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

Trainer Notes

2016

PEPFAR

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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. These include key populations including sex workers (SW), men who have sex with men (MSM), transgender persons (TG), 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 prevention 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 "prevention toolbox", and that it should be offered to people at substantial risk of HIV infection as part of combination HIV prevention approach.

These training notes 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 and it also includes a set of job aids. It is anticipated that adaptation of this training material will be necessary to reflect specific contexts and to include evidence from new research and experience in the use of PrEP.

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

We welcome feedback regarding this document.

ICAP at Columbia University
New York, December 2016
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Acronyms

AHI	Acute HIV Infection
ART	Antiretroviral Therapy
ARV	Antiretroviral
CDC	US Centers for Disease Control and Prevention
FSW	Female Sex Worker
FTC	Emtricitabine
Ab/Ag	Antibody/Antigen
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HIV-DR	HIV Drug Resistance
HTS	HIV Testing Services *or* HIV Testing Strategy
iNSC	Integrated Next Step Counselling
MSM	Men who have Sex with Men
NSC	Next Step Counselling
PEP	Post-Exposure Prophylaxis
PMTCT	Preventing Mother To Child Transmission
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
RCT	Randomized Controlled Trial
RNA	Ribonucleic Acid
RPR	Rapid Plasma Regain test (syphilis)
STI	Sexually Transmitted Infection
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

Trainer Notes Introduction
Section 1: Overview of the Training and Trainer Notes

About this Training

The goal of the *Pre-exposure prophylaxis (PrEP) Training for Providers in Clinical Settings* is to equip health 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.

Approach to the development of the training:

ICAP at Columbia University (ICAP) utilized a backward design approach to develop this training program. First, content and training experts were identified. Together these experts developed a series of competency statements (tasks or skills) that health care providers would need to be able to perform in order to provide PrEP to appropriate candidates with the required level of proficiency. Next, the team created learning objectives and assessment measures, which described what health care providers should be able to achieve at the end of the training program. These learning objectives were then sequenced, where appropriate, and grouped into four learning modules. Thereafter, learning activities and support tools were created to enable achievement of each learning objective. Finally, essential content and visuals were identified, organized and incorporated into a comprehensive slide set that included talking points for most slides used in the training.

The core competencies health providers will learn during the training are to:

- Identify eligible candidates for PrEP
- Conduct an individualized risk assessment
- Educate and counsel PrEP candidates and users
- Conduct clinical and laboratory assessments during the initial PrEP visit
- Prescribe PrEP
- Conduct clinical and laboratory assessments during follow-up PrEP visits
- Review PrEP Monitoring and Evaluation tools for future local use

This training is primarily classroom-based and content-focused. The training covers:

- PrEP basics
- PrEP screening and eligibility
- Initial and follow-up PrEP visits
- Monitoring and managing PrEP side effects, seroconversion, and stigma

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
- PrEP and HIV counselors

Generic Training Program and Adaptation Process

This training program is generic. It was developed for adaption at the country, state/provincial, or facility-level and 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 tools, whether clinical or educational, need local review and adaptation to ensure that they meet local needs and have the support of key stakeholders and health providers, as well as that they reflect national guidelines and policies.

Components of this Training Package

You — the trainer and/or co-trainers — should familiarize yourself with all components of this training package well in advance of the training. Key components to support implementation of PrEP include these Trainer Notes, which includes the PowerPoint slides, trainer notes, and job aids/tools.

Trainer Notes

The Trainer Notes were developed to support trainers and co-trainers to plan and implement the one day program. Each of the four modules provides technical content and also guidance on how to teach that content. In the PowerPoint slides included in each module, you will find the following: module time, learning objectives, interactive exercises, trainer notes/instructions and references. Suggested questions are also provided to help you engage and draw responses from participants.

Before facilitating the training, you should read through the introductory sections of the Trainer Notes carefully. Then, study each of the four modules, read the technical content to ensure you understand it (including any job aids/tools in the participant folder), review the clinical scenarios closely, take note of exercises that require advance preparation (e.g. exercise to develop strategies to minimize stigma), and try to anticipate participant questions.

PowerPoint Slides

The PowerPoint slide set was developed to facilitate the presentations and discussions throughout the training. When conducting the training, use this Trainer Notes document for reference. This documents contains all of the slides for beginning the training program, the four modules, along with trainer notes/instructions for many of the slides and screen shots of various job aids/tools (contained within the participant folder) and ending the training program.

Adapting to Specific Context:

There are a variety of reasons that may motivate the need to adapt a clinical scenario/exercise that is included in this document. For example:

- If you have simplified a session to suit the target group (possibly based on results of the pre-program assessment), the clinical scenario(s)/exercise(s) may also have to be changed.
- You may want to substitute a certain clinical scenario/exercise with one that is more relevant to a specific context. However, make sure that all the points that the original scenario/exercise was designed to illustrate are included in the replacement scenario/exercise.

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

1. *Is the task in the new scenario/exercise clearly defined?*
2. *Is the new scenario/exercise consistent with the content of the module?*
3. *Does the new scenario/exercise achieve the same objective(s) as the original scenario/exercise?*
4. *Does the new scenario/exercise fit in the time allotted?*
5. *Does the new scenario/exercise contribute to the variety of scenarios/exercises?*
6. *Will the new scenario/exercise make participants think?*
7. *What advantages does the replacement scenario/exercise have over the original scenario/exercise?*
8. *What materials will be needed?*
9. *Do new PowerPoint slides need to be created for the new scenario/exercise?*

Training Program Schedule

PrEP Training for Providers in Clinical Settings was developed as a four module face-to-face training program that should take one day (or two days) to complete.

Modules 1-4 should be taught sequentially. An illustrative training agenda is provided below.

Time	
8:00-8:30	Registration and completion of pre-program assessment
8:30-10:00	Module 1
10:00-10:15	TEA BREAK
10:15-12:00	Module 2
12:00-12:30	LUNCH
12:30-14:30	Module 3
14:30-14:45	TEA BREAK
14:45-16:30	Module 4
16:30-17:00	Summary and completion of post-test and training evaluation form

Participant Registration

It is recommended that the trainer(s) 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 the following information: name, job title, place of employment, address of employer, work phone number, cell phone number, and e-mail address.
- Fill in their name tags. Trainers and participants should wear their name tags throughout the training to facilitate the learning of names and future networking.

Depending on the size of the group, it is probably sufficient if one trainer and one support person staff the registration table. However, trainers should be available at this time to not only meet and greet participants but also to troubleshoot any problems. Their presence will help ensure a positive first impression and learning environment.

Starting the Day

It is recommended that the training day begin with time to answer any questions and to review the agenda for the day. You can also use this time to talk about topics unrelated to training, such as participants' morning commute to the training venue. This should take no more than 5–10 minutes.

Approach to the evaluation of the training

Pre-Program Assessment and Post-Test

The evaluation design for the training program is a post-test only design. However, a pre-program assessment is strongly recommended. This pre-program assessment uses an open-ended response format and is meant to give participants a sense of what they need to know and be able to do by the end of the day-long training program. Because this type of pre-program assessment includes open-ended questions, it eliminates guessing by participants. In addition, the participants' responses will give the trainer(s) a quick snapshot of what participants know and don't know and areas in the training program that may need more or less time. The pre-program assessment will not be graded and will not be given back to participants.

Post-Test and Training Evaluation Form

At the end of the day, after completion of Module 4, the trainers will ask the participants to complete a post-test and a training evaluation form. The post-test uses a close-ended, multiple-choice format. The questions that are asked are the exact same ones that were asked in the pre-program assessment. Both the pre-program assessment and the post-test are designed to assess important knowledge and skills related to implementing PrEP prior to the start of the training and then immediately after the training to determine knowledge and skills gained as a result of the training.

A copy of the Training Evaluation Form is located in the participant folder. This evaluation form is an important source of feedback and provides much information on how the training program should be improved in the future so as to better meet participant training needs. Remember to only distribute program completion certificates to participants after they have handed in their completed post-tests and evaluation forms!

Trainer Notes Introduction
Section 2: Trainer Roles and Responsibilities and Training Tips

Roles and Responsibilities of the Trainer

1. ***Trainers and co-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 — how the tables and chairs are set up, 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 the atmosphere and for making changes, as needed.
3. ***Trainers are mindful of keeping 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 clinical scenario/exercise or discussion and its significance to participants.*** It is important to clearly state the goal and function of each activity. 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 are responsible for paying attention to participants' behaviors.*** You should be observant of 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 setting. 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 needs to remain confidential. Also, ensure that you, as a trainer, serve a role model in maintaining this confidentiality. Below is a Trainer Preparation Checklist that will help you remember key tasks you need to accomplish before the training program starts.

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, and clinical scenarios/exercises.
	Prepare for each of the clinical scenarios/exercises according to the *Trainer Notes/ Instructions*.
	Obtain and organize the materials needed for the participant folders.
	Review the PowerPoint slides and become familiar with their content and note sections. Practice using the computer and LCD projector and also practice 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 complicated exercises or discussions, consider co-facilitation.
	Develop a plan and strategies for monitoring time and keeping to the schedule. For example, where discussion questions are posed throughout the four modules you can choose not to utilize such questions, or to utilize them but limit the time for discussion of each question.
	Familiarize yourself about the participants before the training (for example, their worksites, roles, responsibilities, skills, and experiences). This effort should continue throughout the training.

Training as a Team

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

- *Which parts of the modules would you like to be responsible for?*
- *Which parts would you like your colleague to handle?*
- *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 be used by you and your colleague for interrupting 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?*

Below is a Team Training Checklist that will help you remember key tasks you and your co-trainer need to accomplish before the training program starts.

Team Training Checklist

Table 2: Team training checklist

✓	Preparation
	Decide who will lead and teach each section of each module, including who will lead each clinical scenario/exercise within each section.
	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.
✓	**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, such as when you do not know the answer to a question or if 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.
✓	**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 the next time.
	Discuss ways to help support one another during future trainings.

Setting the Environment

To create an environment that supports participants, it is important to ensure that participants feel safe, supported, and respected. Make sure you take the time to carefully plan the first part of the training in a way that creates a psychologically safe and supportive environment.

Strategies for reducing early group discomfort and for fostering trust are:

- 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.

Knowing Your Audience

One of the most important assets that you, as trainer or co-trainer, have is to get to "know your audience." This means knowing something about the individuals who will be participants in the training so you can tailor content and clinical scenarios/exercises to their learning needs.

For example, you may want to know 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/exercises.

Education — knowing the educational background of participants can help you gauge the type of language to use and to tailor it to their area of education and educational attainment.

Job/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/exercises or learning methods for the group. Consider inviting participants with more experience to contribute to the discussion, to model role plays, and — during small group work — to pair up with participants who have less experience.

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. Ask what participants are saying about the 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 get to know your audience

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

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

Ways to 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 other resources. Find out how the content can be shortened or lengthened, depending on participant learning needs. Consider how the timetable can be adjusted to create 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 or clinical scenarios/exercises and/or discussion questions in areas that participants know well.
2. Practice before the training. Practice 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 training scenarios/exercises using this Trainer Notes 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") that tell co-trainers and/or participant presenters how much time they have left.
5. Keep the training focused on the learning objectives.
6. Use the "parking lot" for discussions that take too much time or are related, but not critical, to the topic under discussion (see box below).

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 "car park" 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 revisit the topic or question and remove it from the "parking lot."

Being an Effective Trainer

Trainers should always keep the following "dos and don'ts" in mind.[2]

DOs

- Do maintain good eye contact.
- Do prepare in advance.
- Do involve participants.
- Do use visual aids.
- Do speak clearly.
- Do speak loud enough.
- Do encourage questions.
- Do recap at the end of each module.
- Do bridge one topic to the next.
- Do encourage participation.
- Do write clearly and boldly.
- Do summarize.
- Do use logical sequencing of topics.
- Do use good time management.
- Do K.I.S. (Keep It Simple).
- Do give feedback.
- Do position visuals so everyone can see them.
- Do avoid distracting mannerisms and distractions in the room.
- Do be aware of the participants' body language.

- Do keep the group focused on the task.
- Do provide clear instructions.
- Do check to see if your instructions are understood.
- Do evaluate as you go.
- Do be patient.

