not meant to be discussed outside of the classroom. Typically, these stories are brought up to illustrate a lesson learned or as an example of current practice. Encourage participants to feel safe sharing by explaining to them that all such information will remain confidential. Also, ensure that you serve as a role model in maintaining this confidentiality.

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 $<sup>^1\</sup> Bonner\ Curriculum\ (updated).\ \textit{Facilitation 202: More techniques and strategies}.\ Available\ at: http://bonnernetwork.pbworks.com/w/page/13112080/Bonner-Training-Modules-(with-Descriptions)$ 

#### **Trainer Preparation Checklist**

#### Table 1: Trainer checklist

✓	Complete the following before starting the training program
	Read the competency statements, learning objectives, technical content, discussion
	questions, session steps, and clinical and role-play scenarios/exercises
	Prepare for each of the sessions by reading all session steps, scenarios, and exercise
	instructions.
	Obtain and organize the materials needed for the training.
	Review the PowerPoint slides and become familiar with their content. Practice using
	the computer and LCD projector and presenting technical content using the slides.
	Consider how to explain group exercises or to draw responses from an audience. Be
	prepared by thinking ahead and developing strategies for moving discussion forward.
	For complicated exercises or discussions, consider co-facilitation.
	Develop a plan and strategies for monitoring time and keeping to the schedule. For
	example, consider where you might shorten a discussion or role-play activity if needed.
	Familiarize yourself with participants' worksites, roles, responsibilities, skills, and
	experiences before and throughout the training.

### Training as a Team

When planning a module presentation with another trainer or co-trainer, consider the following questions to help clarify your roles:

- How will you divide up training content with your colleague (s)?
- What is your teaching style? How does your teaching style differ from that of your colleague?
- What challenges might arise? How can you and your colleague ensure that you will work well together?
- What signal could you and your colleague use to get each other's attention when the other person is presenting?
- How will you handle staying on task?
- How will you field participant questions?
- How will you make transitions between each of your presentations?
- How will you get participants back from breaks in a timely manner?

The Team Training Checklist below will help you to plan the key tasks you and your co-trainer need to accomplish before the training program starts.

## **Team Training Checklist**

Table 2: Team training checklist

$\checkmark$	Preparation
	Decide who will lead and teach each session of each module, including who will lead
	each exercise within each session.
	Decide on a plan for staying on schedule, including how you and your colleague will
	signal each other when time is up.
	Decide together how to arrange the room.
$\checkmark$	During training
	Support your colleague while he or she is presenting by paying attention. Never
	correct your colleague in front of the group.
	Ask for help from your training colleague when you need it, for example, when you do
	not know the answer to a question or you are not sure of something.
	Sit somewhere so that you and your colleague can make eye contact, but also in such a
	way that the person presenting has the spotlight.
$\checkmark$	After training
	Review the completed Training Evaluation Form and discuss what you thought went
	well and what could have been done better. Take notes so that you will remember for
	the next training.
	Discuss ways to help support one another during future trainings.

#### Set the Environment

You are responsible for creating an environment that supports learning by ensuring that participants feel safe, supported, and respected. Take the time to carefully plan and deliver the training in a way that creates a psychologically safe and supportive environment.

Strategies for making participants comfortable and fostering trust include:

- Arrange the seats so that participants can see each other as well as the trainer.
- Establish rapport with participants by greeting them warmly and being pleasant, knowledgeable, and approachable.
- Ask participants to introduce themselves at the beginning of the training program by stating their name, organization, and position.
- Encourage participants to share their expertise and answer each other's questions when appropriate.

#### **Know Your Audience**

It is important to learn about your audience. This means learning something about the individuals who will be participants in the training so you can tailor content and

For example, you may want to learn the following about the participants of an upcoming training:

**Participant demographics** (for example, age, sex, place of employment) — this will help with planning logistics (venue and timing of the training) and with adapting clinical scenarios or other exercises.

**Education** — knowing the educational background of participants can help you gauge the type of language to use and to tailor it to participants' educational background and level of attainment.

**Job or position** — Knowing participants' jobs or positions will help you relate training competencies and content to their work.

Knowledge, experience, and skills in HIV prevention, care, and treatment — Knowing the knowledge, experience, and skill level of participants will help determine the level at which content should be taught, the time and methods needed to teach content, and the best types of clinical scenarios or learning methods for the group. Consider inviting participants with more experience to contribute to the discussion, model role-plays, pair up with participants who have less experience during small group work.

You can get some indication of participant baseline knowledge, experience, and skill by finding out where participants work, their job positions, how long they have been in those positions, and whether they currently see HIV positive and negative clients. The pre-program assessment will also help determine participant knowledge and skill level related to implementing PrEP.

**Attitudes** — Knowing participant attitudes toward the training can give you a sense of issues that will need to be addressed. Try to find out how participants feel about the upcoming training. Are they looking forward to it? Or do they see it as a waste of time? What is their attitude toward the topics to be presented?

#### Ways to learn about your audience

There are many ways to learn about your audience, including:

- Ask participants to complete a training registration form that includes questions on current job title, number of years in this position, educational background, length of time working in HIV, details of the type of programs they have been engaged in (e.g. pediatrics, adolescent and/or adult HIV services), and expectations and concerns they have regarding the training.
- Have participants complete the pre-program assessment.
- Talk with participants before the start of the training, during breaks and meals, and at the end of the day.

#### Manage Time

- 1. Know the content to be taught. Well in advance of the training, study the content to ensure you understand it fully. If you need help, seek support from an expert or the resources listed at the end of this introduction. Find Consider how the content can be shortened or lengthened, depending on participant learning needs. Consider how the timetable can be adjusted to create more time if it is needed. For example:
  - Shorten breaks or lunch.
  - Lengthen the day (for example, start 30 minutes earlier or end 15 minutes later).
  - Shorten or skip presentations, exercises, or discussion questions in content areas that participants know well.
- 2. Practice before the training. Practice giving exercise introductions, general content, and instructions out loud, using the material that will be used for the actual presentation. Practice co-facilitating technical content and exercises using the facilitator manual and PowerPoint slides.
- 3. Be flexible, but also use and follow the agenda. The agenda will let participants know how long modules are expected to last.
- 4. Keep time. Place a clock or watch in a place where you can see it and where it will not distract participants. Use signs ("5 minutes," "1 minute," and "stop") to tell co-trainers and participants how much time they have left.
- 5. Use the "parking lot" for discussions that take too much time or are related, but not critical, to the topic under discussion:

#### Parking Lot

The "parking lot" is a sheet of flip chart paper posted in the training room. The purpose is to provide a place to document important, but currently tangential, issues that are raised. For example, when a discussion strays too far from a particular module's objectives or when a discussion runs over time, the trainer can record the topic or question being discussed on the "parking lot" flip chart. The topic or question then remains in the "parking lot" until an agreed upon time, such as at the end of the training, during a break, or during an upcoming, relevant module. At this time, the group should remove the topic or question from the "parking lot" and revisit it.

## Effective Training<sup>2</sup>

Trainers should always keep the following tips in mind.

- Prepare in advance.
- Keep track of time and pace activities accordingly.
- Maintain good eye contact.
- Encourage participation and questions.
- Speak clearly and loudly enough.
- Explain instructions clearly and repeat them as needed.
- Summarize and emphasize key points at the end of each module.
- Write clearly and boldly.
- Give constructive and positive feedback.
- Be aware of the participants' body language.
- Keep the group focused on the task.
- When using visuals, face participants (not the visual).
- Don't assume everyone has the same baseline knowledge.
- Don't assume everyone can read and write at the same level.

## Adult Learning Principles<sup>3</sup>

This training is designed from these 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.
- Relevance Learning must meet the real-life needs of adults.
- Dialogue Facilitators and learners must enter into dialogue and learn from each other.
- Engagement Adult learners must engage with the material to be learned through dialogue, discussion, and learning from peers.
- 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.
- 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.

<sup>&</sup>lt;sup>2</sup> Adapted from: Colton, T., Dillow, A., Hainsworth, G., Israel, E. & Kane, M. (2006). Community home-based care for people and communities affected by HIV/AIDS: A comprehensive training course for community health workers. Watertown, MA: Pathfunder International.

<sup>&</sup>lt;sup>3</sup> Adapted from: Partners In Health. (2011). Household Development Agents and Human Rights Facilitator Manual: A Unit from the Household Development Agent Training Series. Boston, MA: Partners In Health.

## Training Methodologies<sup>4</sup>

To put the principles of adult learning into practice, this training uses a variety of participatory methodologies including brainstorming, scenarios, role-play, and other small group activities. These activities are designed to elicit and build on participants' experience and knowledge, promote discussion and reflection on key issues, provide hands-on practice of content learned, and help participants learn from each other.

In addition, these participatory methodologies promote higher retention of content and create an open, engaging, and supporting learning environment. Adult students typically remember 20% of what they hear, 40% of what they hear and see, and 80% of what they hear, see, and do. If participants only hear facilitator lectures, they will not learn or retain information as effectively.

#### Discussion

A discussion is a dialogue between participants and the facilitator, with participants responding to discussion questions and each other's ideas. During discussions, new questions may also surface. When the facilitator leads a large group discussion, she or he must manage the discussion by keeping participants focused, actively eliciting responses, and limiting participants who like to talk a lot. When participants have small group discussions, they must do likewise. To facilitate a large or small group discussion:

- Set a time limit and keep track of time.
- Explain that participants who want to speak should raise their hands.
- Keep the discussion on target and moving along.
- Encourage everyone to participate and call on everyone who raises her/his hand.
- Limit participants who like to talk a lot.
- Ask questions to encourage more responses to a question, for example: "What else?" "What other ideas do you have?"
- Wrap up the discussion by repeating and summarizing main points.

#### Small Group Work

The facilitator divides participants into small groups to do a learning activity. Examples of small group activities include small group discussions, scenarios, and role-play practice. Small groups allow each person to participate more than they would in the large group. Small group work also helps participants get to know each other and work with new colleagues. To facilitate small group work:

- Before you divide participants into small groups, give clear instructions for the small group task (instructions are included in training session steps).
- Group participants so that they are not always working with people they know well. Counting off is a good way to do this.
- Instruct small groups to make sure that all group members participate.
- Ask small groups to choose a timekeeper for their groups.
- Keep track of time yourself and give small groups half time, 5-minute, and 1-minute warnings.
- As small groups are working, move from group to group to make sure participants have understood the task and are making progress.

<sup>&</sup>lt;sup>4</sup> Adapted from: Partners In Health. (2011). Household Development Agents and Human Rights Facilitator Manual: A Unit from the Household Development Agent Training Series. Boston, MA: Partners In Health.

#### **Brainstorming**

In brainstorming the facilitator asks a question or poses a problem and asks participants to give as many ideas as they can in response. Brainstorming may be used with large or small groups. The purpose of brainstorming is not to get only one correct answer to the question or problem, but to generate as many ideas as possible. To facilitate brainstorming:

- Explain that the purpose of brainstorming is not to arrive at one correct answer, but to generate as many ideas as possible.
- Take one idea per participant, one at a time.
- Keep the pace lively.
- Encourage all participants to give ideas (do not rely on a few participants to do all the talking).
- After the brainstorming, the facilitator and participants can review, organize, and prioritize responses.
- If participants brainstorm in small groups, ask groups to keep the points above in mind as they work.

#### 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. To facilitate a role play:

- If you will divide participants into small groups or pairs for a role-play, give clear instructions for the role-play (instructions are included in training session steps).
- Set a time limit for role-play practice and performance and manage time well.
- Remind participants that role-play is not a perfect performance, but rather an opportunity to practice handling situations that participants may encounter in reality. It is fine to make mistakes during role-play.
- Debrief the role-play with a large-group discussion (debriefing questions are included in the training session steps).