DON'Ts

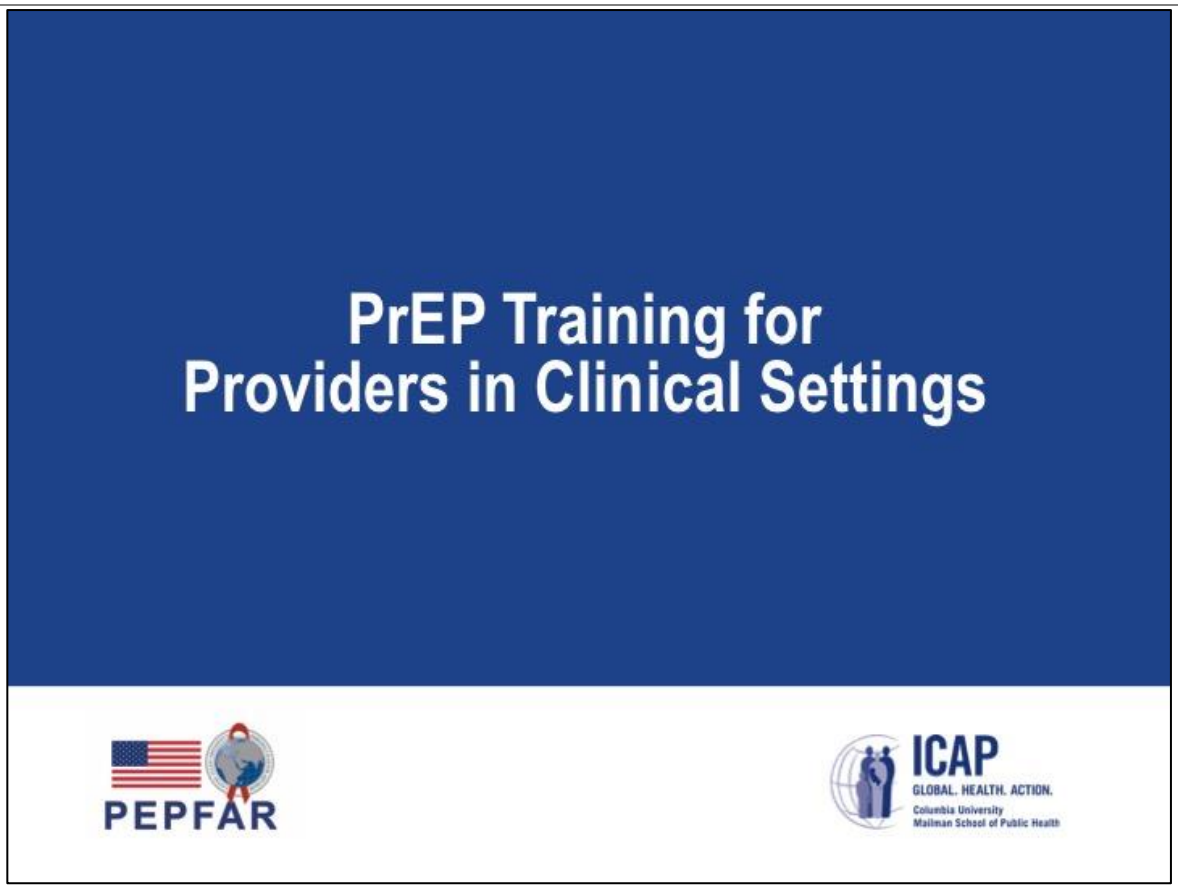
- Don't talk to the flip chart.
- Don't block the visual aids.
- Don't stand in one spot—move around the room.
- Don't ignore the participants' comments and feedback (verbal and non-verbal).
- Don't read from the slides.
- Don't assume everyone has the same level of baseline knowledge.
- Don't assume everyone can read and write at the same level.

[1] Bonner Curriculum (updated). *Facilitation 202: More techniques and strategies.* Available at: http://bonnernetwork.pbworks.com/w/page/13112080/Bonner-Training-Modules-(with-Descriptions)

[2] The dos and don'ts of training were 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: Pathfinder International.

Registration, Completion of Pre-Program Assessment, and Module 1: PrEP Basics

DURATION: 90 MINUTES (1.5 HOURS)



Welcome!

- Please sign the registration sheet.
- Please make a name tag for yourself.
- Please take a participant's folder.

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Pre-Program Assessment

- Please remove the pre-program assessment questionnaire from your participant folder.
- The purpose of this assessment is to determine what you know about implementing PrEP. Your responses will help determine if there is anything in today's program that needs to be adjusted in the future.
  - **The assumption is that you know very little about PrEP, so please don't worry.**
- You have 20 minutes to complete the pre-program assessment questionnaire.
- Please hand in your completed questionnaire when you are finished.

3

Pre-Program Assessment Debriefing

- *How did you feel about the pre-program assessment questions?*
- *Were the questions easy or difficult?*

Answers to the questions will be provided after you complete the post-test at the end of today's training.

4

Introductions

- Take 1 minute (and only 1 minute, please!) to:
  - State your name, organization and position.

5

PrEP-Specific Competencies

After completing today's training program, participants will be able to:

- Identify eligible candidates for PrEP.
- Conduct an individualized risk assessment.
- Educate and counsel PrEP candidates and users.
- Conduct clinical and laboratory assessments during the initial PrEP visit.
- Prescribe PrEP.
- Conduct clinical and laboratory assessments during follow-up PrEP visits.
- Review PrEP monitoring and evaluation (M&E) tools.

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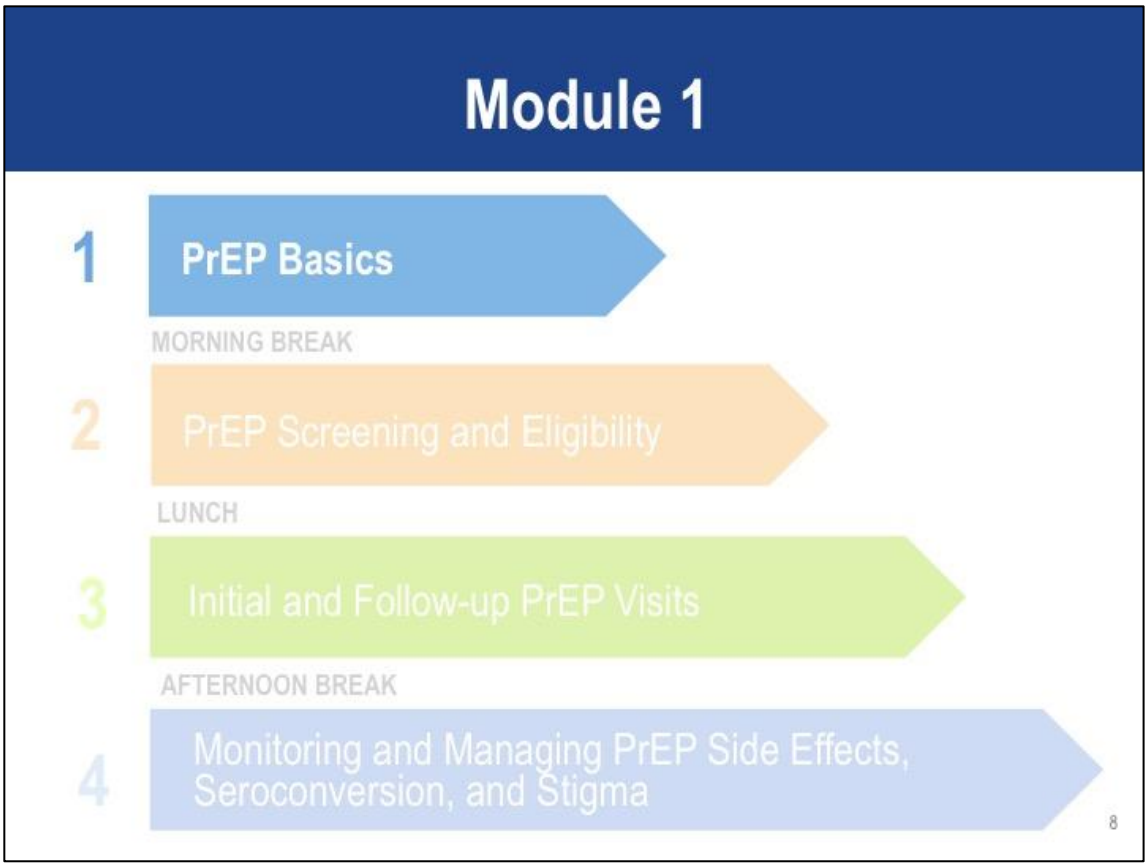
Training Overview
1
PrEP Basics
MORNING BREAK
2
PrEP Screening and Eligibility
LUNCH
3
Initial and Follow-up PrEP Visits
AFTERNOON BREAK
4
Monitoring and Managing PrEP Side Effects, Seroconversion, and Stigma
7


Module 1
1
PrEP Basics
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2
PrEP Screening and Eligibility
LUNCH
3
Initial and Follow-up PrEP Visits
AFTERNOON BREAK
4
Monitoring and Managing PrEP Side Effects, Seroconversion, and Stigma
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Module 1: Learning Objectives

After completing module 1, participants will be able to:

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

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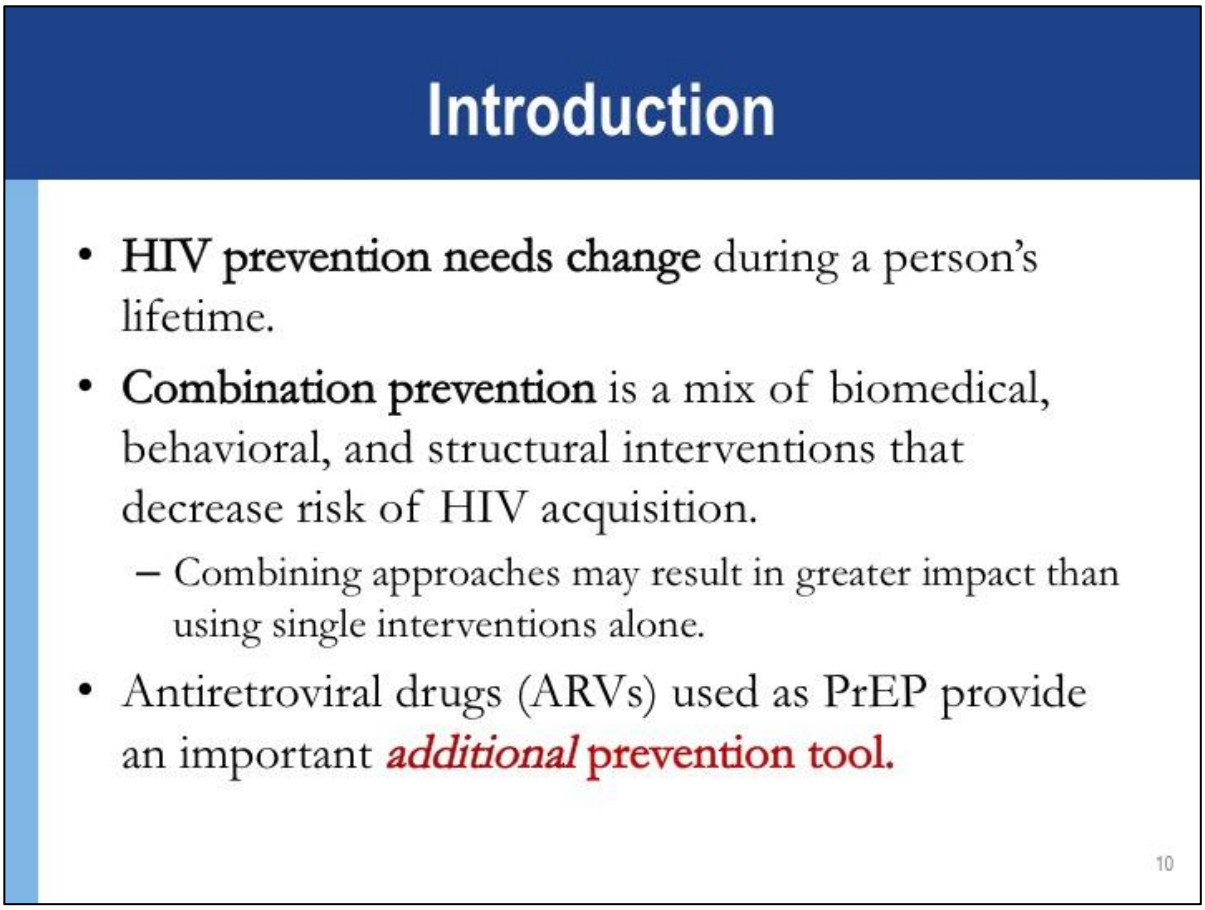
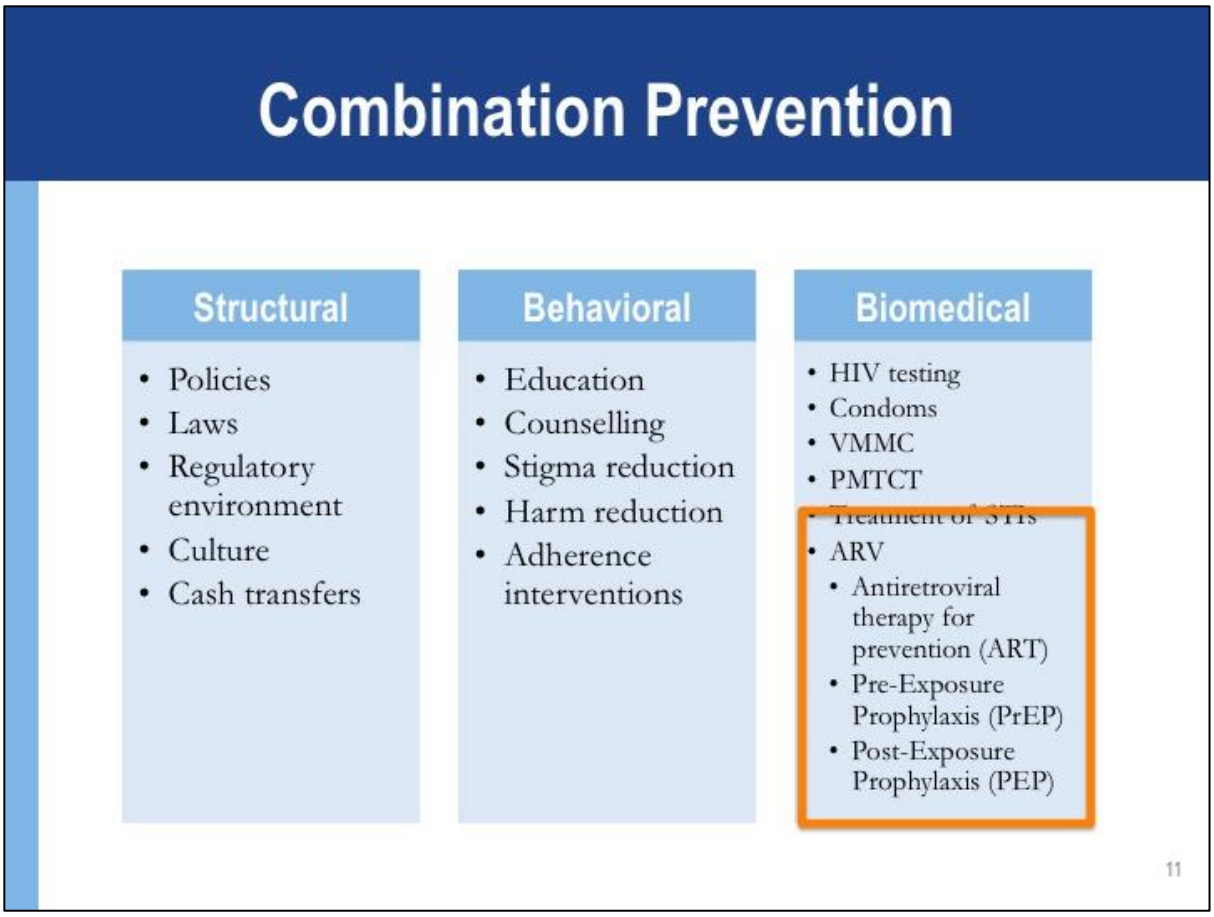


Speaker Notes:

- Different people have different HIV prevention needs and, for a given individual, prevention needs can change over time.
- No single prevention intervention can fully address all prevention needs.
- To prevent HIV infection, a combination of structural, behavioral, and biomedical interventions are used.
- The combination of prevention approaches used are based on both epidemiological and demographic evidence of what is needed in a particular setting.
- Combining approaches result in synergies with greater impact than single interventions alone.
- Antiretroviral drugs (ARVs) are now used as *additional* tools in combination prevention. The use of ARVs for HIV prevention is well established; we have been using ARVs to prevent mother-to-child transmission of HIV (PMTCT) and for post- exposure prophylaxis (PEP) for many years.



Speaker Notes:

- Combination HIV prevention refers to the combination of structural, behavioural, and biomedical interventions aimed at reducing new HIV infections.
- Structural interventions aim to address social, economic, political, environmental, cultural, and also organizational, community, legal, or policy factors that influence vulnerability and predispose different groups of people to HIV infection.
- Behavioral interventions support behavior change to reduce the risk of HIV infection.
- Biomedical interventions are particular tools, commodities, or mechanisms that lower infectiousness of HIV infected persons and/or susceptibility of HIV-negative persons to HIV. Within biomedical interventions is the use of antiretroviral drugs for HIV prevention.
- This training will focus on biomedical interventions, specifically the use of ARV for pre-exposure prophylaxis (PrEP).

Question

What is Pre-Exposure Prophylaxis (PrEP)?

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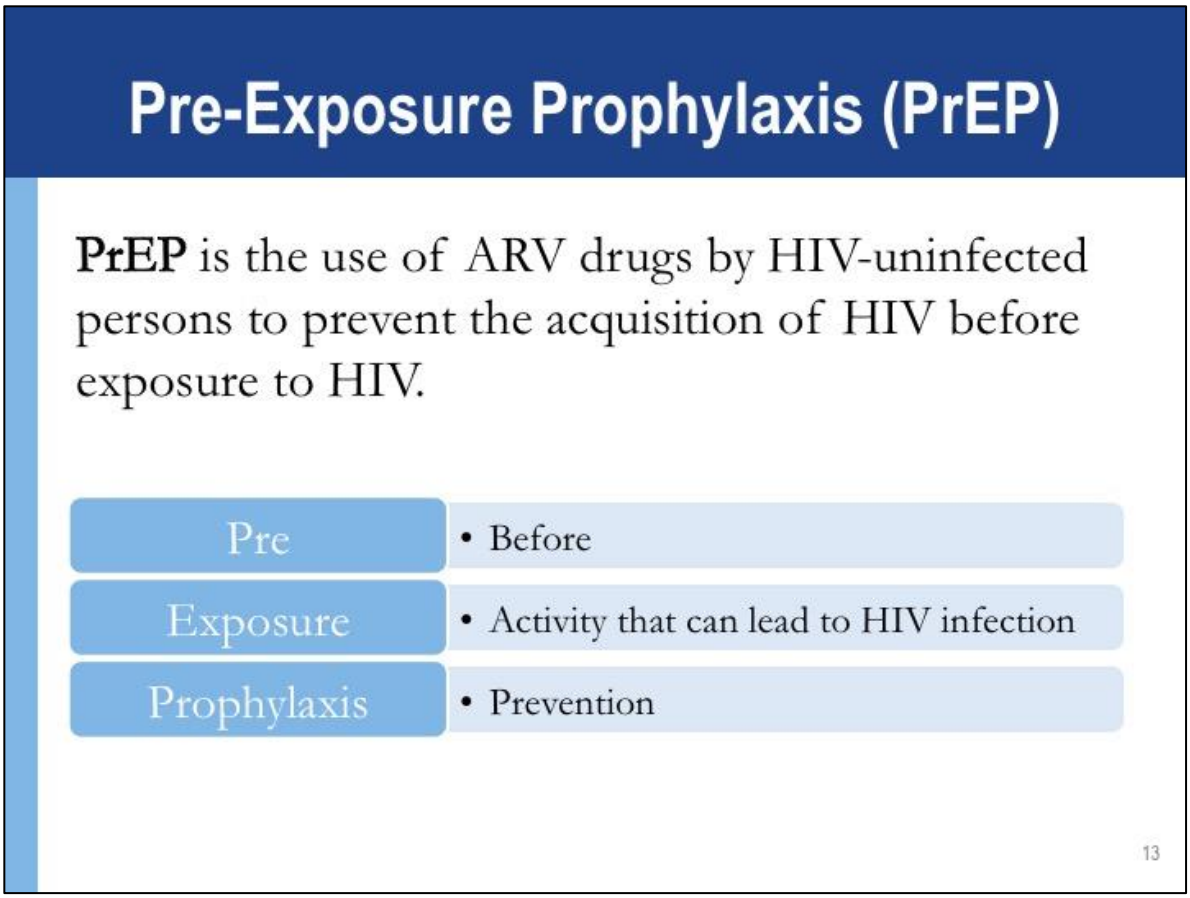

Speaker Notes:

- PrEP is a new biomedical prevention intervention where HIV-**negative** persons take ARVs to prevent acquisition of HIV.
- PrEP is an ARV-based prevention intervention and is part of combination prevention.
- It is the **ongoing** use of ARVs by HIV-negative individuals starting before an exposure and continuing afterwards.
- 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).

Question

What are some similarities and differences between Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP)?

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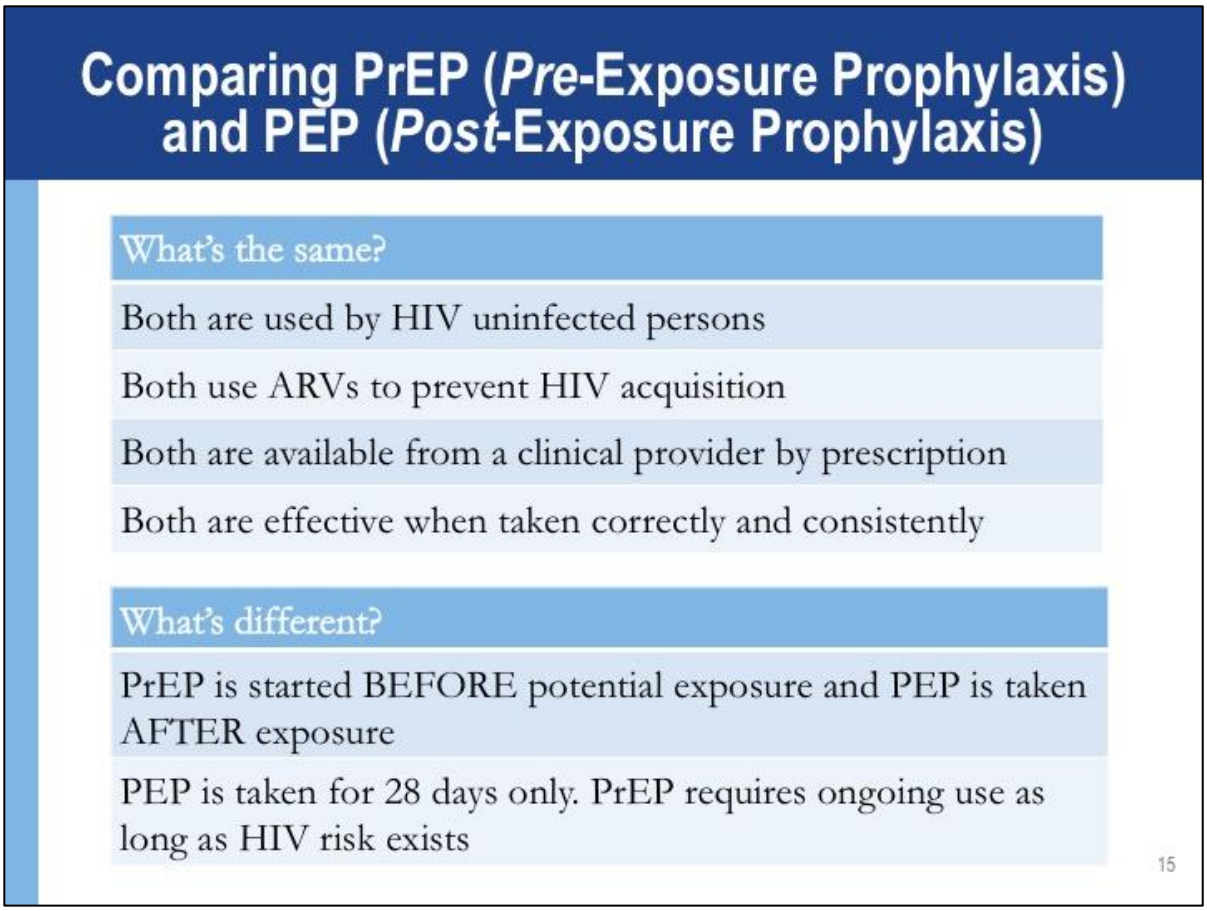
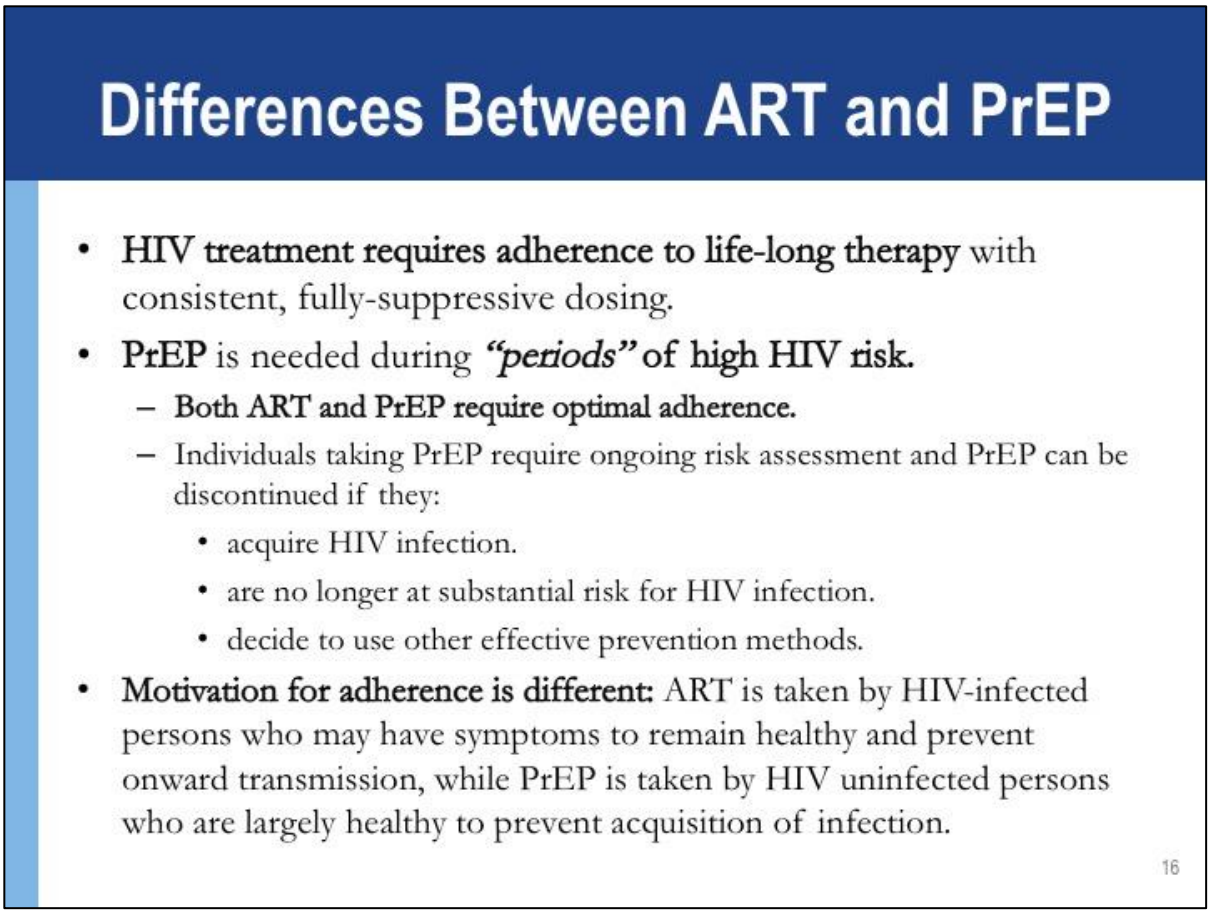