#### **Scenarios**

A scenario is a brief description of a realistic situation that participants discuss and analyze. Scenarios give participants the opportunity to apply newly acquired knowledge to a particular problem or situation, and generate possible solutions to challenges presented in the scenario. To use scenarios effectively:

- If participants will use the scenario in small groups or pairs, give clear instructions (instructions are included in training session steps).
- If you write your own scenarios, make them simple and brief. Use realistic situations similar to those that participants face. Give essential information and leave out unnecessary details.
- Provide questions to guide participants in analyzing the scenario.

#### **Facilitator Presentation**

The facilitator presents information by speaking to the whole group, sometimes using visuals such as slides. Most people are familiar and comfortable with facilitator presentations because many primary, secondary, and university-level classes are taught in this way. Presentations work well for introducing new information, as long as they are brief and accompanied by visuals (slides or flip chart). To do a facilitator presentation:

- Check any equipment (slide projector, flip chart) ahead of time to make sure it is working properly.
- Keep the presentation short, between 5 and 15 minutes if possible.
- Use questions during the presentation to engage participants in the material you are presenting (questions are included in training session steps).
- Use open body language and a friendly, clear tone of voice.
- Watch participants during the presentation; if they look confused or bored, ask questions or move along more quickly.
- Move around the room as you present (if possible).
- Face participants when you are explaining a visual (do not face the visual).
- To wrap up your presentation, summarize and repeat main points.

#### PrEP Resources

#### **PrEP Resources for Providers**

- <a href="http://www.who.int/hiv/pub/arv/arv-2016/en/">http://www.who.int/hiv/pub/arv/arv-2016/en/</a>
- http://www.who.int/hiv/topics/prep/en/
- http://www.unaids.org/sites/default/files/media\_asset/UNAIDS\_IC2764\_en.pdf
- http://www.prepwatch.org/
- http://www.cdc.gov/hiv/risk/prep/
- Glidden, DV, Amico, KR, Liu AY, et al. Symptoms, side effects and adherence in the iPrEx open-label extension. Clin Infect Dis. 2016;62(9):1172-7.
- Fonner, VA, Dalglish, SL, Kennedy, CE, et al. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. AIDS 2016;30(12):1973-1983.
- The Fenway Institute. Pre-exposure prophylaxis clinical study data sheet. http://www.projectinform.org/pdf/prepstudydata.pdf . Accessed October 5, 2016.
- World Health Organization. Review: Safety of tenofovir PrEP in pregnant and breastfeeding HIV-uninfected women and their infants. <a href="http://emtct-iatt.org/wp-content/uploads/2016/08/WHO-TDF-pregnancy-Lynne-Mofenson.August-21-2016.pdf">http://emtct-iatt.org/wp-content/uploads/2016/08/WHO-TDF-pregnancy-Lynne-Mofenson.August-21-2016.pdf</a>. Accessed October 5, 2016.
- http://www.unaids.org/en/dataanalysis/monitoringandevaluationguidance

#### PrEP Resources for PrEP Users

- <a href="http://www.whatisprep.org">http://www.whatisprep.org</a>
- <a href="http://www.PleasePrEPMe.org/resources">http://www.PleasePrEPMe.org/resources</a>
- http://www.iwantprepnow.co.uk
- http://www.cdc.gov/hiv/pdf/risk\_PrEP\_TalkingtoDr\_FINALcleared.pdf
- https://www.facebook.com/groups/PrEPFacts/

## **MODULE 1: PrEP Basics**

#### TIME: 2 hours

#### **OBJECTIVES**

#### After completing Module 1, participants will be able to:

- Define PrEP.
- Differentiate PrEP from PEP and ART.
- Describe the need for PrEP.
- Identify people at risk and people at substantial risk for HIV infection.
- Identify key populations (KP) for PrEP at the local level.
- Explain the relationship between PrEP effectiveness and adherence.
- State key reasons why PrEP is needed.
- Specify the PrEP regimens approved by WHO and within one's own country.
- Identify concerns regarding the implementation of PrEP.
- Explain the risks and benefits of PrEP.

#### **MATERIALS**

- Facilitator manual (needed for all sessions)
- 1 participant manual for each participant (needed for all sessions)
- 1 folder for each participant (needed for all sessions)
- Module 1 slides (needed for all Module 1 sessions)
- Registration sheet
- Name tags
- 1 pen and 1 notebook for each participant
- 1 pre-test for each participant

#### ADVANCE PREPARATION

- Prepare the training room: arrange chairs; put out names tags, participant manuals, pens, and registration sheet; and prepare the slide projector.
- Prepare participant folders.
- Prepare a registration sheet.
- Make 1 copy of the pre-program assessment for each participant.
- Prepare a few slides presenting local HIV epidemiology.
- Add country-specific data to Slide: ARVs Recommended for Oral PrEP.
- Decide how you will divide participants into small groups (by counting or another method).

## Session 1.1. Welcome, Introductions, Training Overview, and Ground Rules

Time: 20 minutes

**Methods:** Interactive trainer presentation

#### **Materials**

- Facilitator manual (needed for all sessions)
- 1 participant manual for each participant (needed for all sessions)
- 1 folder for each participant (needed for all sessions)
- Module 1 slides (needed for all Module 1 sessions)
- Registration sheet
- Name tags
- 1 pen and 1 notebook for each participant

#### **Advance Preparation**

- Prepare the training room: arrange chairs; put out names tags, participant manuals, pens, and registration sheet; and prepare the slide projector.
- Prepare participant folders.
- Prepare a registration sheet.
- Post slide: PrEP Training for Providers in Clinical Settings

- 1. Slide: PrEP Training for Providers in Clinical Settings
  - (Welcome participants to the training and introduce yourself and the other trainers.)
- 2. Slide: Welcome!
  - Please circulate the registration sheet so that everyone may complete it.
  - Please take a nametag and write your name on it.
  - Please take a participant manual, folder, pen, and notebook. You will use your manuals during this training and will take them home at the training's end.
- 3. Slide: Introductions
  - Please introduce yourselves briefly by sharing your name, organization, and position.
- 4. Slide: PrEP-Specific Competencies
  - (Review the competencies aloud.)
- 5. Slide: Training Overview (2 slides)
  - (Review the modules aloud.)

- 6. Slide: Ground Rules
  - For the training to be effective, the group will agree on some ground rules. These ground rules will help the training run smoothly, maximize learning, and encourage participation.
  - (Review the ground rules aloud.)
  - Do any other rules need to be added?
- 7. Ask what questions participants have about the training so far and answer accordingly.

#### Session 1.2. Pre-Program Assessment

Time: 25 minutes

Method: Pre-test

#### **Materials**

- Module 1 slides
- 1 pre-test for each participant

#### **Advance Preparation**

- Make 1 copy of the pre-program assessment for each participant
- Post slide: Pre-Program Assessment

- 1. Explain that participants will now complete a pre-assessment.
- 2. Slide: Pre-Program Assessment
  - The purpose of this assessment is to determine what you know about implementing PrEP. Your responses will help to determine if there is anything in this training that needs to be adjusted in the future.
  - We assume that you know little about PrEP, so do not worry if you do not know all of the answers.
  - You will have approximately 20 minutes to complete the pre-assessment.
  - Please give me your pre-assessment when you have finished.
- 3. Give participants the pre-assessment. As participants are working, circulate and help if needed.
- 4. Collect all pre-assessments.
- 5. Slide: Pre-Program Assessment Debrief
  - How did you feel about the pre-program assessment questions? Were they easy or difficult? Why or why not?
  - You will receive answers to the questions after you complete the post-test at the training's end.

#### Session 1.3. Introduction to Pre-Exposure Prophylaxis

Time: 20 minutes

Methods: Interactive trainer presentation, pair discussion

#### **Learning Objectives**

After completing this session, participants will be able to:

- Define PrEP.
- Differentiate PrEP from PEP and 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 the local level.

#### **Materials**

• Module 1 slides

#### **Advance Preparation**

- Prepare a few slides presenting local HIV epidemiology.
- Post slide: PrEP Training for Providers in Clinical Settings

**Note:** During this and other interactive trainer presentations, you may suggest that participants keep their participant manuals closed as they attend to the presentation. However, some participants may wish to follow along in their manuals; participants may decide which they prefer.

- 1. Slide: PrEP Training for Providers in Clinical Settings
  - (Review the information on the slide.)
- 2. Slide: Module 1
  - The next several sessions will cover Module 1 content.
- 3. Slide: Module 1 Learning Objectives (2 slides)
  - (Review the learning objectives aloud.)
- 4. Slide: Introduction
  - (Review the information aloud.)
- 5. Slide: Combination Prevention
  - (Review the information aloud.)
  - This training will focus on biomedical interventions, specifically the use of ARV for pre-exposure prophylaxis (PrEP).
- 6. Slide: Question
  - What is Pre-Exposure Prophylaxis (PrEP)?

- 7. Take a few volunteer responses and then show the next slide.
- 8. Slide: Pre-Exposure Prophylaxis (PrEP)
  - (Review the information aloud.)
  - The concept of providing a preventive drug before exposure to an infectious agent is not new. We have been using this concept for other diseases (e.g., for malaria prophylaxis—taking anti-malarial drugs before traveling to an endemic area to prevent infection).
- 9. Slide: Question
  - What is Post-Exposure Prophylaxis (PEP)?
- 10. Take a few volunteer responses and then show the next slide.
- 11. Slide: Post-exposure Prophylaxis (PEP)
  - (Read the definition aloud.)
- 12. Slide: Questions
  - 1) What are some similarities and differences between Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP)?
  - 2) What are the main differences between ART and PrEP?
- 13. Ask participants to turn to the person next to them and discuss in pairs for a few minutes the 2 questions on the slide. (Participants do not need to write anything.)
- 14. After a few minutes, ask for some volunteer responses to question 1.
- 15. Then show Slide: Comparing PrEP and PEP
  - (Review the comparisons aloud.)
- 16. Slide: Questions
  - (Ask for some volunteer responses to question 2.)
- 17. Then show Slide: Differences between ART and PrEP
  - (Review the information aloud.)
- 18. Slide: Why We Need PrEP
  - (Review the information aloud.)
- 19. Slide: Local HIV Epidemiology
  - (Explain local HIV epidemiology, where most new HIV infections are happening, and the different KPs targeted for PrEP use at a local level.)

- 20. Slide: Question
  - Who are key populations (KPs) or other populations targeted for PrEP at the local level?
- 21. Take some volunteer responses and confirm or correct as needed.
- 22. Ask what questions participants have about the content presented thus far, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 23. Explain that the content covered in this session is in the participant manual. Participants may review the content during a break or lunch.

#### Session 1.4. Evidence that PrEP Works

Time: 35 minutes

Methods: Small group activity, interactive trainer presentation

#### **Learning Objectives**

After completing this session, participants will be able to:

- Explain the relationship between PrEP effectiveness and adherence.
- State key reasons why PrEP is needed.

#### **Materials**

• Module 1 slides

#### **Advance Preparation**

- Decide how you will divide participants into small groups (by counting or another method).
- Review the PrEP Studies information in the participant manual.
- Post slide: Small Group Activity

- 1. Explain that participants will now work in small groups to review studies that examined the effectiveness of PrEP.
- 2. Divide participants into small groups of 4-6 participants each.
- 3. Slide: Small Group Activity
  - (Explain the small group activity.)
- 4. As small groups are working, circulate and help as needed.
- 5. When groups have finished, ask each of the questions in turn and take volunteer responses from small groups. Confirm or correct responses as needed.
- 6. Present the next 2 slides in order to summarize and confirm what participants have deduced from the studies.
- 7. Slide: Evidence PrEP Works
  - (Review the information aloud.)
- 8. Slide: PrEP Efficacy Depends on Adherence
  - (Review the information aloud.)
- 9. Slide: Question
  - How would you define adherence?