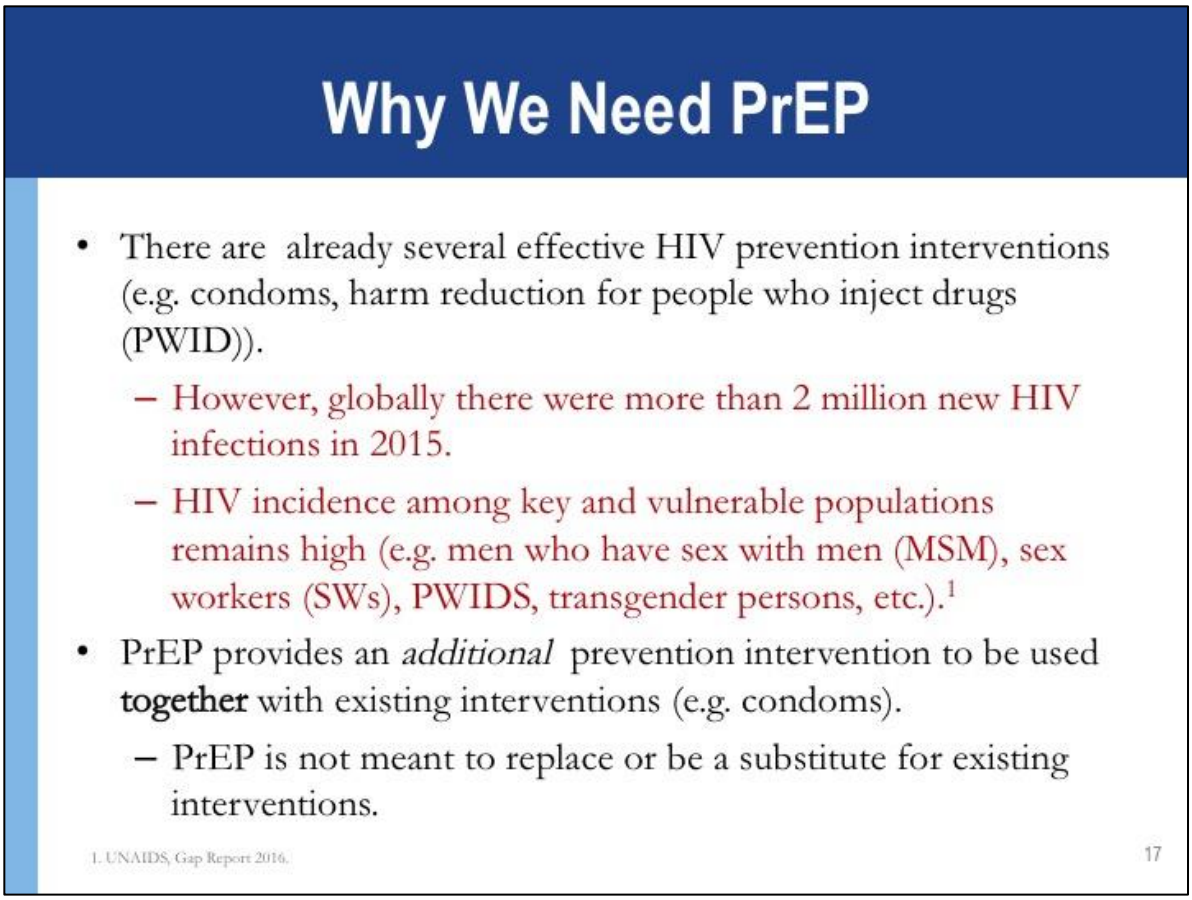
Speaker Notes:

- Comparing pre- and post-exposure prophylaxis. Let's look at what is similar and what is different.
- What's the same?
  - Both PrEP and PEP are used by HIV negative persons
  - Both PrEP and PEP use ARVS to prevention HIV infection
  - Both are available from a medical provider by prescription
  - Both are effective when if taken consistently
- There are however differences between PrEP and PEP.
  - PrEP is started BEFORE and PEP is taken AFTER the exposure
  - PEP is taken only for 28 days. PrEP requires ongoing use of ARVs as long as HIV risk exists.



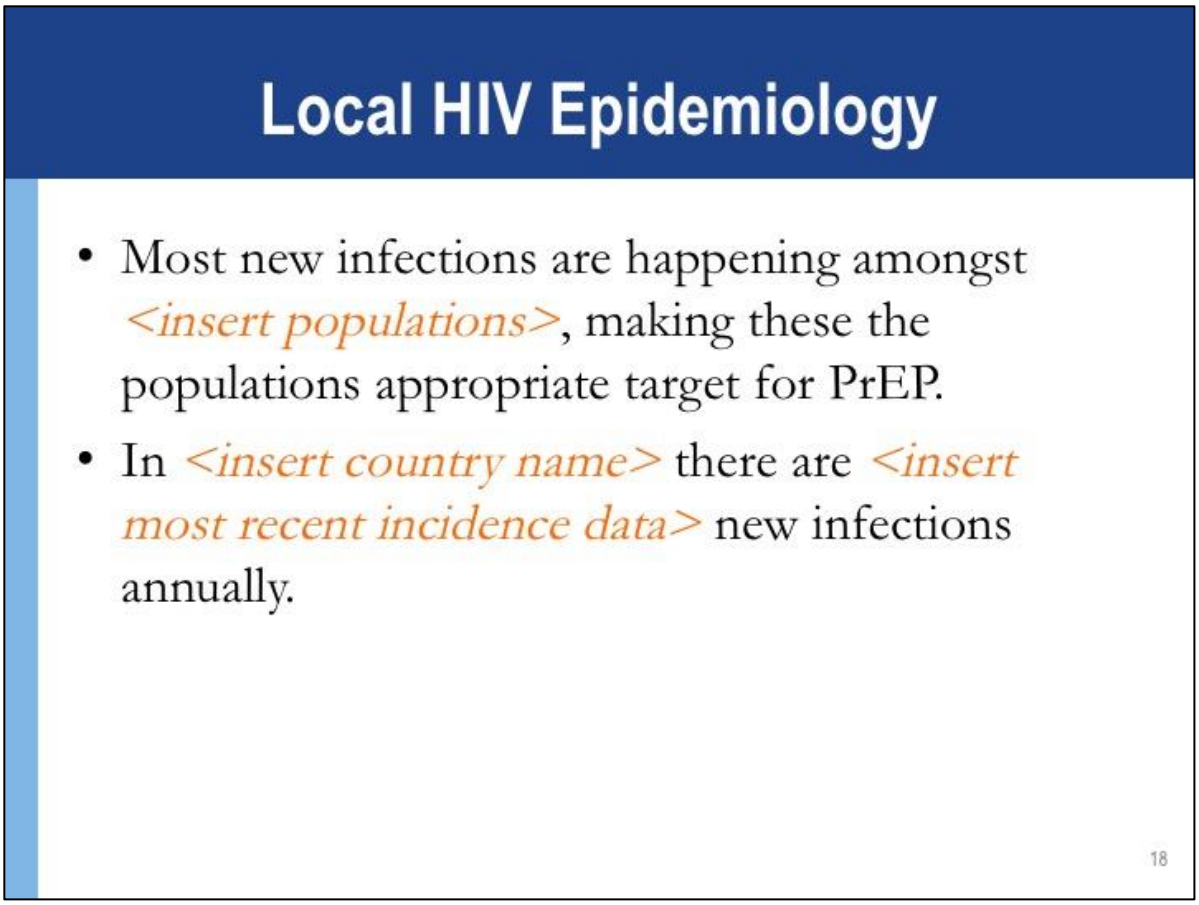
Speaker Notes:

- There are some differences between ART and PrEP.
- ART is taken by HIV infected persons for treatment.
- PrEP is used by HIV uninfected persons for prevention. There are alternative prevention methods a person can use.
- HIV treatment requires life-long therapy with constant dosing.
- PrEP is needed during *periods* of high HIV risk. Clients can discontinue PrEP if they feel they are no longer at risk (e.g. in a mutually monogamous relationship with HIV-negative partner).
- Or if they decide to use other effective prevention methods (e.g. consistent use of male or female condoms).
- Motivation for adherence is different: ART is taken by HIV infected persons so they can remain healthy, while PrEP is taken by HIV uninfected persons to prevent infection.



Speaker Notes:

- We have several effective HIV prevention interventions already (e.g. condoms, harm reduction for PWID), why do we need another prevention intervention? Because…
    - New HIV infections still occur despite prevention efforts
    - New HIV infections among key populations are quite high
- PrEP will not replace or be a substitute for existing prevention interventions, but rather will be an additional prevention tool.



Speaker Notes:

ADD COUNTRY-SPECIFIC DATA TO THIS SLIDE

- Countries to add 1 or 2 slides to explain the HIV epidemiology, where most new HIV infections are happening and the different KP targeted for PrEP use at a local level.

Question

Who are Key Populations (KPs) or other populations targeted for PrEP at the local level?

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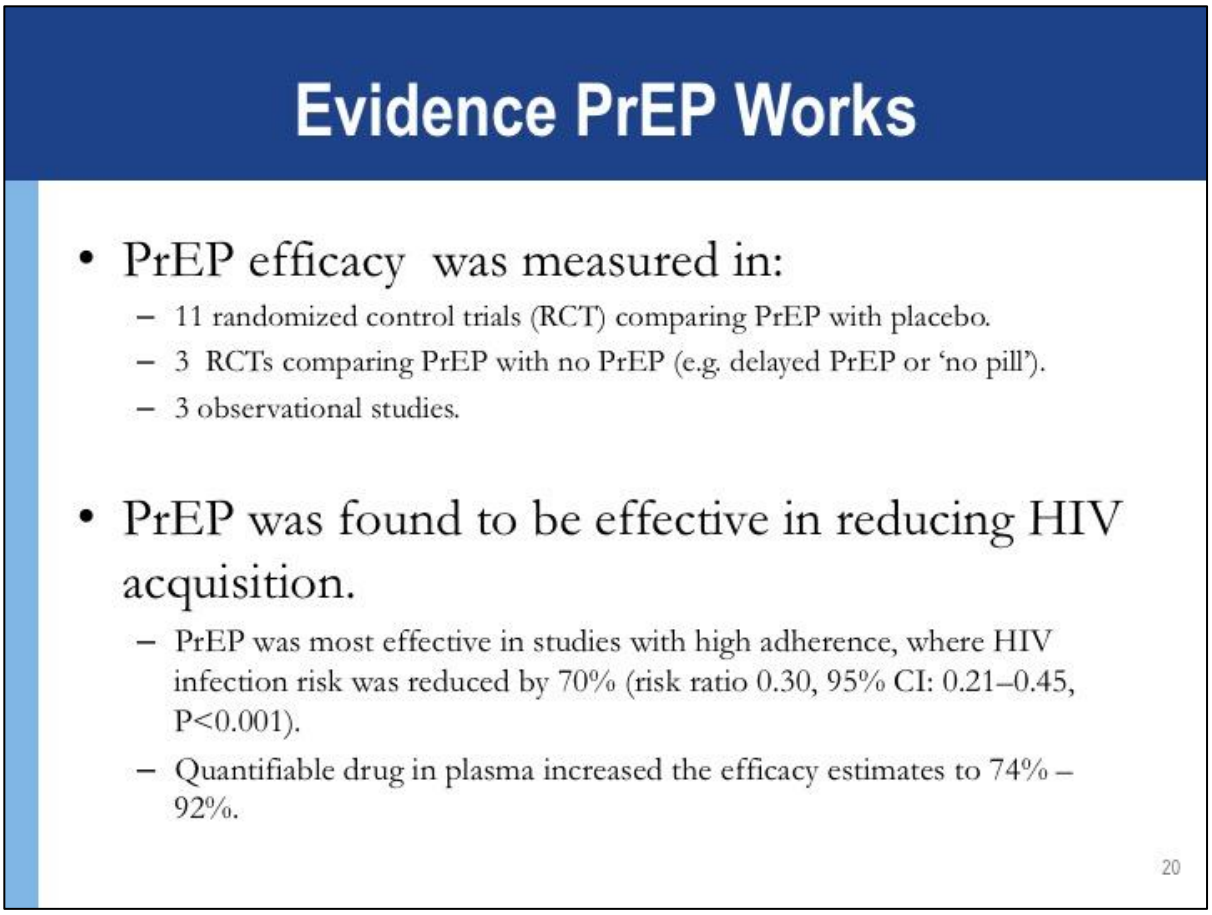
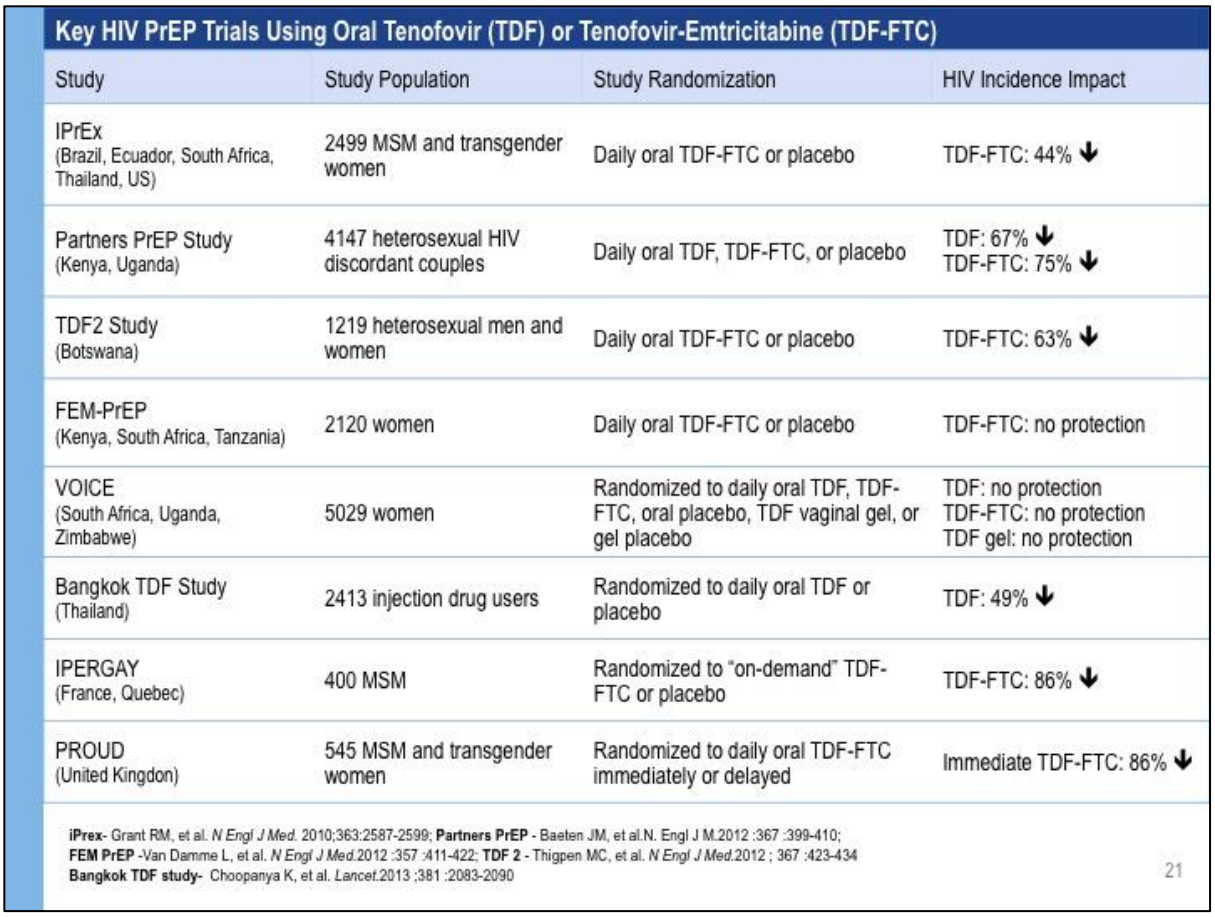