- 10. Take a few volunteer responses and confirm or correct as needed.
- 11. Slide: Defining Adherence
  - (Read the definition aloud.)
- 12. Slide: Planned, Ongoing, and Completed PrEP Evaluation Studies
  - This slide shows planned, ongoing, and completed PrEP studies as of June 2015. You can get updated information on the PrEPwatch website.
- 13. Slide: Summary
  - (Summarize as needed.)

#### Session 1.5. PrEP Regimens, Side Effects, HIVDR, and STIs

Time: 20 minutes

Methods: Interactive trainer presentation, pair discussion, large group discussion

#### **Learning Objectives**

- Specify the PrEP regimens approved by WHO and within one's own country.
- Identify concerns regarding the implementation of PrEP.
- Explain the risks and benefits of PrEP.

#### Materials

• Module 1 slides

#### **Advance Preparation**

- Add country-specific data to Slide: ARVs Recommended for Oral PrEP.
- Post slide: ARVs Recommended for Oral PrEP.

- 1. Slide: ARVs Recommended for Oral PrEP
  - This training focuses on daily oral PrEP.
  - (Provide country-specific data here.)
- 2. Slide: PrEP Side Effects: Reports from RCTs
  - (Review the information aloud.)
- 3. Slide: Side-effects Reported from iPrEx Open-Label Extension (iPrEx OLE)
  - (Review the information aloud.)
  - Participants in the study reported a "start syndrome" with GI symptoms, headaches and some skin problems. This start—up syndrome was transient in most cases, and it is important to counsel clients about this.
- 4. Slide: Will PrEP users engage in more risk behaviors?
  - (Review the information aloud.)
- 5. Slide: Will PrEP lead to more HIV drug resistance (HIVDR)?
  - o (Review the information aloud.)
- 6. Slide: Questions
  - 1) Does PrEP protect against other STIs?
  - 2) What can people do to protect themselves against STIs while they are taking PrEP? What should the package of prevention services include?
- 7. Ask participants to turn to the person next to them and discuss in pairs for a few minutes the 2 questions on the slide.

- 8. After a few minutes, ask for some volunteer responses to the questions.
- 9. Then show Slide: Does PrEP protect against other STI?
  - (Review the information aloud.)
- 10. Slide: Module 1 Summary
  - (Read the summary aloud.)
- 24. Ask what questions participants have about the content presented in Module 1, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 25. Explain that the content covered in this session is in the participant manual. Participants may review the content during the break or lunch.
- 26. Slide: Morning Break
  - We will reconvene in 15 minutes.

## MODULE 2: PrEP Screening and Eligibility

#### TIME: 4 hours 10 minutes

#### **OBJECTIVES**

#### 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 acute HIV infection.

#### **MATERIALS**

- Module 2 slides (needed for all Module 2 sessions)
- Session 2.4 Clinical scenarios 1-4 (below and in slides and participant manual)
- Session 2.5 Screening role-play scenarios (below and in participant manual)
- Photocopies of the Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility form, 1 for each trainer and participant (in participant folder)

#### ADVANCE PREPARATION

- Add your country's national HIV testing algorithm to the algorithm slide.
- Review the Session 2.4 clinical scenarios.
- Review the Session 2.5 Screening Role-play Scenario for Trainers (below).
- Review the Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility form.
- Ask your fellow trainer or an experienced colleague to be prepared to perform the roleplay with you during this session. Practice ahead of time if possible.
- Review Screening Role-play Scenarios 1 and 2 (below and in participant manual).
- Decide how you will divide participants into pairs so that they work with someone new, not just the person next to them.
- Decide how you will divide participants into small groups (by counting or another method).

## Session 2.1. Eligibility Criteria – HIV Testing & Acute HIV Infection

Time: 15 minutes

**Methods:** Interactive trainer presentation

#### **Learning Objectives**

After completing this session, participants will be able to:

- Name the 5 main eligibility criteria for PrEP.
- Explain how to exclude acute HIV infection.
- Name the contraindications for PrEP.

#### **Materials**

• Module 2 slides

#### **Advance Preparation**

- Post slide: Module 2
- Add your country's national HIV testing algorithm to the algorithm slide.

- 1. Slide: Module 2
  - The next several sessions will cover Module 2 content.
- 2. Slide: Module 2 Learning Objectives
  - (Review the learning objectives aloud.)
- 3. Slide: WHO Recommendations
  - (Review the information aloud.)
- 4. Slide: Questions
  - Who should receive PrEP?
  - What are the eligibility criteria for initiating PrEP?
- 5. Take a few volunteer responses and then show the next slide.
- 6. Slide: Eligibility for PrEP
  - (Read the eligibility criteria aloud.)
- 7. Slide: Exclude HIV infection before starting PrEP
  - (Review the information aloud.)
- 8. Slide: National HIV Testing Algorithm
  - (Review your county's HIV testing algorithm aloud.)

- 9. Slide: Question
  - What is acute HIV infection?
- 10. Take a few volunteer responses and then show the next slide.
- 11. Slide: Acute HIV Infection
  - (Review the information aloud.)
- 12. Slide: Main Symptoms of Acute HIV Infection
  - An estimated 40-90 percent of patients with acute HIV infection will experience 'flu-like" symptoms which usually appear days to weeks after exposure and include:
    - o Fever
    - o Fatigue
    - o Anorexia
    - o Rash (often erythematous maculopapular)
    - o Pharyngitis
    - o Generalized lymphadenopathy
    - o Mucocutaneous ulceration
    - o Headache
    - o Aseptic meningitis
    - o Radiculitis, myelitis
    - o May present with OI, thrush, zoster (if CD4 depressed)
  - These symptoms are not specific to HIV; they occur in many other viral infections.
  - Remember that some patients with acute HIV infection will be asymptomatic.
- 13. Slide: Question
  - Why must you diagnose for acute HIV infection before prescribing PrEP?
- 14. Take a few volunteer responses and then show the next slide.
- 15. Slide: Diagnosis of Acute HIV Infection
  - (Review the information aloud.)
- 16. Ask participants what questions they have about the content presented thus far, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 17. Remind participants that the information presented in this session is in their manuals. They may review the information during a break or lunch.

#### Session 2.2. Eligibility Criteria – Substantial Risk of HIV Infection

Time: 40 minutes

Methods: Small group brainstorm, interactive trainer presentation

#### **Learning Objectives**

After completing this session, participants will be able to:

• Name the 5 main eligibility criteria for PrEP.

#### **Materials**

Module 2 slides

#### **Advance Preparation**

- Post Slide: Question
- Decide how you will divide participants into small groups (by counting or another method).

- 1. Slide: Question
  - Who is at substantial risk for HIV infection?
- 2. Take a few volunteer responses and then show the next slide.
- 3. Slide: Substantial Risk for HIV Infection
  - (Review the risk categories aloud.)
- 4. Explain that participants will practice using a screening form in order to determine eligibility. But first, participants will work in small groups to brainstorm the types of questions that providers should ask in order to screen for substantial risk.
- 5. Divide participants into small groups of 4-6 participants each.
- 6. Slide: Small Group Brainstorm
  - Close your participant manuals. With your small group, brainstorm a list of questions to screen for substantial risk.
  - Please keep in mind that you must ask about the person's sexual behaviors, their partners' sexual behaviors, issues with serodiscordant couples, and other aspects of a person's situation, for example their current life circumstances.
  - Choose one group member to record your questions on a sheet of notebook paper.
  - 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 types of questions you missed. Also note any questions on
    your list that do not appear in the manual.
  - You will have 15 minutes to work.

- 7. As small groups are working, circulate and help as needed.
- 8. When small groups have finished, post Slide: Screening for Substantial Risk
  - Asking questions should not be seen as a way of rationing PrEP or excluding people from PrEP services.
  - Screening questions can be used to introduce the consideration of PrEP and to offer PrEP to people who are attending services but had not presented specifically to access PrEP.
- 9. Slide: General Screening Questions
  - Of these questions, which did you include in your brainstormed lists (more or less)?
  - Did you brainstorm any questions NOT on this list? What questions? Why would you ask these?
- 10. Confirm or correct participants' responses as needed. Make sure to take responses from all small groups.
- 11. Point out that a client's ability to adhere to a daily regimen is important, and that adherence will be discussed in greater detail later in this training.
- 12. Slide: Serodiscordant Couples
  - (Review the information on the slide aloud.)
  - ART that suppresses viral load is highly effective for preventing transmission to partners.
  - PrEP may provide additional protection to serodiscordant couples in a number of situations.
  - In addition, any sign of intimate partner violence (IPV), controlling behavior, or anger or fear in response to questions about HIV treatment should prompt discussion about PrEP as a way to control risk for HIV.
- 13. Slide: For a Person Who Has a Partner with HIV
  - These types of questions aim to assess whether the partner with HIV is virally suppressed, and the level of risk during sex (are condoms used).
  - Of these questions, which did you include in your brainstormed lists (more or less)?
  - Did you brainstorm any questions NOT on this list? What questions? Why would you ask these?

- 14. Slide: Additional Factors to Ask About
  - These types of questions help to identify additional proximate factors that might give you context and help you to better understand the client's level of risk.
  - (Repeat the process for the previous slide.)
- 15. Explain that in later sessions, participants will practice using a standard PrEP screening form.

## Session 2.3. Eligibility Criteria – Creatinine Clearance, Pregnancy, and Willingness to Use PrEP as Prescribed

Time: 15 minutes

**Methods:** Interactive trainer presentation

#### **Learning Objectives**

After completing this session, participants will be able to:

- Name the 5 main eligibility criteria for PrEP.
- Name the contraindications for PrEP.

#### **Materials**

• Module 2 slides

#### **Advance Preparation**

• Post slide: Creatinine and Estimated Creatinine Clearance

- 1. Slide: Creatinine and Estimated Creatinine Clearance
  - (Review the information and equation aloud.)
- 2. Slide: Online Cockcroft-Gault Calculator
  - You can also use an online calculator to calculate the eGFR.
  - Let's use the example of a 26 year-old woman with a weight of 55Kg and serum creatinine is 6.9 umol/L.
- 3. Slide: Question
  - Is PrEP safe during pregnancy?
- 4. Take a few volunteer responses and then show the next slide.
- 5. Slide: PrEP Use during Pregnancy
  - Several systematic reviews have evaluated TDF safety in pregnant women with chronic hepatitis B (HBV) and TDF safety in pregnant women living with HIV.
  - FEM-PrEP and Partners PrEP also evaluated effects of PREP on adverse pregnancy-related events, however the study drug was discontinued for women once pregnancy was confirmed across trials; therefore, the effect of PrEP throughout pregnancy duration was not assessed.
  - TDF appears to be safe in pregnancy, and while the safety data are reassuring, most are not from the population of interest HIV-uninfected women.
  - PrEP benefits in women at high risk of HIV acquisition appear to outweigh any risks observed to date.

- As PrEP in women of childbearing age is implemented, it will be important to continue surveillance of maternal, pregnancy, and infant outcomes to confirm the safety that reviews to date suggest.
- 6. Slide: Willingness to Use PrEP as Prescribed
  - (Review the points aloud.)
  - Education and counseling is provided to support clients to make an informed choice about PrEP.
  - Clients should not be coerced into using PrEP.
- 7. Slide: Eligibility Criteria Recap
  - (Review the criteria aloud.)
- 8. Ask what questions participants have about criteria for PrEP eligibility, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 9. Remind participants that the information presented in this session is in their manuals. They may review the information during a break or lunch.
- 10. Slide: Lunch
  - We will reconvene in 30 minutes.

## Session 2.4. PrEP Eligibility - Screening Tool

Time: 1 hour

Methods: Small group scenarios, large group discussion

#### **Learning Objectives**

After completing this session, participants will be able to:

- Name the 5 main eligibility criteria for PrEP.
- Use the standard medical screening form to determine PrEP eligibility and substantial risk.