Speaker Notes:

- There have been several studies to assess the efficacy of PrEP.
- PrEP effectiveness was measured in several randomized control trials (RCT) comparing PrEP with placebo and also in RCTs comparing PrEP with no PrEP (e.g. delayed PrEP or 'no pill'), and in observational studies.
- PrEP was found to be effective in reducing HIV acquisition.
- PrEP was most effective in studies when adherence was high.



Key HIV PrEP Trials Using Oral Tenofovir (TDF) or Tenofovir-Emtricitabine (TDF-FTC)

Study	Study Population	Study Randomization	HIV Incidence Impact
IPrEx (Brazil, Ecuador, South Africa, Thailand, US)	2499 MSM and transgender women	Daily oral TDF-FTC or placebo	TDF-FTC: 44% ↓
Partners PrEP Study (Kenya, Uganda)	4147 heterosexual HIV discordant couples	Daily oral TDF, TDF-FTC, or placebo	TDF: 67% ↓ TDF-FTC: 75% ↓
TDF2 Study (Botswana)	1219 heterosexual men and women	Daily oral TDF-FTC or placebo	TDF-FTC: 63% ↓
FEM-PrEP (Kenya, South Africa, Tanzania)	2120 women	Daily oral TDF-FTC or placebo	TDF-FTC: no protection
VOICE (South Africa, Uganda, Zimbabwe)	5029 women	Randomized to daily oral TDF, TDF-FTC, oral placebo, TDF vaginal gel, or gel placebo	TDF: no protection TDF-FTC: no protection TDF gel: no protection
Bangkok TDF Study (Thailand)	2413 injection drug users	Randomized to daily oral TDF or placebo	TDF: 49% ↓
IPERGAY (France, Quebec)	400 MSM	Randomized to "on-demand" TDF-FTC or placebo	TDF-FTC: 86% ↓
PROUD (United Kingdon)	545 MSM and transgender women	Randomized to daily oral TDF-FTC immediately or delayed	Immediate TDF-FTC: 86% ↓

iPrex- Grant RM, et al. *N Engl J Med.* 2010;363:2587-2599; **Partners PrEP** - Baeten JM, et al.N. Engl J M.2012 :367 :399-410;
FEM PrEP -Van Damme L, et al. *N Engl J Med.*2012 :357 :411-422; **TDF 2** - Thigpen MC, et al. *N Engl J Med.*2012 ; 367 :423-434
Bangkok TDF study- Choopanya K, et al. *Lancet.*2013 ;381 :2083-2090

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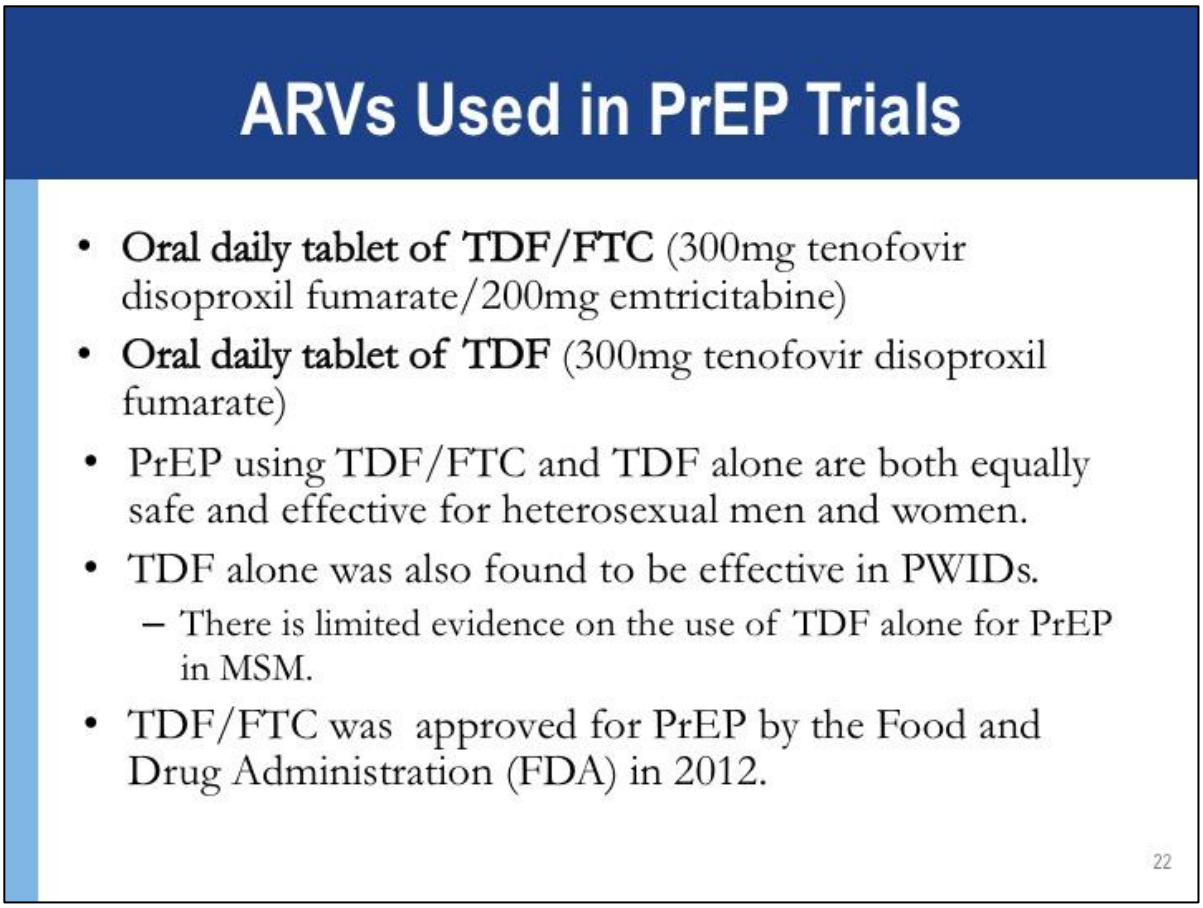
Speaker Notes:

- We have evidence of efficacy from several clinical trials among MSM, heterosexual men and women, and people who inject drugs. For study participants with Truvada in plasma, efficacy reached 92%.
- There were disappointing results in the FEMPreP and VOICE trials which were discontinued for futility.
- References for some studies:
  - iPrex- Grant RM, et al. *N Engl J Med.* 2010;363:2587-2599
  - Partners PrEP - Baeten JM, et al.N. Engl J M.2012 :367 :399-410
  - TDF 2 - Thigpen MC, et al. *N Engl J Med.*2012 ; 367 :423-434
  - FEM PrEP -Van Damme L, et al. *N Engl J Med.*2012 :357 :411-422
  - Bangkok TDF study- Choopanya K, et al. *Lancet.*2013 ;381 :2083-2090



Speaker Notes:

- Tenofovir/emtricitabine (TDF/FTC) was found to be safe and effective in MSM, transgender women, and heterosexual men and women in several clinical trials.
- TDF/FTC was approved for PrEP by the FDA in 2012
- A lot of countries already use TDF/FTC as part of their first-line HIV treatment regimen.

iPREX study

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Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

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ABSTRACT

BACKGROUND

Antiretroviral chemoprophylaxis before exposure is a promising approach for the prevention of human immunodeficiency virus (HIV) acquisition.

METHODS

We randomly assigned 2499 HIV-seronegative men or transgender women who have sex with men to receive a combination of two oral antiretroviral drugs, emtricitabine and tenofovir disoproxil fumarate (FTC–TDF), or placebo once daily. All subjects received HIV testing, risk-reduction counseling, condoms, and management of sexually transmitted infections.

RESULTS

The study subjects were followed for 5324 person-years (median, 1.2 years; maximum, 2.8 years). Of these subjects, 10 were found to have been infected with HIV at enrollment, and 100 became infected during follow-up (36 in the FTC–TDF group and 64 in the placebo group), indicating a 44% reduction in the incidence of HIV (95% confidence interval, 15 to 65; P=0.005). In the FTC–TDF group, the study drug was detected in 22 of 43 of seronegative subjects (51%) and in 3 of 34 HIV-infected subjects (9%) (P<0.001). Nausea was reported more frequently during the first 4 weeks in the FTC–TDF group than in the placebo group (P<0.001). The two groups had similar rates of serious adverse events (P=0.57).

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Grant at the J. David Gladstone Institutes, University of California at San Francisco, 1650 Owens St., San Francisco, CA 94158, or at robert.grant@ucsf.edu.

*Other members of the Preexposure Prophylaxis Initiative (iPrEx) study team are listed in the Supplementary Appendix, available at NEJM.org.

This article (10.1056/NEJMoa1011205) was published on November 10, 2010, and updated on December 1, 2010, at NEJM.org.

N Engl J Med 2010;363:2587-99.