#### **Materials**

- Module 2 slides
- Clinical scenarios 1-4 (below, in Module 2 slides, and in the participant manual)

#### **Advance Preparation**

- Review the clinical scenarios (below).
- Review the Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility form.
- Decide how you will divide participants into small groups (by counting or another method).
- Post slide: Standard PrEP Screening Form

- 1. Slide: Standard PrEP Screening Form
  - In the brainstorming session, we identified what types of questions you must ask in order to screen for PrEP eligibility.
  - Use of a standard form can ensure that screening is done in a consistent manner and is well documented.
  - Please find the Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility form in your participant manuals.
- 2. Review the form sections briefly with participants.
  - Section 4: This section provides question prompts that will help you to determine if the client belongs to each category. You may need to use other prompts as well, for example, the questions that you brainstormed earlier about serodiscordant couples, proximate factors, etc.
  - Section 6: This section's questions will help you to assess suspected acute HIV infection. Remember that you must exclude AHI in order to prescribe PrEP.
- 3. Explain that participants will now work on scenarios in small groups in order to practice determining eligibility for PrEP.
- 4. Divide participants into small groups of 4-6 participants each (different groups from previous sessions).

- 5. Slide: Small Group Clinical Scenarios
  - Read the clinical scenario assigned to your small group.
  - Then discuss the scenario questions.
  - Refer to the PrEP screening tool during your discussion as needed.
  - You will have 10 minutes to work.
- 6. Assign each small group one of the clinical scenarios (you may need to assign more than one group to each scenario).
- 7. As small groups are working, circulate and help as needed.
- 8. When small groups have finished work, post Slide: Clinical Scenario 1
  - Would someone from the group(s) that discussed this scenario please read the scenario aloud?
  - How did your small group answer the scenario questions?
  - What questions or comments do other small groups have about this scenario?
- 9. Take volunteer responses and confirm or correct as needed. Encourage a discussion.
- 10. Slides: Clinical Scenarios 2, 3, and 4 (3 slides)
  - (Repeat the process from Clinical Scenario 1.)
- 11. Explain that these clinical scenarios have given participants some practice working with the eligibility criteria. In the next session, participants will practice using the screening form.
- 12. Slide: Afternoon Break
  - We will reconvene in 15 minutes.

**Note:** You may wish to revise and adapt these scenarios, or write new ones, to reflect participants' local context and client populations, or to include client situations more relevant to your area.

#### Clinical Scenario 1

Joseph is a 22 year-old man who 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 is taking no medications. His rapid HIV antibody test today is negative.

Is Joseph a candidate for PrEP?

• Yes

If so, what did you consider in order to determine eligibility?

- Joseph is at substantial risk for HIV infection (intercourse without condoms, partner with HIV)
- Joseph's partner's viral load
- Rapid HIV antibody test window
- No other eligibility issues. Any potential modifiable challenges or barriers should not be equated with eligibility. Eg., we know he is 'in good health' so he might have limited experience taking a daily medication. Developing the habit can be a topic for adherence education and counseling.

#### Clinical Scenario 2

Marie is an 18 year-old woman who presents at 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 two children. Some of her partners have used condoms and others have not. She does not know if 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?

- Yes, if she does not have AHI or creatinine clearance greater than 60ml/min If so, why?
  - Marie is at substantial risk (multiple partners sometimes without condoms)

What other information would you need in order to determine eligibility?

- AHI must be ruled out
- Creatinine clearance must be determined

#### 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?

• Yes

If so, why?

• Geraldine is at substantial risk (partner possibly using drugs)

What other information might you need in order to determine eligibility?

• AHI must be ruled out; creatinine clearance determined

#### 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?

• Not at this visit.

Why?

• Daniel is possibly at substantial risk (a possible STI) but has declined HIV testing.

## Session 2.5. PrEP Screening Tool Practice

Time: 2 hours

Methods: Role-play, large group discussion

#### **Learning Objectives**

After completing this session, participants will be able to:

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

#### **Materials**

- Module 2 slides
- Screening role-play scenarios (below and in participant manual)
- Photocopies of the Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility form, 1 for each trainer and participant (in participant folder)

#### **Advance Preparation**

- Review the Screening Role-play Scenario for Trainers (below).
- Ask your fellow trainer or an experienced colleague to be prepared to perform the roleplay with you during this session. Practice ahead of time if possible.
- Review Screening Role-play Scenarios 1 and 2 (below).
- Decide how you will divide participants into pairs so that they work with someone new, not just the person next to them.

**Note:** if you are short on time, you may need to shorten or skip 3 of this session. For example, you may choose to not have a pair perform in Part 3.

#### **Steps**

Part 1 – Trainer role-play (30 minutes)

- 1. Invite your fellow trainer or colleague to the front of the room. Explain that you will perform a role-play where a clinician screens someone for PrEP eligibility using the screening tool. Ask participants to listen and watch carefully, and follow along with the forms in their participant manuals.
- 2. Perform the role-play (5-10 minutes). The person playing the clinician should use the screening tool while role-playing, as if with a real client.
- 3. Debrief the role-play with Slide: Trainer Role-play Debrief
  - Based on the role-play, how would you complete Section 5 of the screening tool?
     What other information would you need to gather in order to determine eligibility?
  - What was most challenging about this screening?
  - How did the clinician handle the challenges?
  - What other questions or comments do you have about the role-play?

4. Take volunteer responses and encourage a discussion. Summarize challenges and strategies as needed.

#### Part 2 – Participant role-play 1 (45 minutes)

- 5. Explain that participants will now role-play in pairs in order to practice using the screening tool.
- 6. Divide participants into pairs (different pairs from previous sessions) and give each participant a copy of the screening tool.
- 7. Slide: Screening Role-play 1
  - Find Screening Role-play Scenario 1 in your manuals.
  - Decide who will play the clinician 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 clinician should use the screening tool and complete it as if he/she were interviewing a real client. Start with Section 3 of the form.
  - As you are practicing, I will observe and choose a pair perform. I will not tell you which pair I choose, so everyone must be prepared to perform.
  - You will have 15 minutes to work.
- 8. As pairs are working, circulate, observe role-playing, and help as needed.
- 9. As you circulate and observe, choose a pair to perform. Do not tell participants whom you have chosen.
- 10. When pairs have role-played for about 15 minutes, call everyone's attention.
- 11. Slide: Screening Role-play 1 Debrief. Encourage a discussion:
  - Based on the role-play, how would you complete Section 5 of the form? What other information would you need in order to determine eligibility?
  - 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?
- 12. Ask a pair of participants to come to the front of the room and perform the role-play (5-10 minutes).
- 13. Slide: Screening Role-play Performance Debrief
  - What challenges did the clinician encounter and how did she/he handle them?
  - What did the clinician do well?
  - What could the clinician improve the next time around?'

#### Part 3 – Participant role-play 2 (45 minutes)

- 14. Slide: Screening Role-play 2
  - Repeat the process for Role-play Scenario 1 and debrief. Participants who played the clinician for Role-play Scenario 1 should play the client; those who played the client should play the clinician.
- 15. Slide: Screening Role-play 2 Debrief
- 16. Slide: Module 2 Summary
  - (Read the summary points aloud.)
- 17. Thank participants for their participation and work during Day 1.

**Note:** You may wish to revise and adapt these scenarios, or write new ones, to reflect participants' local context and client populations, or to include client situations more relevant to your area.

#### Screening Role-play Scenario for Trainers

Gabrielle is a 25 year-old married woman. She has come to the clinic for a routine maternal/child health visit, and confides to the nurse attending too her that she is distressed because of her husband's behaviour. Lately, he has been staying out all night sometimes and refuses to tell her where he has been. Gabrielle has seen marks on his arms. She is afraid that he might be using drugs. She is worried that he is at risk of acquiring diseases through injecting behaviour.

Despite the problems with her husband, Gabrielle has sex (vaginal) with her husband almost every week. Her husband does not like to use condoms. Gabrielle does not know if her husband has HIV or not, as he refuses to get tested; he says that such tests are for "bad people." She fears, though, that he may be having sex with other women.

Gabrielle has not had any STIs. She has not taken PEP. She last had sex with her husband 2 nights ago. She feels fine and does not have a fever, or cold or flu-like symptoms.

**Instructions:** Skip sections 1 and 2 of the screening tool. Role-play Sections 3, 4, and 6 of the screening tool. (After the role-play, you will ask participants how they would complete Section 5.)

#### Screening Role-play Scenario 1

Justine is a 19 year-old sex worker with a live-in boyfriend. She was born a male but has been living as a woman since she was 15 years old. She has had sex with multiple partners (men) during the last six months, a few times without condoms. She does not know if she has any STIs, but she has no symptoms.

Justine's boyfriend is living with HIV and he has been on ART for about 1 year. He has adhered to the treatment regimen very well and is in good health. Justine is proud of him for this. Justine and her boyfriend use condoms during sex.

A few weeks ago, Justine was tested for HIV after a scary encounter with a client. The test was negative. Justine has come to the clinic today because she is feeling poorly. She has had a fever and chills in recent days, and wants medicine in order to feel better.

**Instructions:** Skip sections 1 and 2 of the screening tool. Role-play Sections 3, 4, and 6 of the screening tool. After the role-play, you will complete Section 5 with the whole group. In addition to the question prompts in Section 4, you may need to use other questions such as the ones brainstormed earlier.

## Screening Role-play Scenario 2

Lucien is 25 years old. He is a sexually active married man who has sex regularly with his wife, and also with men outside of his marriage. His wife does not know about the sex with men. Lucien insists on using condoms during sex with men, but he does not use condoms with his wife

Lucien has come to the clinic because the last time he was with a man, the condom broke and he is worried that he might have gotten HIV. He does not know the HIV status of his male sex partners. He assumes that his wife does not have HIV but she has not been tested. He does not use drugs or share injecting material with others.

**Instructions:** Skip sections 1 and 2 of the screening tool. Role-play Sections 3, 4, and 6 of the screening tool. After the role-play, you will complete Section 5 with the whole group. In addition to the question prompts in Section 4, you may need to use other questions such as the ones brainstormed earlier.

## MODULE 3: Initial and Follow-Up PrEP Visits

#### TIME: 4 hours 15 minutes

#### **OBJECTIVES**

#### After completing Module 3, participants will be able to:

- Specify the procedures for the initial PrEP visit.
- Demonstrate knowledge of national HTS guidelines and local algorithms for HIV testing.
- Describe the rationale and content for brief counseling during the initial PrEP visit.
- Follow the Integrated Next Step Counseling (iNSC) process to counsel clients on sexual health and PrEP adherence.

#### **MATERIALS**

- Module 3 slides (needed for all Module 3 sessions)
- Session 3.3 iNSC Role-play Scenarios (below and in participant manual)
- Photocopies of the table of iNSC steps, components, and examples, 1 for each trainer and participant (in participant manual)
- 2 blank sheets of flip chart paper
- Marker (for writing on the flip chart paper)

#### ADVANCE PREPARATION

- Review the iNSC Role-play Scenario for Trainers (below).
- Ask your fellow trainer or an experienced colleague to be prepared to perform the roleplay with you during this session. Practice ahead of time if possible.
- Review the Session 3.3 iNSC Role-play Scenarios 1 and 2 (below and in participant manual).
- Post 2 blank sheets of flip chart paper on the wall or easel where everyone can see them. Label one sheet "PrEP Challenges" and the other, "PrEP Strategies."
- Decide how you will divide participants into pairs so that they are with different partners from the previous role-play session.
- Decide how you will divide participants into small groups (by counting or another method).

## Session 3.1. Initial Counseling: Key Messages

Time: 15 minutes

**Methods:** Interactive trainer presentation

#### **Learning Objectives**

After completing this session, participants will be able to:

- Specify the procedures for the initial PrEP visit.
- Describe the rationale and content for brief counseling during the initial PrEP visit.

#### **Materials**

• Module 3 slides

#### **Advance Preparation**

• Post Slide: Module 3

- 1. Slide: Module 3
  - The next several sessions will cover Module 3 content.
- 2. Slide: Module 3 Learning Objectives
  - (Review the learning objectives aloud.)
- 3. Slide: Initial PrEP Visit: Suggested Procedures
  - After you have determined that a client is eligible for PrEP, your initial PrEP visit with the client should follow these suggested procedures.
  - (Review the procedures on the slide.)
- 4. Slide: Initial PrEP Counseling
  - Before the client starts PrEP, you should counsel the client (this is the last of the suggested procedures from the previous slide).
  - This initial counseling should focus on these areas.
  - (Review the counseling points on the slide aloud.)
- 5. Slide: Initial PrEP Counseling (cont.)
  - (Review the counseling points on the slides aloud.)
- 6. Slide: PrEP Counseling
  - (Read the slide aloud.)
- 7. Slide: Key Initial Visit Counseling Messaging: PrEP Efficacy
  - These are key messages that you should give during counseling at the initial visit. These messages emphasize how PrEP works best.
  - (Review the messages on the slide aloud.)

- 8. Slide: Key Initial Counseling Messaging: Supporting Adherence
  - These messages will help the client to adhere to the PrEP regimen.
  - (Review the messages on the slide aloud.)
- 9. Ask what questions participants have about the information presented thus far, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 10. Remind participants that the information presented in this session is in their manuals. They may review the information during a break or lunch.

## Session 3.2. Initial Counseling: Adherence Support

Time: 45 minutes

Methods: Small group brainstorm, large group discussion

#### **Learning Objectives**

After completing this session, participants will be able to:

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

#### **Materials**

• Module 3 slides

#### **Advance Preparation**

- Post Slide: Small Group Brainstorm
- Decide how you will divide participants into small groups (by counting or another method).

- 1. Explain that a crucial part of initial PrEP counseling is to support adherence. Participants will now work in small groups to brainstorm the reasons for low adherence and ways to support adherence.
- 2. Divide participants into small groups of 4-6 participants each.
- 3. Slide: Small Group Brainstorm
  - Close your participant manuals.
  - With your small group, you will brainstorm one of these questions:
    - o 1) What are some common reasons for low adherence? Remember to include individual, medication, and structural reasons.
    - 2) What can providers do in order to promote and support adherence?
       Include counseling and programmatic strategies.
  - Choose one group member to record your questions on a sheet of notebook paper.
  - You will have 10 minutes to work.
- 4. Assign each small group either Question 1 or Question 2.
- 5. As small groups are working, circulate and help as needed.

- 6. When small groups have finished, post Slide: Common Reasons for Low Adherence to ART
  - (Review the *individual* factors on the slide aloud.)
  - Small groups that brainstormed Question 1 which of these factors did you include on your brainstormed lists? Which did you miss? What other factors did you brainstorm (if any)?
  - (Repeat this process for the *medication* factors and *structural* factors on the slide.)
  - Remember that reasons for low adherence may be related to the client, the ARV drug regimen, or the health system.
- 7. Slide: Understanding Voluntary vs. Involuntary Non-adherence (2 slides)
  - It is helpful to think about non-adherence as voluntary or involuntary non-adherence in order to better target adherence support strategies.
- 8. Slide: Adherence: Lessons from ART Programs
  - The health provider can support adherence by learning from ART programs some of the general strategies that have been shown to positively influence adherence.
  - (Review the points on the slide aloud.)
  - Small groups that brainstormed Question 2 which of these points did you include on your brainstormed lists? Which did you miss?
- 9. Slides: Approaches to PrEP Medication Adherence Support (2 slides)
  - The provider can use each of the options/strategies on the right side of the table to address each of the specific support issues listed on the left side of the table.
  - (Review the support issues and provider options on the slide aloud.)
  - Small groups that brainstormed Question 2 which of these points did you include on your brainstormed lists? Which did you miss? What other approaches did you brainstorm (if any)?
- 10. Slide: Adherence Assessments
  - Note that measuring drug levels in blood and hair samples is more expensive than the other options.
- 11. Remind participants that, in addition to the adherence strategies presented here (which are also in the participant manual), they should make note of any other strategies named by participants during the brainstorm that are appropriate for their context and setting.

## Session 3.3. Integrated Next Step Counseling (iNSC)

Time: 2 hours

Methods: Role-play, large group discussion

#### **Learning Objectives**

After completing this session, participants will be able to:

• Follow the recommended Integrated Next Step Counseling (iNSC) process to counsel clients on sexual health and PrEP adherence.

#### **Materials**

- Module 3 slides
- iNSC Role-play Scenarios (below and in participant manual)
- Photocopies of the table of iNSC steps, components, and examples, 1 for each trainer and participant (in participant manual)

#### **Advance Preparation**

- Post Slide: Promoting Adherence
- Review the iNSC Role-play Scenario for Trainers (below).
- Ask your fellow trainer or an experienced colleague to be prepared to perform the roleplay with you during this session. Practice ahead of time if possible.
- Review iNSC Role-play Scenarios 1 and 2 (below).
- Decide how you will divide participants into pairs so that they are with different partners from the previous role-play session.

**Note:** Schedule the morning break for after Part 1 or Part 2 of this session (or before this session if you are running late). If you are running short on time, you may choose not to have a pair perform in Parts 3 and/or 4.

#### **Steps**

Part 1 – Introduction to iNSC (10 minutes)

- 1. Slide: Promoting Adherence
  - (Review the approaches on the slide aloud.)
  - In this session, we will learn more about one of these approaches Integrated Next Step Counseling (iNSC).
- 2. Slide: Integrated Next Step Counseling (iNSC)
  - (Review the information on the slide aloud.)
- 3. Slide: Figure 1: iNSC Process Discussion Flow
  - This is the recommended flow for a step-by-step counseling process that leads to clear strategies and formal plans for PrEP use and non-PrEP-related sexual health
  - (Review the steps on the slide aloud.)

- 4. Slide: Table of iNSC steps, components, and examples
  - o (Review each step, component, and example aloud.)

#### Part 2 – Trainer Role-play (20 minutes)

- 5. Invite your fellow trainer or colleague to the front of the room. Explain that you will perform a role-play where a provider conducts Integrated Next Step Counseling with a client.
- 6. Slide: Clinical Scenario for Role-play
  - (Read the scenario aloud.)
  - 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.
- 7. Perform the role-play (5-10 minutes).
- 8. Debrief the role play with Slide: 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?
- 9. Take volunteer responses and encourage a discussion. Summarize challenges and strategies as needed.
- 10. Slide: Morning Break
  - We will reconvene in 15 minutes.

#### Part 3 – Participant role-play 1 (45 minutes)

- 11. Explain that participants will now role-play in pairs in order to practice following the iNSC steps when counseling clients on PrEP adherence.
- 12. Divide participants into pairs (different pairs from previous sessions) and give each participant a copy of the iNSC steps, components, and examples.
- 13. Slide: 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/she were counselling a real client.

- As you are practicing, I will observe and choose a pair perform. I will not tell you which pair I choose, so everyone must be prepared to perform.
- You will have 15 minutes to work.
- 14. As pairs are working, circulate, observe role-playing, and help as needed.
- 15. As you circulate and observe, choose a pair to perform. Do not tell participants whom you have chosen. (Choose a different pair from Module 2.)
- 16. When pairs have role-played for about 15 minutes, call everyone's attention.
- 17. Slide: iNSC Role-play 1 Debrief. Encourage a discussion:
  - 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?
- 18. Ask a pair of participants to come to the front of the room and perform the role-play (5-10 minutes).
- 19. Slide: 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 clinician improve the next time around?

#### Part 4 – Participant role-play 2 (45 minutes)

- 20. Slide: iNSC Role-play 2
  - (Repeat the process for Role-play Scenario 1 and debrief. Participants who played the provider for Role-play Scenario 1 should play the client; those who played the client should play the provider.)
- 21. Slide: iNSC Role-play 2 Debrief
- 22. Slide: Key Initial Visit Consideration: Drug Supply
  - (Review the information on the slide aloud.)
- 23. Provider Checklist for Initial PrEP Visit
  - Please find this checklist in your participant manuals. You may customize this checklist to align with national guidelines.
  - (Review the checklist aloud.)
- 24. Slide: Lunch
  - We will re-convene in 30 minutes.

**Note:** You may wish to revise and adapt these scenarios, or write new ones, to reflect participants' local context and client populations, or to include client situations more relevant to your area.

#### iNSC Role-play Scenario for Trainers

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

#### iNSC Role-play Scenario 1

Geraldine, a 30 year-old wife and mother, is interested in starting PrEP. She presented at the clinic because she heard that she could get drugs that will prevent her from getting HIV. She suspects that her husband has been injecting drugs and 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 was negative. She is eager to start PrEP but is worried that her husband might see her taking pills and become abusive or make her stop taking the medication.

#### iNSC Role-play Scenario 2

Joseph is a 22 year-old man who presented 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 is taking no medications. His rapid HIV antibody test today was negative. Joseph reports that he loves to live life from moment to moment. He says that he is not good at "following orders" and is worried that he might forget to take his pills.

## Session 3.4. PrEP Follow-up Visits

Time: 25 minutes

Methods: Interactive trainer presentation, large group discussion

#### **Learning Objectives**

After completing this session, participants will be able to:

- Specify the suggested procedures for follow-up PrEP visits.
- Describe the rationale and content for follow-up counseling at each visit.

#### **Materials**

Module 3 slides

#### **Advance Preparation**

• Post Slide: PrEP Follow-up Visits

- 1. Slide: PrEP Follow-up Visits
  - o (Review the points on the slide.)
- 2. Slide: Follow-up PrEP Visit Procedures
  - During the follow-up visit repeat the HIV test to confirm HIV-negative status.
     You need repeat HIV testing to inform decisions on whether to continue or discontinue PrEP.
  - Repeat HIV testing:
    - o One month after starting PrEP
    - o Every three months thereafter
  - Programs should use national HIV testing algorithms.
  - It is useful to remember that the main limitation of serological tests is that they will not detect acute HIV infection, which must be clinically assessed at every follow up visit.
- 3. Slide: Repeat HIV Testing
  - (Review the points on the slide aloud.)
- 4. Follow-up PrEP Counseling
  - (Review the points on the slide aloud.)
- 5. Slide: Provider Checklist for Follow-up PrEP Visits
  - Please find this checklist in your participant manuals.
  - (Review the checklist aloud.)
  - This checklist may be customized to align with national guidelines.
- 6. Slide: PrEP Clinical Pathway
  - Please find this checklist in your participant manuals.

- (Review the checklist aloud.)
- 7. This checklist may be customized to align with national guidelines.
- 8. Slide: Clinical Scenario for Discussion
  - (Read the scenario aloud.)
  - How would you manage this case?
- 9. Take volunteer responses and confirm or correct as needed. Encourage a brief discussion.
- 10. Make sure that these points are included in the discussion:
  - PrEP can be started and stopped as needed.
  - People can move through periods of substantial risk (change in sexual practices, change in relationship status, etc.).
    - Clients can choose to discontinue PrEP if they are no longer at substantial risk of HIV:
    - o Clients should inform the provider of their wish to stop PrEP.
    - o Provider should document HIV test result at the time of stopping PrEP.
    - o Providers should counsel about other prevention methods.
    - Clients wishing to restart PrEP later should undergo HIV testing and other baseline tests (covered in Module 2).
  - Please note that PrEP is also discontinued if:
    - O Client tests HIV positive (in which case you would refer for treatment and care).
    - o There is suspicion of acute HIV infection.
    - o There is an increase in creatinine clearance >60ml/min.
  - Discontinuation of TDF-containing PrEP in patients with active hepatitis B virus can cause exacerbations of hepatitis B (hepatic flare).
- 11. Ask what questions participants have about the information presented thus far, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 11. Remind participants that the information presented in this session is in their manuals. They may review the information during a break or lunch.

## Session 3.5. PrEP Challenges and Strategies

**Time:** 50 minutes

Methods: Small group brainstorm, large group discussion

#### Learning objectives

After completing this session, participants will be able to:

• Name typical challenges that facilities and providers may face when implementing PrEP, and strategies for addressing them.