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- **Study Design**
  - N = 2499 HIV-seronegative men (or transgender women)
  - Sexual orientation: sex with men
  - All received risk reduction counseling, condoms, & STI Rx
- **Regimens**
  - TDF/FTC (*Truvada*): 1 pill PO daily
  - Placebo: 1 pill PO daily
- **Result**
  - 44 % reduction in incident HIV in the TDF/FTC arm

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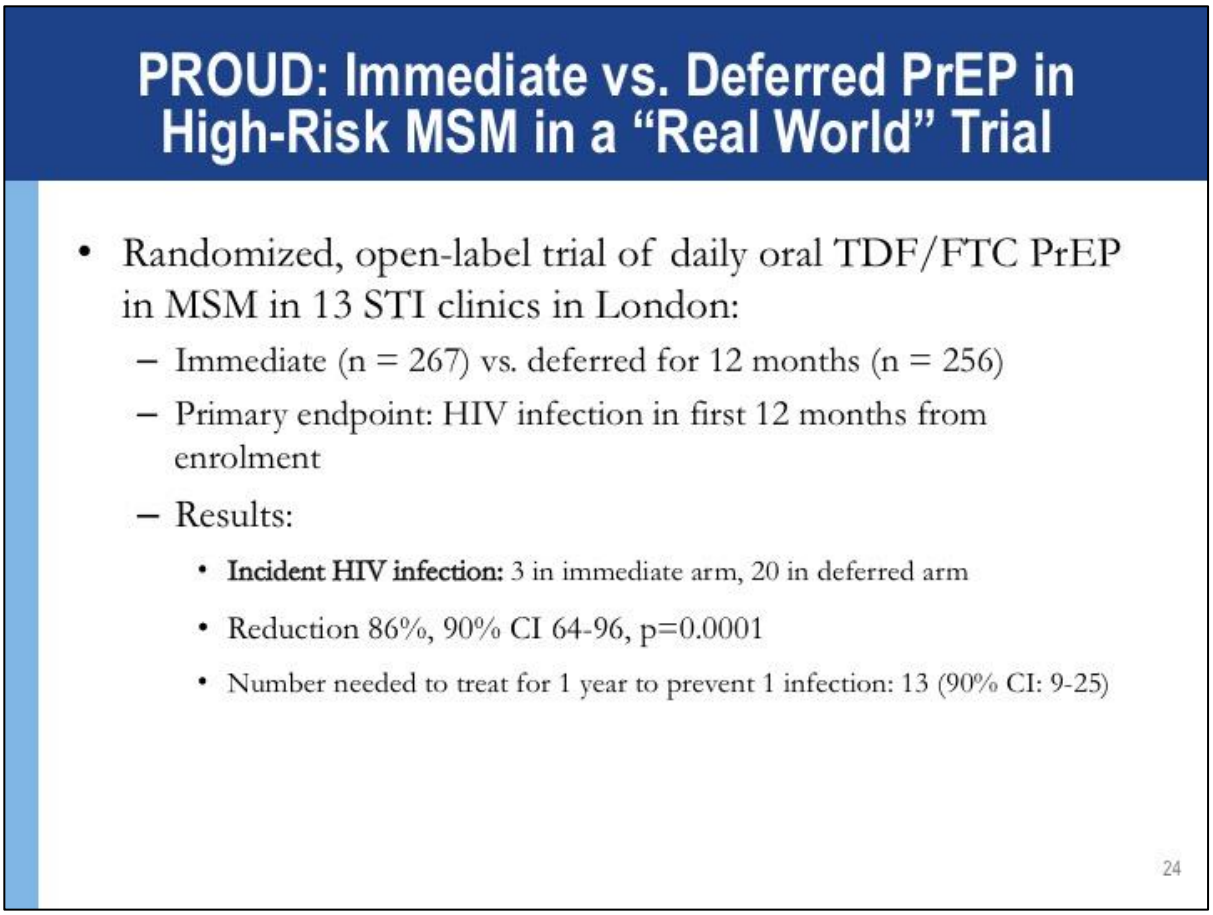
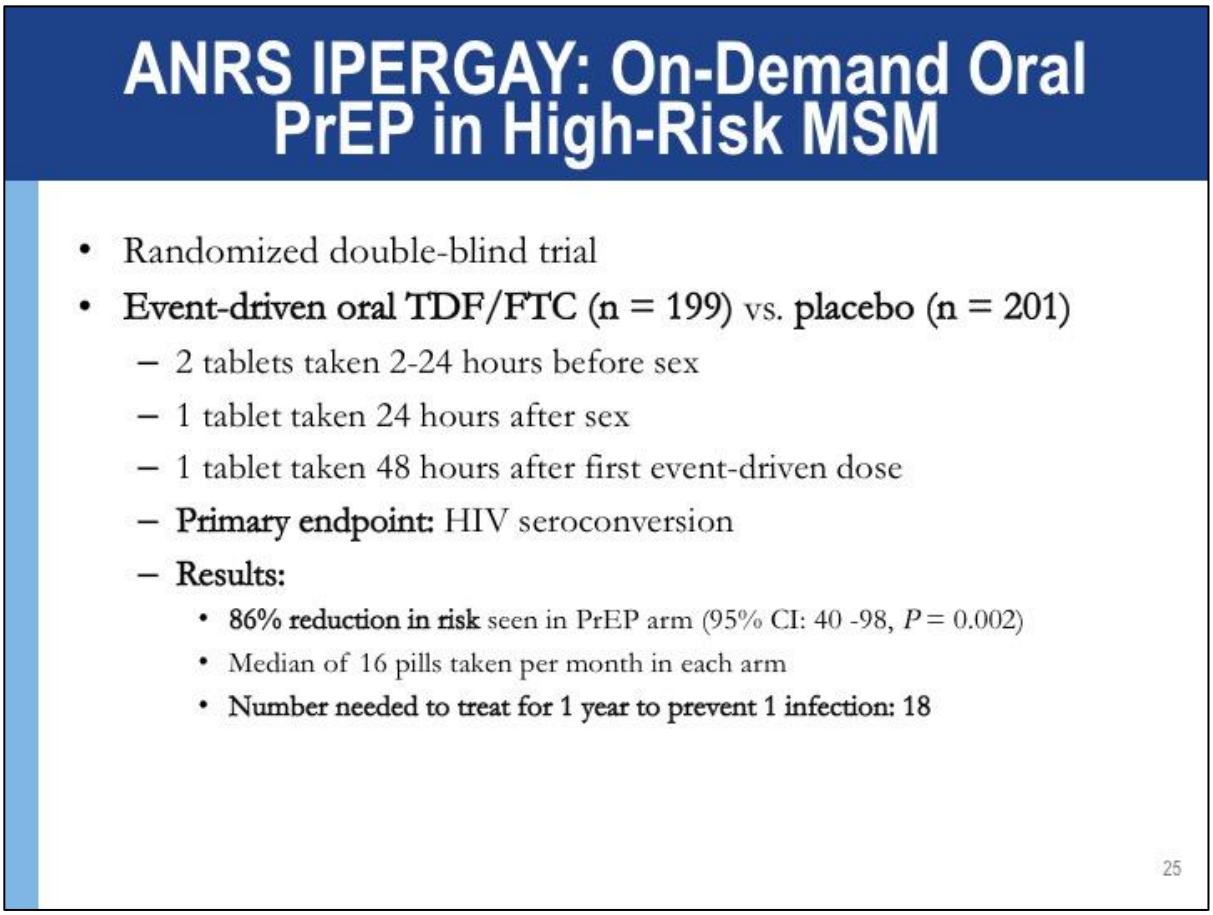
Speaker Notes:

- In 2010 we had the first results on pre-exposure chemoprophylaxis for HIV prevention among MSM.
- The iPREX study was conducted in Brazil, Ecuador, South Africa, Thailand, and the U.S.
- The study enrolled HIV-negative men and transgender women.
- There was a 44% reduction in incident HIV in the TDF/FTC arm.



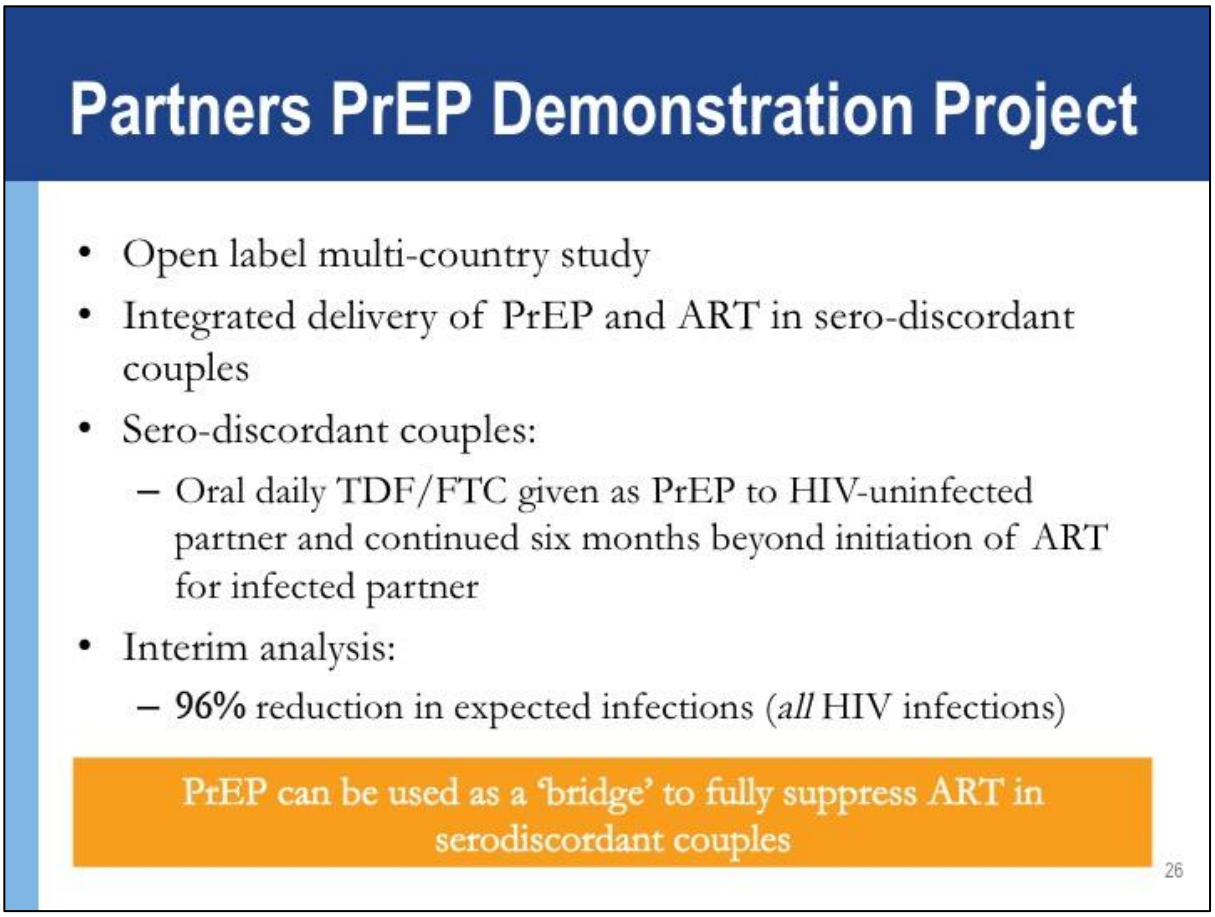
Speaker Notes:

- The PROUD study looked at immediate versus deferred PrEP in high risk MSM in London, UK.
- The study was designed to mimic a "real world" environment. PrEP services were provided in public Sexual Health Clinics. The clinics that took part in the PROUD study were able to integrate PrEP into their routine HIV risk reduction package with ease. Participants incorporated PrEP into existing personal risk reduction strategies, which included condom use.
- Results showed an 86% reduction in HIV risk in the immediate arm.



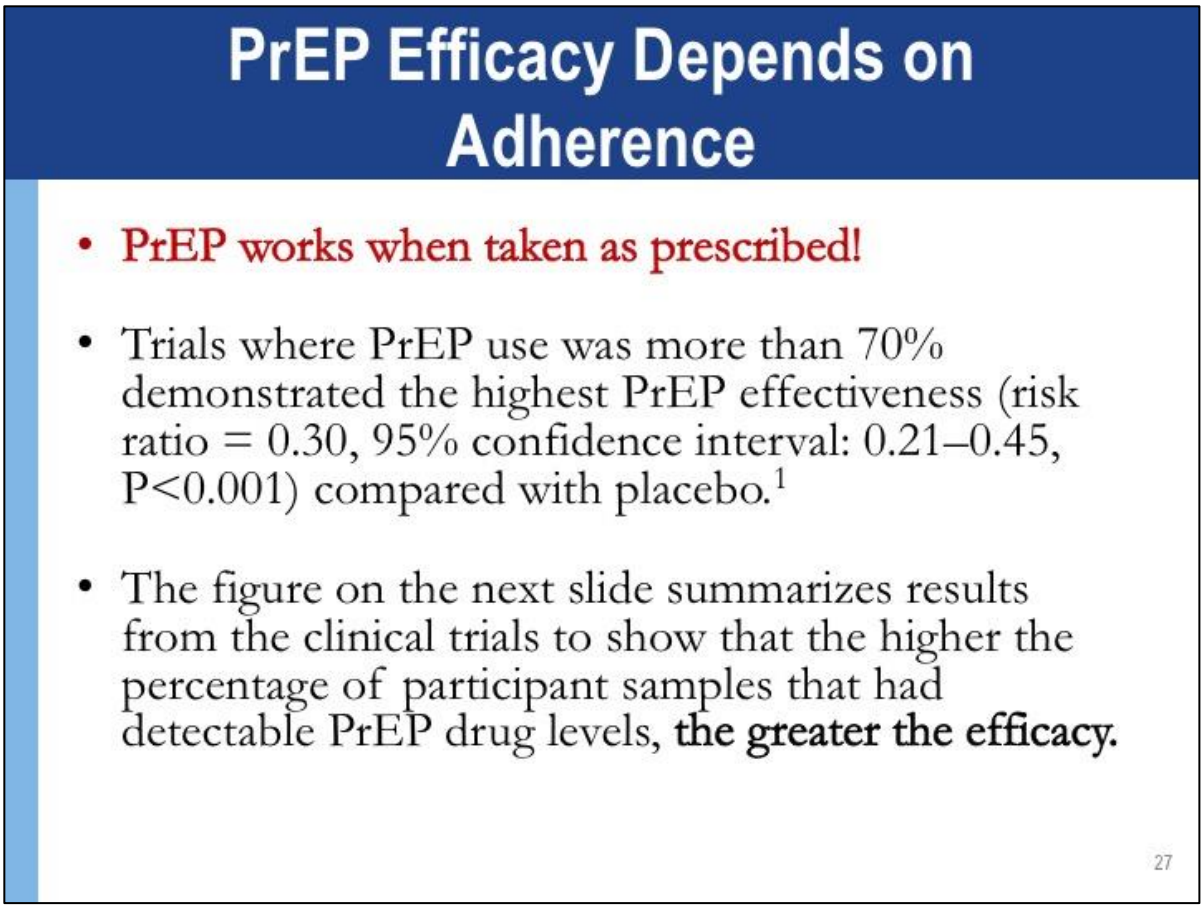
Speaker Notes:

- A second study - The IPERGAY trial - studied "on- demand" PrEP in high risk MSM in France and Canada.
- Results showed 86 percent reduction in PrEP arm.