#### **Materials**

- Module 3 slides
- 2 blank sheets of flip chart paper
- Marker (for writing on the flip chart paper)

#### Advance preparation

- Decide how you will divide participants into small groups (by counting or another method).
- Post 2 blank sheets of flip chart paper on the wall or easel where everyone can see them. Label one sheet "PrEP Challenges" and the other, "PrEP Strategies."
- Post slide: Small Group Brainstorm

- 1. Explain that participants have now learned about PrEP screening, and initial and follow up visits. In this session, they will consider challenges to implementing PrEP and how to address those challenges.
- 2. Divide participants into small groups of 4-6 participants each (different groups from previous sessions).
- 3. Slide: Small Group Brainstorm
  - With your small group, you will brainstorm responses to these questions:
    - o 1) What are some of the challenges you will face when implementing PrEP?
    - o 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.
- 4. As small groups are working, circulate and help as needed.
- 5. When small groups have finished, take one response to Question 1 from each group in turn, until all ideas have been shared. As small groups share ideas, write them briefly on the flip chart paper Labeled "PrEP Challenges."

- 6. Encourage a discussion. Participants may ask questions or comment on other small groups' ideas.
- 7. Repeat this process for Question 2.
- 8. Summarize by pointing out that participants have shared valuable strategies in this session. They may wish to write the strategies in their notebooks.
- 9. Slide: Module 3 Summary
  - (Review the points on the slide aloud.)
- 10. Leave the challenges and strategies sheets posted for the remainder of the training.
- 11. Slide: Afternoon Break
  - We will reconvene in 15 minutes.

# MODULE 4: Monitoring and Managing PrEP Side Effects, Seroconversion, and Stigma

TIME: 1 hour 15 minutes

#### **OBJECTIVES**

#### 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.

#### **MATERIALS**

- Module 4 slides (needed for all Module 4 sessions)
- 1 blank sheet of flip chart paper for each small group (groups of 4-6 participants each)
- 1 marker for each small group (for writing on flip chart paper)
- Tape (for posting flip chart sheets on the walls)

#### **ADVANCE PREPARATION**

 Decide how you will divide participants into small groups (by counting or another method).

## Session 4.1. Managing Creatinine Elevation, Seroconversion, and Special Situations

Time: 15 minutes

**Methods:** Interactive trainer presentation

#### **Learning Objectives**

After completing this session, participants will be able to:

- Explain how to manage creatinine elevation.
- List additional causes of creatinine elevation.
- Explain how to manage seroconversion.

#### **Materials**

• Module 4 slides

#### **Advance Preparation**

• Post Slide: Module 4

- 1. Slide: Module 4
  - The next several sessions will cover Module 4 content.
- 2. Slide: Module 4 Learning Objectives
  - (Review the learning objectives aloud.)
- 3. Slide: Monitoring Creatinine Elevation
  - (Review the points on the slide aloud.)
  - Ideally, clients should have eGFR measured at baseline and after six months of PrEP.
- 4. Slide: Question
  - How would you manage increase in creatinine clearance?
- 5. Take a few volunteer responses and then show the next slide.
- 6. Managing Creatinine Elevation
  - (Review the points on the slide aloud.)
- 7. Slide: Seroconversion on PrEP
  - In clinical trials there were very few cases of seroconversion on PrEP.
- 8. Slide: Question
  - How would you manage seroconversion on PrEP?

- 9. Take a few volunteer responses and then show the next slide.
- 10. Slide: Managing Seroconversion
  - (Review the points on the slide aloud.)
- 11. Slide: PrEP "Special Situations"
  - (Review the situations and recommendations on the slide aloud.)
- 12. Ask what questions participants have about the information presented thus far, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 13. Remind participants that the information presented in this session is in their manuals. They may review the information at the end of the training or at home.

## Session 4.2. Minimizing Stigma

Time: 1 hour

Methods: Small group brainstorm, gallery walk, interactive trainer presentation

#### **Learning Objectives**

After completing this session, participants will be able to:

- Develop strategies to minimize PrEP stigma.
- Give examples of gaps in knowledge about PrEP.
- Describe how PrEP M&E tools might be adapted for local use.

#### **Materials**

- Module 4 slides
- 1 blank sheet of flip chart paper for each small group (groups of 4-6 participants each)
- 1 marker for each small group
- Tape (for posting flip chart sheets on the walls)

#### **Advance Preparation**

- Post Slide: Minimizing PrEP Stigma
- Decide how you will divide participants into small groups (by counting or another method).

- 1. Slide: Minimizing PrEP Stigma
  - Key populations usually face stigma and discrimination. Use of PrEP may add more stigma.
- 2. Remind participants that they already have experience in dealing with the stigma related to HIV testing and ART services. Now they will brainstorm strategies for minimizing potential stigma associated with PrEP.
- 3. Divide participants into small groups of 4-6 participants each (different groups from previous sessions). Give each small group a sheet of flip chart paper and a marker.
- 4. Slide: 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.
- 5. As small groups are working, circulate and help as needed.

- 6. When small groups have finished, ask them to post their sheets with tape on the walls around the room. They should use all the walls so that sheets are not grouped too close together.
- 7. When sheets are posted, invite all participants to walk around the "gallery" and read the strategies on the sheets (5-10 minutes).
- 8. Ask participants to return to their seats.
- 9. Encourage a brief discussion by asking:
  - What strategies did small groups have in common?
  - What experiences with, or tips for, implementing these strategies can you share with the group?
  - What new strategies did you discover during this activity and how might you implement them at your facilities?
  - What other questions or comments do you have about strategies for minimizing stigma?
- 10. Slide: Current Gaps in Knowledge and Need for Continued Surveillance
  - You have learned the basics of implementing PrEP at you sites. However, there are still gaps in knowledge related to the implementation of PrEP.
  - (Review the information on the slide aloud.)
  - The evidence for PrEP efficacy and safety presented in theses slides is based on current knowledge. There are ongoing PrEP studies and knowledge will evolve.
  - There are still gaps in knowledge related to PrEP safety, especially among pregnant women.
- 11. Post Slide: PrEP M&E Tools and invite participants to begin considering how the M&E tools in their participant manuals might be adapted for use in their facilities.
  - You will receive further training on using and adapting these tools at your facilities.
  - (If your training includes Module 6, tell participants that they will practice using these M&E tools in Module 6.)

#### 12. Slide: PrEP Cascade

- PrEP is a biomedical intervention but it is more than prescribing a medication.
   PrEP effectiveness depends on the complementary provision of structural and behavioral interventions.
- There is a need for concerted efforts at each step of the cascade to:
  - o Create demand for PrEP
  - o Link potential PrEP clients to services
  - o Start PrEP
  - o Retain clients on PrEP

- o Counsel and support clients on behavioral risk reduction
- o Support good adherence
- 13. Slide: Module 4 Summary
  - (Review the points on the slide aloud.)
- 14. Slide: Question
  - What final questions or concerns do you have about implementing PrEP?
- 15. Invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 16. Point out the resources lists in participants' manuals and invite them to explore them after the training.
- 17. Thank participants for their participation and work during Day 2.

## MODULE 5: Post-Test, Evaluation, and Closing

Note: If your training will include Module 6, skip Module 5 and return to it after completing Module 6.

#### TIME: 30 minutes

#### **MATERIALS**

- Module 5 slides
- 1 post-test and 1 Training Evaluation Form for each participant
- 1 completion certificate for each participant

#### ADVANCE PREPARATION

- Make 1 copy for each participant of: post-test, post-test with correct answers, Training Evaluation Form
- Create completion certificates for all participants

## Session 5.1. Post-Test, Training Evaluation, and Closing

Time: 30 minutes

Methods: Post-test, written evaluation

#### **Materials**

- Module 5 slides
- 1 post-test and 1 Training Evaluation Form for each participant
- 1 completion certificate for each participant

#### **Advance Preparation**

- Make 1 copy for each participant of: post-test, post-test with correct answers, Training Evaluation Form
- Create completion certificates for all participants
- Post slide: Module 5

- 1. Slide: Module 5
  - In Module 5 you will take a post-test and complete an evaluation of the training.
- 2. Slide: Training Post-test
  - (Review the points on the slide aloud.)
- 3. Give participants the post-test and give them 15 minutes to complete it. As participants are working, circulate and help as needed.
- 4. Collect all the post-tests. Take a few minutes to mark participants' post-tests (perhaps while participants are completing the Training Evaluation Form).
- 5. Slide: PrEP Specific Competencies
  - (Remind participants that this training has focused on these competencies. Review the competencies aloud.)
- 6. Give participants copies of the Training Evaluation Form.
- 7. Slide: 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.
- 8. Thank everyone for their participation and wish them the best in implementing PrEP at their facilities. Make sure that participants take their manuals home with them.

- 9. Give participants' marked tests back to them.
- 10. Slide: PrEP Resources for Providers
  - (Review the resources aloud. They are also listed in the front of the participant manual.)
- 11. Slide: PrEP Resources for PrEP Users
  - (Review the resources aloud. They are also listed in the front of the participant manual.)
- 12. Slide: Thank you for your participation!
- 13. Give participants their completion certificates. (If your training includes Module 6, you may give certificates after Module 6.)

## MODULE 6: PrEP Monitoring & Evaluation Tools

#### TIME: 3 hours

#### **OBJECTIVES**

#### After completing Module 6, participants will be able to:

- Complete the PrEP Facility Record, PrEP Follow-up Visits Form, and the PrEP Client register correctly.
- Complete the PrEP Monthly Summary Form and PrEP Quarterly Cohort Report correctly.
- Describe how PrEP M&E tools might be adapted for local use.

#### **MATERIALS**

- Module 6 slides (needed for all Module 6 sessions)
- 1 PrEP Provider Checklist for Follow-up PrEP Visits, 1 PrEP Facility Record, 1 PrEP Follow-up Visits Form, and 1 PrEP Client Register for each participant (in participant folder)
- 1 copy of the completed PrEP Monthly Summary Form and PrEP Quarterly Cohort Report for each participant
- Session 6.1 Scenarios for M&E Practice (below and in participant manual)
- Sample data during 1 month (below and in participant manual)

#### ADVANCE PREPARATION

- Make another 50% extra copies of each of the forms above (in case some participants need to start a form over).
- Review the forms and Session 6.1 Scenarios for M&E Practice ahead of time.
- Complete a PrEP Monthly Summary Form and a PrEP Quarterly Cohort using the data below.
- Decide how you will divide participants into pairs (by counting or another method).
- Decide how you will divide participants into small groups (by counting or another method).

## Session 6.1. PrEP Facility Record, Follow-up Visits, and Client Register

Time: 1 hour and 30 minutes

Methods: Role-play, large group discussion

#### **Learning Objectives**

After completing this session, participants will be able to:

- Complete the PrEP Facility Record, PrEP Follow-up Visits Form, and the PrEP Client register correctly.
- Describe how PrEP M&E tools might be adapted for local use.

#### **Materials**

- Module 6 slides
- 1 PrEP Provider Checklist for Follow-up PrEP Visits, 1 PrEP Facility Record, 1 PrEP Follow-up Visits Form, and 1 PrEP Client Register for each participant (in participant folder)
- Scenarios for M&E Practice (below and in participant manual)

### **Advance Preparation**

- Make another 50% extra copies of each of the forms above (in case some participants need to start a form over).
- Post slide: PrEP Facility Record
- Review the forms ahead of time.
- Decide how you will divide participants into pairs (by counting or another method).

#### Steps

Part 1 – PrEP Facility Record (40 minutes)

- 1. Slide: Module 6
  - In Module 6 you will practice using 3 PrEP monitoring and evaluation (M&E) tools the PrEP Facility Record, PrEP Follow-up Visits Form and PrEP Client Register.
- 2. Slide: Module 6 Learning Objectives
  - (Review the learning objectives aloud.)
- 3. Slide: PrEP Facility Record.
  - Please find the PrEP Facility Record in your participant folders.
  - This form is completed after the initial PrEP screening, for patients 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.
- 4. Explain briefly how to complete the form, section by section. Point out that the provider must ask the client the questions in Sections C.
- 5. Explain that participants will now practice completing this form in pairs. Divide participants into pairs (different pairs from previous sessions).
- 6. Slide: 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.
  - The participant playing the client should review the synopsis of their character in order to be able 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.
  - Then repeat this process for another scenario, with roles reversed.
  - You will have approximately 15 minutes to work.
- 7. As pairs are working, circulate and help as needed. Check to make sure that participants are completing the form correctly.
- 8. When pairs have finished, call everyone's attention. Invite one pair to come to the front of the room and explain how they completed Sections C and D of the form for one scenario.
- 9. Confirm or correct their answers as needed, and explain any other information for the form as needed.
- 10. Ask what questions participants have about the PrEP Facility Record, invite participants to answer each other's questions, and complement and clarify their answers as needed.

#### Part 2 – PrEP Follow-up Visits & PrEP Client Register (50 minutes)

- 11. Slide: PrEP Follow-up Visits
  - Please find the PrEP Follow-up Visits Form in your participant folders.
  - One form per client is used to record information after each follow-up visit.
- 12. Explain briefly how to complete the form, section by section.

- 13. Slide: PrEP Client Register
  - Please find the PrEP Client Register in your participant folders.
  - As each new client starts PrEP, the relevant information is added to this register, and the client's follow-up visits recorded.
- 14. Explain briefly how to complete the form, section by section.
- 15. Explain that participants will now practice completing this form in pairs. Ask participants to pair up again with their partners from the previous role-play. Give each participant 1 PrEP Provider Checklist for Follow-up PrEP Visits, 1 PrEP Follow-up Visits Form, and 1 PrEP Client Register.
- 16. Slide: Practice: PrEP Follow-up Visits & Client Register (2 slides)
  - 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. The provider should use the Provider Checklist for Follow-up PrEP Visits as a guide. The client should invent appropriate answers for questions about adherence, side effects, signs and symptoms of acute HIV infection, etc. Use the date 1 month from today for the visit date, and other appropriate dates, as needed.
  - Repeat this process for another scenario, with roles reversed.
  - Then complete the PrEP Follow-up Visits and PrEP Client Register forms (follow-up visit 1) for the "client" that you interviewed. You will each complete your own form.
  - You will have approximately 20 minutes to work.
- 17. As pairs are working, circulate and help as needed. Check to make sure that participants are completing the forms correctly.
- 18. When pairs have finished, call everyone's attention. Invite one pair to come to the front of the room and explain how they completed the PrEP Follow-up Visit and PrEP Client Register for one of their scenarios.
- 19. Confirm or correct their answers as needed, and explain any other aspects of the forms as needed.
- 20. Ask what questions participants have about the PrEP Follow-up Visits and Client Register, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 21. Slide: Question
  - How might you adapt and use these forms at your facilities?

22. Take volunteer responses and encourage a brief discussion.

#### 23. Slide: Morning Break

• We will reconvene in 15 minutes.

**Note:** You may wish to revise and adapt these scenarios, or write new ones, to reflect participants' local context and client populations, or to include client situations more relevant to your area.

#### **M&E Practice Scenarios**

#### M&E Scenario 1

Joseph is a 22 year-old man who presented 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 is taking no medications. His rapid HIV antibody test today was negative. Joseph reports that he loves to live life from moment to moment. He says that he is not good at "following orders" and is worried that he might forget to take his pills. Joseph has agreed to start PrEP.

#### M&E Scenario 2

Marie is an 18 year-old woman who presented at 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 two children. Some of her partners have used condoms and others have not. She does not know if 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. After you determine that there is no suspicion of AHI, Marie has agreed to start PrEP.

#### M&E Scenario 3

Geraldine, a 30 year-old wife and mother, is interested in starting PrEP. She presented at the clinic because she heard that she could get drugs that will prevent her from getting HIV. She suspects that her husband has been injecting drugs, as he comes home with 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 was negative. She is eager to start PrEP but is worried that her husband might see her taking pills and become abusive or make her stop taking the medication. Geraldine has agreed to start PrEP.

#### M&E Scenario 4

Gabrielle is a 25 year-old married woman. She has come to the clinic distressed because of her husband's behaviour. Lately, he has been staying out all night sometimes. When he returns he has needle marks on his arms. She is afraid that he might be using drugs. Gabrielle has come to the clinic to get medicine to protect against any infection that her husband might have. She feels that she cannot control his behaviour, but she can try to protect herself.

Despite the problems with her husband, Gabrielle has sex (vaginal) with her husband almost every week. Her husband does not like to use condoms. Gabrielle does not know if her husband has HIV or not, as he refuses to get tested; he says that such tests are for "bad people." She fears, though, that he may be having sex with other women.

Gabrielle has not had any STIs. She has not taken PEP. She does not use drugs or share injecting material with others. She last had sex with her husband 2 nights ago. She feels fine and does not have a fever, or cold or flu-like symptoms. Her rapid HIV antibody test today is negative. Gabrielle has decided to start PrEP.

#### M&E Scenario 5

Justine is a 19 year-old sex worker with a live-in boyfriend. She was born a male but has been living as a woman since she was 15 years old. She has had sex with multiple partners (men) during the last six months, a few times without condoms. She does not know if she has any STIs, but she has no symptoms.

Justine's boyfriend is living with HIV and he has been on ART for about 1 year. He has adhered to the treatment regimen very well and is in good health. Justine is proud of him for this. Justine and her boyfriend use condoms during sex.

A few weeks ago, Justine was tested for HIV after a scary encounter with a client. The test was negative. Justine has come to the clinic today because she is feeling poorly. She has had a fever and chills in recent days, and wants medicine in order to feel better. You determine that there is no suspicion of AHI. Justine agrees to start PrEP.

#### M&E Scenario 7

Lucien is 25 years old. He is a sexually active married man who has sex regularly with his wife, and also with men outside of his marriage. His wife does not know about the sex with men. Lucien insists on using condoms during sex with men, but he does not use condoms with his wife.

Lucien has come to the clinic because the last time he was with a man, the condom broke and he is worried that he might have gotten HIV. He does not know the HIV status of his male sex partners. He assumes that his wife does not have HIV but she has not been tested. He does not use drugs or share injecting material with others. Lucien's HIV test is negative. He agrees to start PrEP.

#### M&E Scenario 7

Anne is a sex worker and is interested in starting PrEP. She uses condoms during sex with commercial clients but not with her stable partner of unknown HIV status. She had a negative HIV test 6 months ago and wants to avoid HIV infection, as she would like to have a baby with her partner. She is using injectable hormonal contraceptive as she used to forget to take oral contraceptives on a daily basis. Anne's HIV test is negative. She has decided to start PrEP.

#### Session 6.2. Monthly & Quarterly Forms

**Time:** 1 hour and 30 minutes

Methods: Small group activity, large group discussion

#### **Learning Objectives**

After completing this session, participants will be able to:

- Complete the PrEP Monthly Summary Form and PrEP Quarterly Cohort Report correctly.
- Describe how PrEP M&E tools might be adapted for local use.

#### **Materials**

- Module 6 slides
- 1 PrEP Monthly Summary Form and 1 PrEP Quarterly Cohort Report for each participant (in participant folder)
- 1 copy of the completed PrEP Monthly Summary Form and PrEP Quarterly Cohort Report for each participant (see Advance Preparation)
- Sample data during 1 month (below and in participant manual)

#### **Advance Preparation**

- Make another 50% extra copies of each the forms above (in case some participants need to start a form over).
- Post slide: PrEP Monthly Summary Form
- Review the forms ahead of time.
- Complete a PrEP Monthly Summary Form and a PrEP Quarterly Cohort Report using the data below and photocopy them.
- Decide how you will divide participants into small groups (by counting or another method).

**Note:** If you plan to do Module 5 after Module 6, you will need 30 minutes more.

**Note:** For Part 2 of this session, participants may use the example data for the PrEP Quarterly Cohort Report exercise instead of the data provided below (the example is on the first page of the report).

#### Steps

Part 1 – PrEP Monthly Summary Form (45 minutes)

- Explain that in this session participants will practice using 2 more PrEP monitoring and evaluation tools – the PrEP Monthly Summary Form and the PrEP Quarterly Cohort Report.
- 2. Slide: PrEP Monthly Summary Form
  - Please find the PrEP Monthly Summary Form in your participant s.
  - This form is used to collect and summarize monthly PrEP data.

- 3. Explain briefly how to complete the form, section by section.
- 4. Explain that participants will now practice completing this form in small groups. Divide participants into small groups of 4-6 participants each (different groups from previous sessions). Give each participant a PrEP Monthly Summary Form.
- 5. Slide: 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.
- 6. As small groups are working, circulate and help as needed. Check to make sure that participants are completing the form correctly.
- 7. When small groups have finished, call everyone's attention. Give each participant a copy of the completed PrEP Monthly Summary form and ask small groups to check their forms against the completed form.
- 8. Then ask small groups how their work compares to the completed form and explain any answers as needed.
- 9. Ask what questions participants have about the PrEP Monthly Summary Form, invite participants to answer each other's questions, and complement and clarify their answers as needed.

#### Part 2 – PrEP Quarterly Cohort Report (45 minutes)

- 10. Ask participants to stay with their small groups.
- 11. Slide: PrEP Quarterly Cohort Report
  - Please find the PrEP Quarterly Cohort Report and completed example in your folders.
  - This form is used to collect and track data per quarter and PrEP Cohort.
- 12. Explain briefly how to complete the form, section by section. Explain briefly how to calculate cohort outcomes (% of cohort alive and on PrEP, % receiving HIV test, etc.)
- 13. Slide: 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 her or his own form.
- You will have 15 minutes to work.
- 14. As small groups are working, circulate and help as needed. Check to make sure that participants are completing the form correctly.
- 15. When small groups have finished, call everyone's attention. Give each participant a copy of the completed PrEP Quarterly Cohort Report and ask small groups to check their forms against the completed form.
- 16. Then ask small groups how their work compares to the completed form and explain any answers as needed.
- 17. Ask what questions participants have about the PrEP Quarterly Cohort Report, invite participants to answer each other's questions, and complement and clarify their answers as needed.
- 18. Slide: Question
  - How might you adapt and use these M&E forms for your facilities?
- 19. Encourage a brief discussion.
- 20. Thank everyone for their participation and wish them the best in implementing PrEP at their facilities. Make sure that participants take their manuals home with them.
- 21. Slide: Thank you for your participation!
- 22. Give participants their completion certificates (if you will not do Module 5 next).

### Sample data for PrEP Monthly Summary Form

Clients who received HIV testing for PrEP screening

Gender	Age	HIV status	Situation
Female	21	Negative	Male partner is HIV positive
Female	18	Positive	Sex worker
Male	35	Negative	Injects drugs; AHI suspected
Female	17	Negative	Was born a male
Male	19	Negative	Has sex with men
Male	25	Negative	Female partner is HIV positive
Female	31	Negative	Husband has sex with men
Female	26	Negative	Was born a male
Male	45	Positive	has sex with men
Female	20	Negative	Sex worker
Male	28	Negative	Has sex with SW; AHI suspected
Male	23	Negative	Has sex with men
Female	32	positive	Injects drugs
Male	22	Negative	Sex worker
Female	52	Negative	Husband has sex with sex workers
Female	19	Negative	Injects drugs

#### Clients who started PrEP

• Determine based on HIV test results and AHI information above.