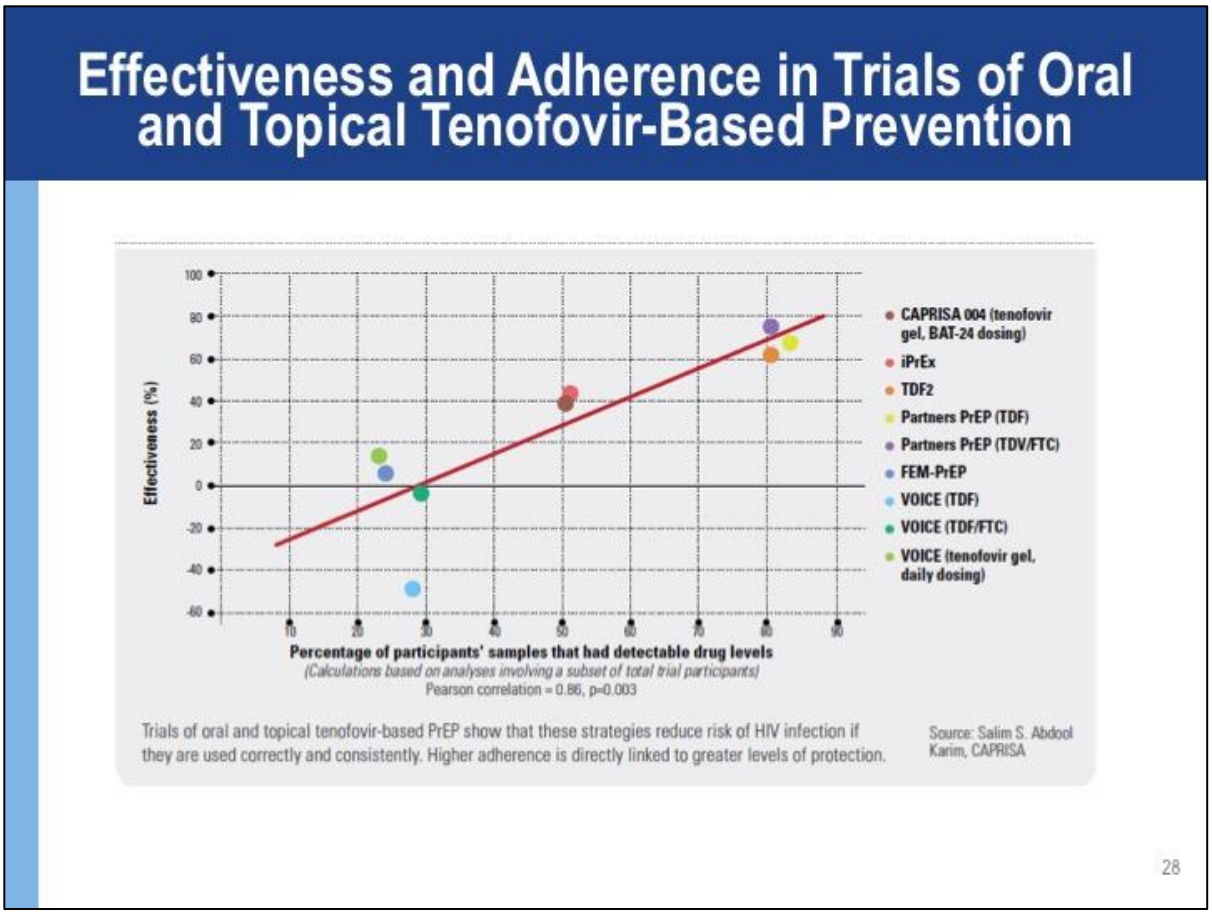
Speaker Notes:

- A third study, the Partners PrEP demonstration project, studied the integrated delivery of PREP and ART in high-risk sero-discordant couples.
- The study found that PrEP can provide protection for the HIV uninfected partner while the HIV infected partner starts ART and achieves viral load suppression.



Speaker Notes:

- Across populations and PrEP regimens, PrEP significantly reduced the risk of HIV acquisition compared with placebo. However, efficacy was strongly correlated to adherence.



Speaker Notes:

- You can see on the graph that when there was high level of PrEP drug in the blood (e.g,. for the Partners PrEP study), effectiveness was high.
- However, when blood level of ARV was low (because of poor adherence) as in the Voice study, PrEP was not effective.

Defining Adherence

- **Adherence to drug(s)** means that an individual is taking prescribed medications ***correctly*** **and** ***consistently***, it involves taking the correct drug:
  - in the correct dose,
  - at a consistent frequency (number of times per day), and
  - at a consistent time of day.
- **Adherence with follow–up** means patients attend *all* scheduled clinical visits/procedures, including:
  - Clinic and lab assessments.
  - Drug collection/repeat prescription.

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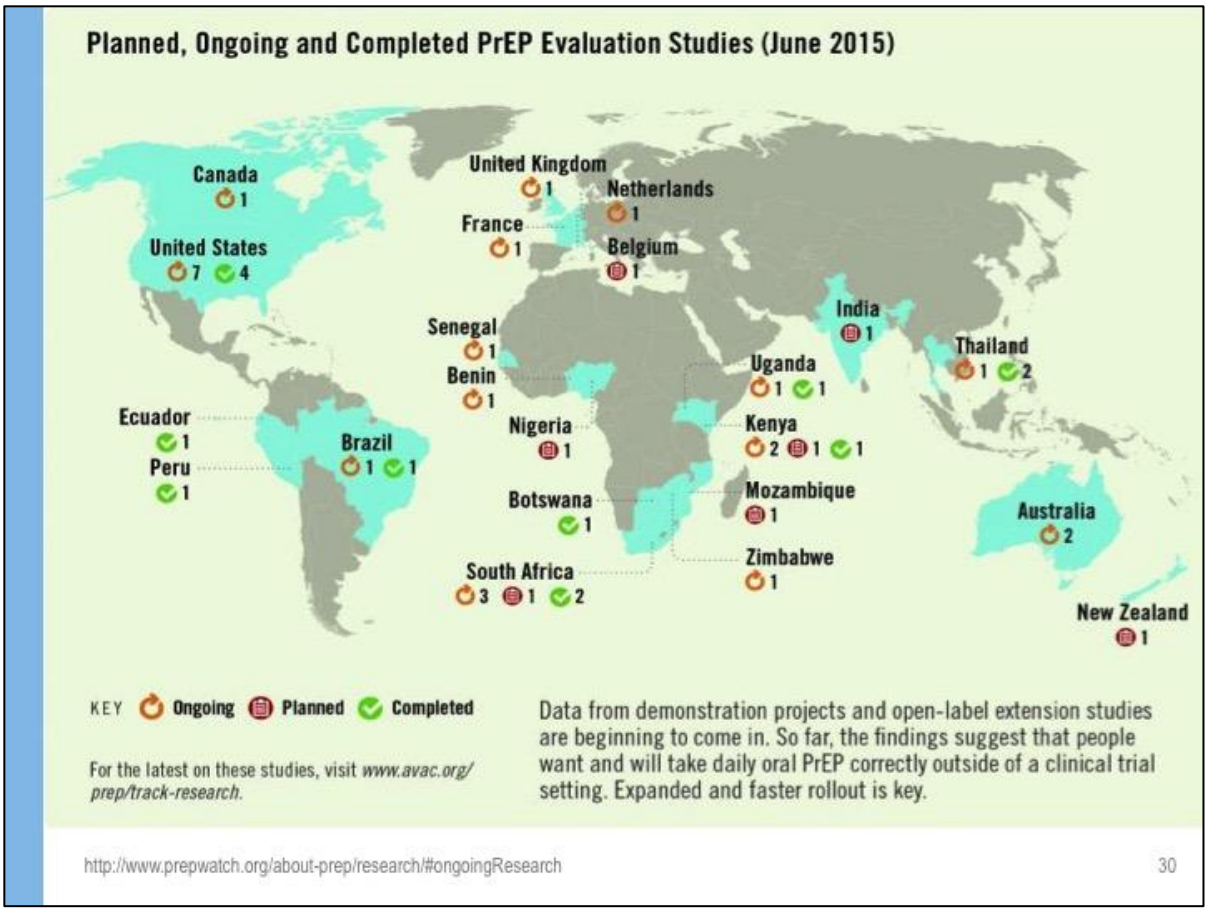
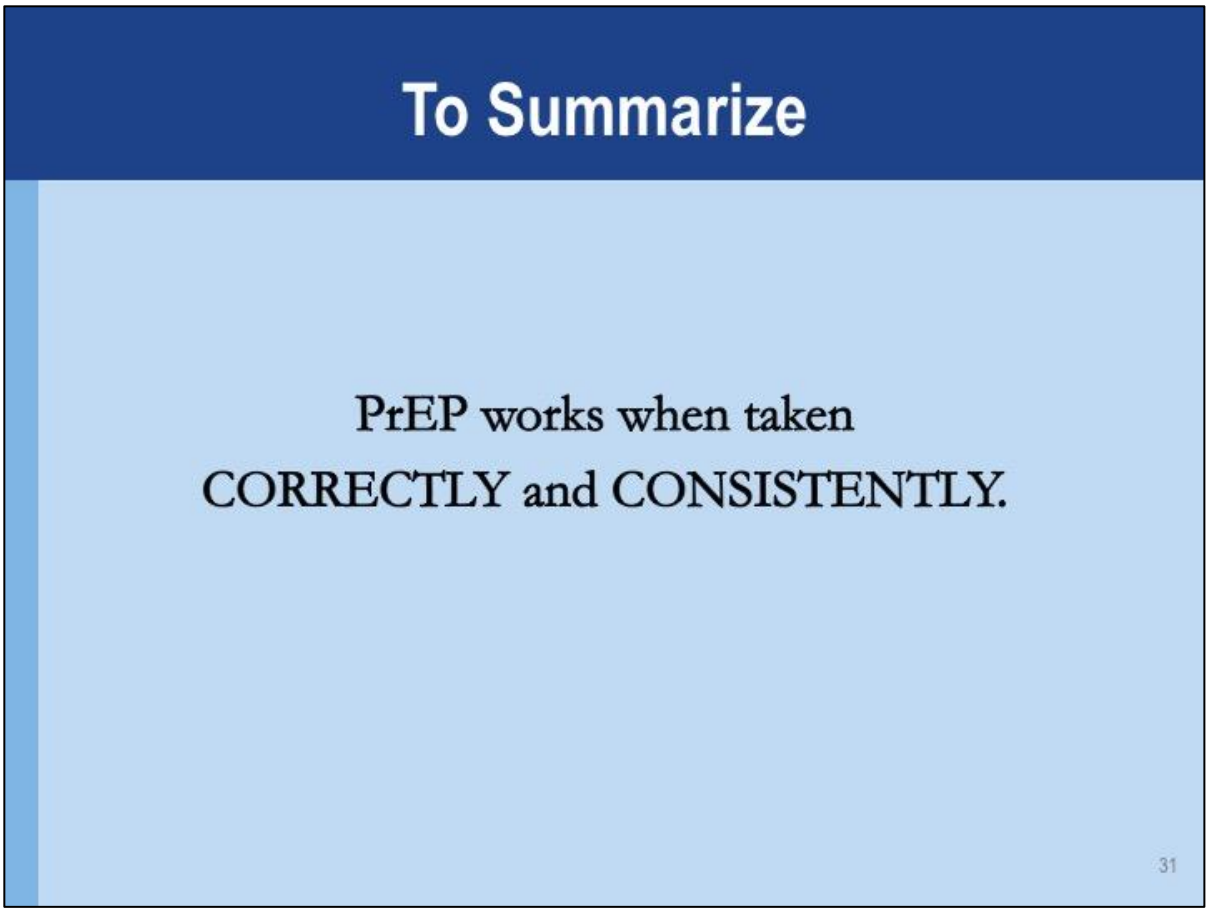