#### Returning PrEP clients who received follow-up HIV testing

Gender	Age	HIV status	Situation	Follow-up test	
Female	21	Negative	Male partner is HIV positive	Negative	
Female	18	Positive	Sex worker		
Male	35	Negative	Injects drugs; AHI suspected	Negative	
Female	17	Negative	Was born a male	Negative	
Male	19	Negative	Has sex with men	Negative	
Male	25	Negative	Female partner is HIV positive	Negative	
Female	31	Negative	Husband has sex with men	Positive	
Female	26	Negative	Was born a male	Negative	
Male	45	Positive	has sex with men	Positive	
Female	20	Negative	Sex worker	Negative	
Male	28	Negative	Has sex with SW; AHI suspected	Positive	
Male	23	Negative	Has sex with men	Negative	
Female	32	Positive	Injects drugs		
Male	22	Negative	Sex worker	Positive	
Female	52	Negative	Husband has sex with sex workers	Negative	
Female	19	Negative	Injects drugs	Negative	

#### Instructions for PrEP Quarterly Cohort Report

- Use your completed PrEP Monthly Summary Form and the information below to complete the PrEP Quarterly Cohort Report for Cohort 1.
- Transferred in: Female, age 24, HIV status negative, sex worker.
- Transferred in: Male, age 55, HIV status negative, has sex with men.
- Female, age 19, injects drugs, stopped PrEP due to positive HIV test.
- No PrEP clients stopped because they were no longer at substantial risk.
- Male, 45, has sex with men, was lost.
- No PrEP clients from this cohort died.

# **Appendices:**

- A. Pre-Test Assessment
- **B.** Post-Test Assessment
- C. Post Test Answer Key
- D. Training Evaluation Form
- E. Materials Needed for Participant Folders
- F. Certificate of Participation
- G. PrEP Clinical Pathway
- H. Screening for Substantial Risk of HIV infection
- I. Provider Checklist for Initial PrEP Visit
- J. Provider Checklist for Follow-up PrEP Visit

# A. Pre-Test Assessment for PrEP Training for Providers in Clinical Settings

Please answer the	following questions:	

- 1) What is Pre-Exposure Prophylaxis (PrEP)?
- 2) How is Pre-Exposure Prophylaxis (PrEP) different from Post-Exposure Prophylaxis (PEP) and from antiretroviral treatment?
- 3) Who is eligible for starting PrEP?
- 4) Which antiretroviral drugs are recommended for PrEP?
- 5) When should PrEP be stopped?

# B. Post- Test Assessment for PrEP Training for Providers in Clinical Settings

Please tick the correct answers to each multiple choice question below:

#### 1. Pre-Exposure Prophylaxis (PrEP) is the use of antiretroviral drugs (ARVs):

(select all that apply, if applicable)

- a) To prevent mother-to-child transmission of HIV
- b) To prevent HIV infection after potential exposure to HIV
- c) By HIV-negative persons to prevent HIV acquisition
- d) To treat HIV infection in men who have sex with men

#### 2. Which of the following statements is true?

(select all that apply, if applicable)

- a) Antiretroviral therapy (ART) has not been shown to have prevention benefits
- b) Pre-Exposure Prophylaxis (PrEP) and antiretroviral therapy (ART) are both used by HIV infected persons
- c) Post-exposure prophylaxis (PEP) and Pre-Exposure Prophylaxis (PrEP) are both used by HIV negative persons to prevent HIV acquisition
- d) Pre-Exposure Prophylaxis (PrEP) should be used by health care workers after needle stick injuries to prevent HIV infection

#### 3. Pre-Exposure Prophylaxis (PrEP) should be used:

(select all that apply, if applicable)

- a) As part of a comprehensive HIV-1 prevention strategy that includes other preventive measures
- b) In individuals who have a confirmed negative HIV test
- c) Only by key populations
- d) Only by non-pregnant women

#### 4. The following antiretroviral drugs can be used for Pre-Exposure Prophylaxis (PrEP):

(select all that apply, if applicable)

- a) Tenofovir/emtricitabine (TDF/FTC)
- b) Tenofovir/emtricitabine + Efavirenz (TDF/FTC) +(EFV)
- c) Tenofovir/lamivudine (TDF/3TC)
- d) Zidovudine/lamivudine (AZT/3TC)

#### 5. Pre-Exposure Prophylaxis (PrEP) should be discontinued if:

(select all that apply, if applicable)

- a) The client falls pregnant
- b) The estimated glomerular filtration rate (eGFR) decreases to <60 ml/min
- c) The client reports headaches and stomach upset
- d) The client tests HIV positive

# C. Post Test Answer Key:

- **1.** c
- **2.** c
- **3.** a, b
- **4.** a, c
- **5.** b, d

# D. Training Evaluation Form

Name (optional):

Your position (optional):

Health facility where you work (optional):

**Instructions:** Please rate the following statements on a scale from 1 to 5.

		Strongly Disagree	Disagree	Neither agree nor disagree	Agree	© Strongly Agree
1.	The training objectives were clear.	1	2	3	4	5
2.	This training met my expectations.	1	2	3	4	5
3.	The technical level of this training was appropriate.	1	2	3	4	5
4.	The pace of this training was appropriate.	1	2	3	4	5
5.	The facilitators were engaging (i.e., interesting).	1	2	3	4	5
6.	The information I learned in this training will be useful to my work.	1	2	3	4	5
7.	I am confident that after this training, my facility will be able to implement PrEP for all eligible candidates.	1	2	3	4	5

**Instructions:** How helpful were each of the training modules to you and your work? If you have specific comments, please write them on the next page.

	⊗ Not helpful				© Very helpful
Module 1: PrEP Basics	1	2	3	4	5
Module 2: PrEP Screening and Eligibility	1	2	3	4	5
Module 3: Initial and Follow-up PrEP Visits	1	2	3	4	5
Module 4: Monitoring and Managing PrEP Side Effects, Seroconversion, and Stigma	1	2	3	4	5

What is a second of the second
What was the best part of this training?
How could we improve this training?
riow could we improve this training:
[OII]
Other comments:

Thank you for your participation and for your commitment to implementing PrEP!

## E. Materials Needed for Participant Folders

Each participate folder should include the following:

- 1. Pre-Test Assessment
- 2. Post-Test Assessment
- 3. Training Evaluation Form
- 4. PrEP Clinical Pathway
- 5. Screening for Substantial Risk of HIV Infection Chart
- 6. Provider Checklist for Initial PrEP Visits
- 7. Provider Checklist for Follow-up PrEP Visits
- 8. PrEP M&E Tool Package, which includes:
  - a. PrEP Screening for Substantial Risk and Eligibility
  - b. PrEP Facility Record
  - c. PrEP Patient Register
  - d. PrEP Monthly Summary Form
  - e. PrEP Quarterly Cohort Report

# F. Certificate of Participation

(Attached separately as a Word document for adaptation)





# Certificate of Participation

Participated in the Workshop

PrEP Training for Providers in Clinical Settings

# PrEP Job Aids

- A. PrEP Clinical Pathway
- B. Screening for Substantial Risk of HIV Infection
- C. Provider Checklist for Initial PrEP Visit
- D. Provider Checklist for Follow-up PrEP Visit

## A. PrEP Clinical Pathway

Confirm HIV Negative Status



Screen for Substantial Risk of HIV



Establish Eligibility



Start PrEP



PrEP Follow-up Visits

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

Client who is sexually active in a high HIV prevalence population (either in the general population or key population group) <u>PLUS</u> reports *ANY* of the following in the <u>past six months</u>:

- Vaginal or anal intercourse without condoms with more than one partner, OR
- Sex partner with one or more HIV risk, OR
- History of an STI (based on lab test, syndromic STI treatment, 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 <u>past six months</u>

#### <u>OR</u>

Client who reports having a sexual partner in the past six months\* who is HIV positive AND who has not been on effective HIV treatment

\*On ART for less than six months, or has inconsistent or unknown adherence

Clients are eligible if they fulfill **ALL** the criteria below:

- HIV negative;
- Are at substantial risk of HIV;
- Have no signs/symptoms of acute HIV infection;
- Have creatinine clearance (eGFR) >60 ml/min
- Provide information on PrEP, importance of adherence, potential side effects, follow-up schedule, signs/symptoms of acute HIV infection
- Screen/manage STI
- Do risk-reduction counseling and provide condoms/lubricants
- Do adherence counseling
- Prescribe PrEP
- Give appointment for follow-up visit
- Stress importance of returning to the clinic if client develops <u>serious</u> side effects or signs/symptoms of acute HIV infection
- Plan follow up visits one month after starting PrEP and every three months thereafter

At follow-up visits:

- Repeat HIV test
- Ask about side-effects
- Support/monitor adherence
- Do risk reduction counseling and provide condoms
- Screen for STI
- Repeat eGFR after six months on PrEP
- Schedule next visit
- Provide reminder card with appointment and contact information

PREP TRAINING FOR

# B. Screening for Substantial Risk of HIV Infection

#### SCREENING FOR SUBSTANTIAL RISK of HIV INFECTION

(Based on history in the past six months)

- Client who is sexually active in a high HIV prevalence population (either in the general population or key population group) <u>PLUS</u> reports ANY of the following in the <u>past 6 months</u>:
  - Vaginal or anal intercourse without condoms with more than 1 partner, OR
  - Sex partner with one or more HIV risk, OR
  - History of an STI (based on lab test, syndromic STI treatment, self-report), OR
  - History of use of post-exposure prophylaxis (PEP)



 Client who reports history of sharing of injection material/equipment with another person in the past 6 months



 Client who reports having a sexual partner in the <u>past 6 months\*</u> 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

#### C. Provider Checklist for Initial PrEP Visit

# Provider Checklist for Initial PrEP Visit HIV test (using algorithm in national HIV Testing guidelines) o Assessment of HIV infection status Exclude acute HIV infection o Ask about last potential exposure to HIV Ask/look for 'flu-like' symptoms Screen for substantial HIV risk Serum creatinine (calculate eGFR) o To identify pre-existing renal impairment Hepatitis B surface antigen (HBsAg) – if available To identify undiagnosed Hepatitis B (HBV) infection To identify those eligible for vaccination against Hepatitis B STI screening o Perform syndromic or etiological STI testing (depending on local guidelines) o Rapid Plasma Reagin test (RPR) for syphilis (if available) Pregnancy test o Ask about last menstrual period (perform pregnancy test if needed) Conduct risk reduction counseling Clients will be referred based on specific needs, i.e. social support, harm reduction, genderbased violence programs, etc. Provide information on PrEP and conduct adherence counseling Provide condoms and lubricants Provide (or refer to) reproductive health services (as needed) Schedule next appointment (provide appointment card)

\*Please adapt this checklist to align with national guidelines on PrEP\*

## D. Provider Checklist for Follow-up PrEP Visits

# Provider Checklist for Follow-up PrEP Visits Brief counseling (every visit) Review/ask about signs and symptoms of acute HIV infection Check on current context of sexual health Desires to remain on PrEP Facilitators & barriers to PrEP use Adherence counseling (every visit) o Monitor adherence (recall, pill count, etc.) o Brief adherence counseling Discuss importance of effective use of PrEP Assessment and management of side effects (every visit) Ask about and manage side-effects Confirmation of HIV-negative status (recommended frequencies) Repeat HIV test one month after starting PrEP (especially if HIV RNA or antigen testing was not performed before starting PrEP) Every three months thereafter Calculation of estimated creatinine clearance (eGFR) (recommended frequencies) o At least every six months OR more frequently if there is history of conditions affecting the kidney (e.g., diabetes, hypertension, or any chronic nephropathy) STI screening Risk reduction counseling Clients will be referred based on specific needs, i.e. social support, harm reduction, gender-based violence programs, etc. Provision of condoms and lubricants Provision of contraception (as needed) Perform pregnancy test if needed Provision of follow-up prescription for PrEP Scheduling of next appointment (provide appointment card) If a client using PrEP tests positive for HIV, stop PrEP and link promptly to treatment

\*Please adapt this checklist to align with national guidelines on PrEP\*

and care services. Start suppressive therapy for HIV infection (ART) immediately.