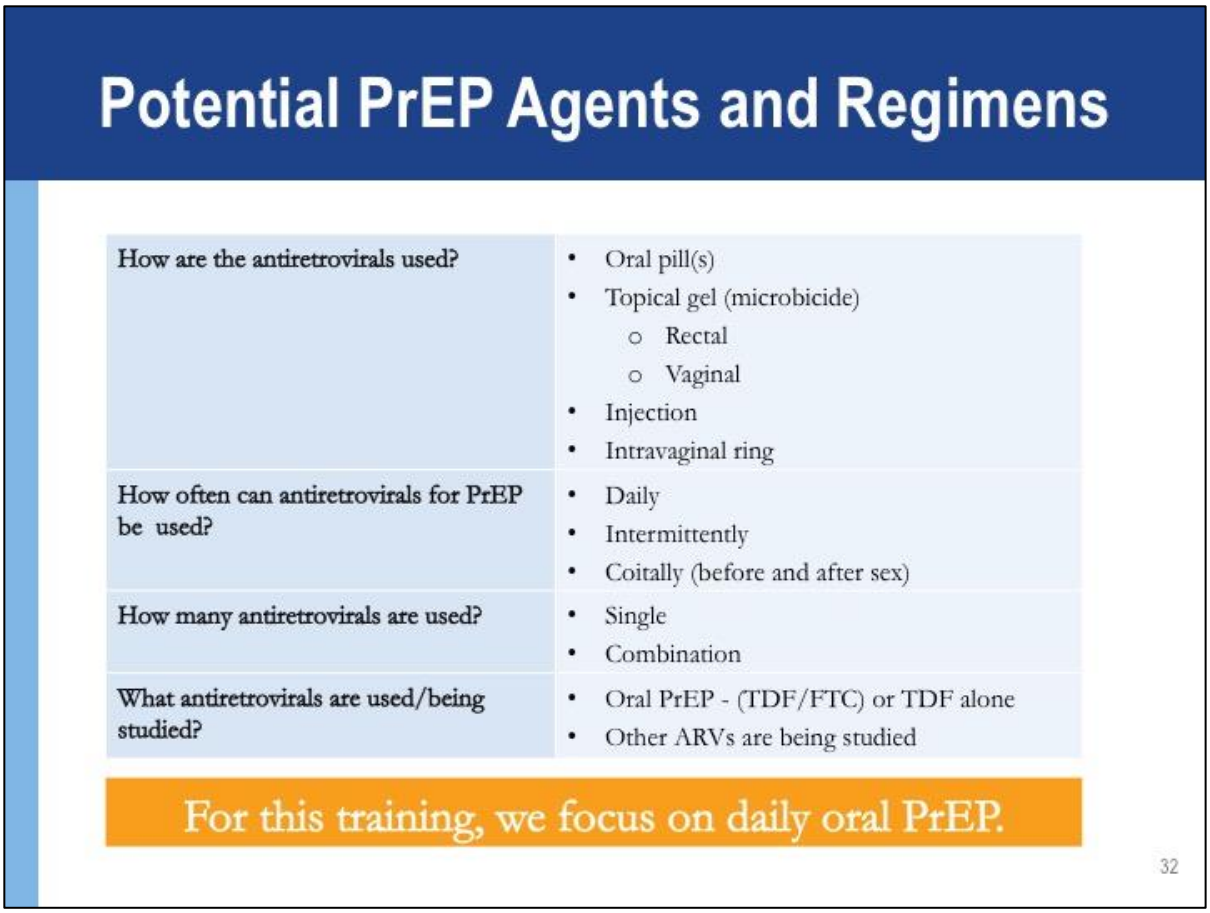
Speaker Notes:

- This slide shows planned, ongoing and completed PrEP studies. You can get updated information on the PrEPwatch website.



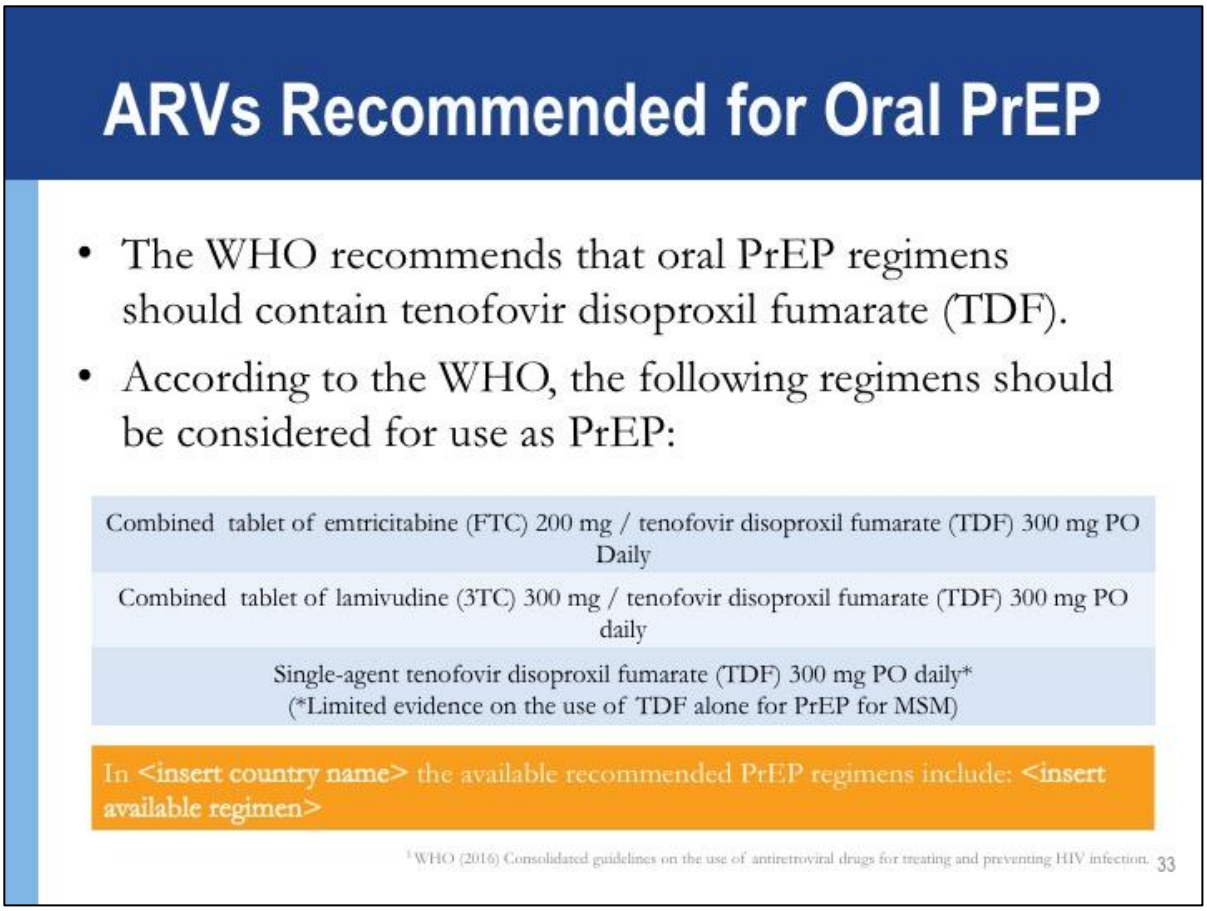
Speaker Notes:

- So what do we know about PrEP? The evidence shows that PrEP works. PrEP works when taken correctly and consistently.



Speaker Notes:

- PrEP can be used as oral pills, a topical gel and by injection.
- PrEP can be taken daily, intermittently, or at the time of sex.
- Orally, a single ARV (tenofovir) as well as a combination of two ARVs (tenofovir/emtricitabine) have been used in several studies.
- For this training we focus on daily oral PrEP.



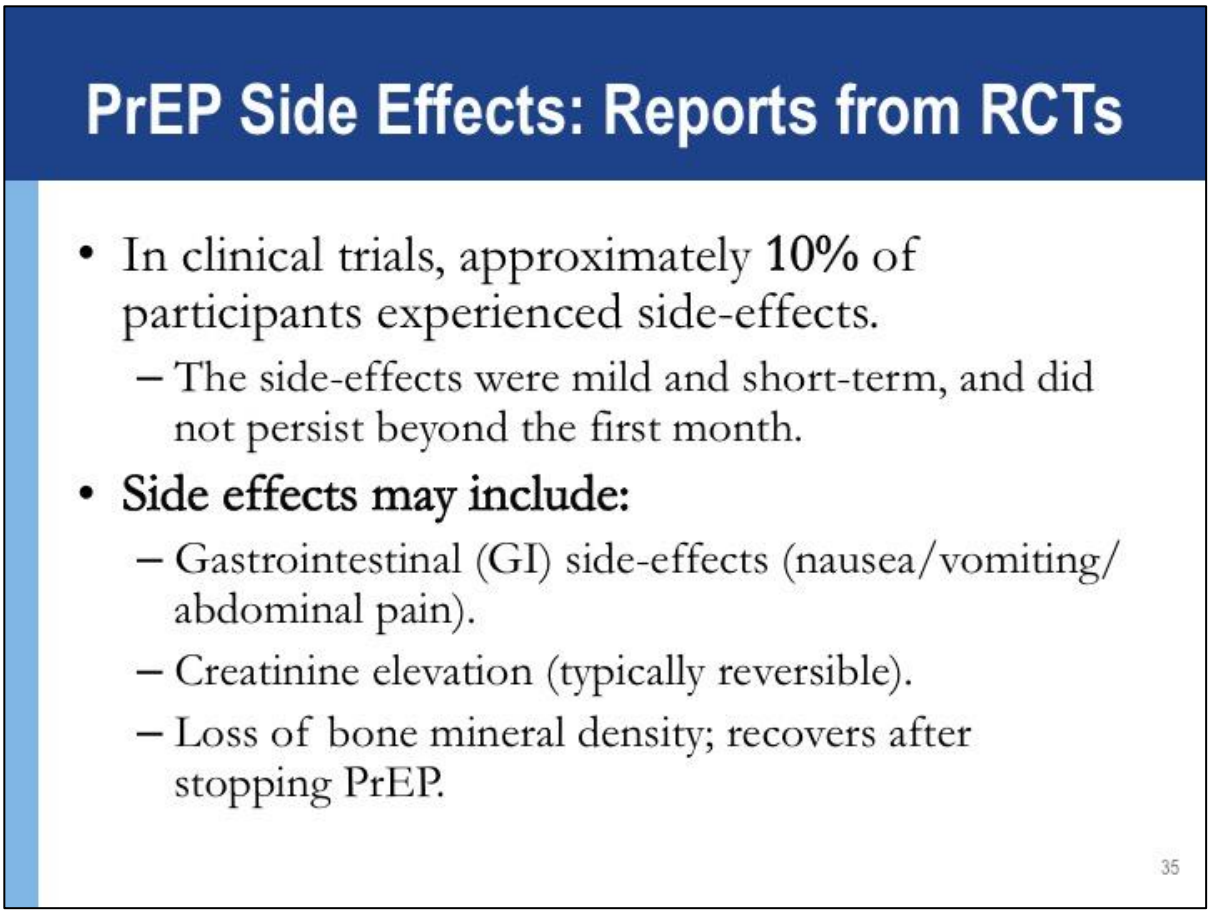
Speaker Notes:

- ADD COUNTRY-SPECIFIC DATA TO THIS SLIDE

Concerns about PrEP

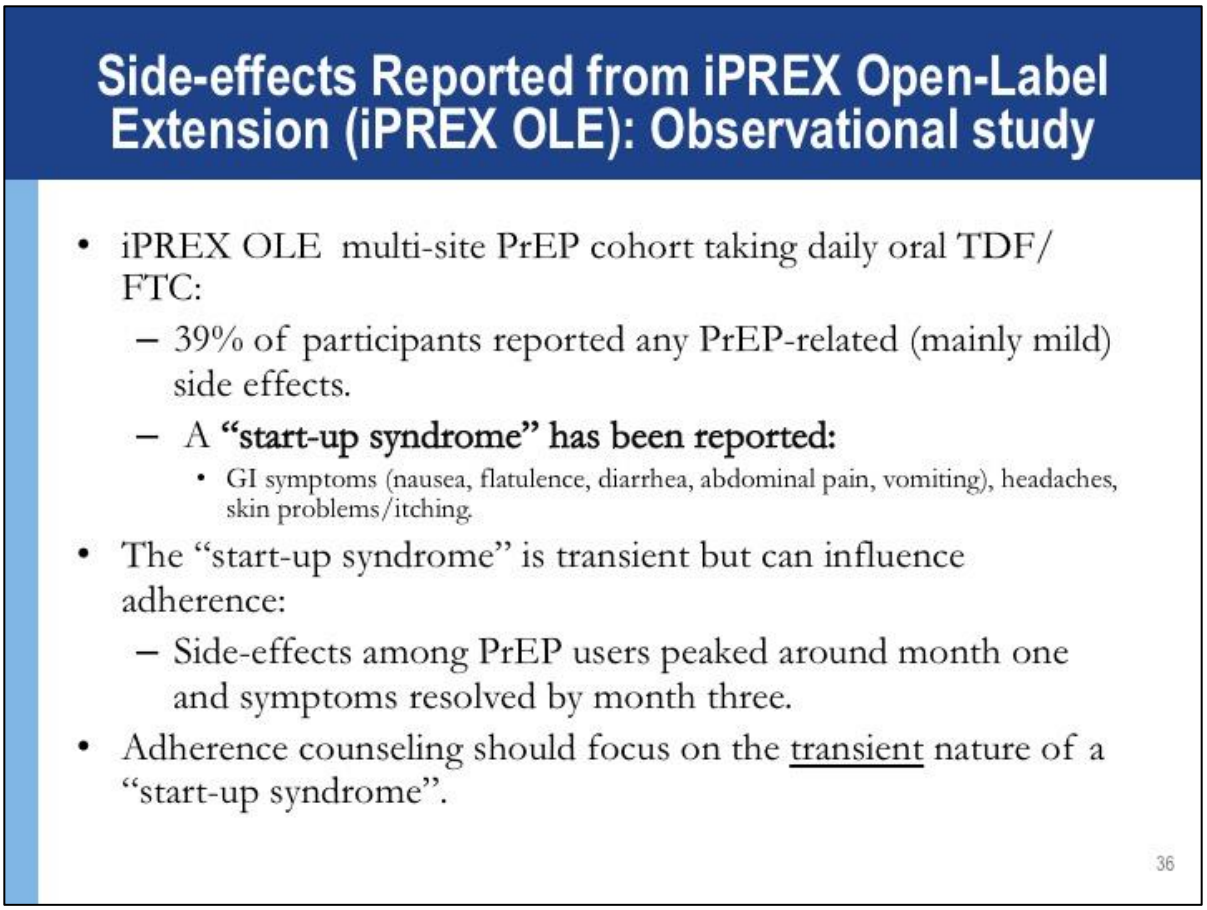
- Is PrEP safe?

34



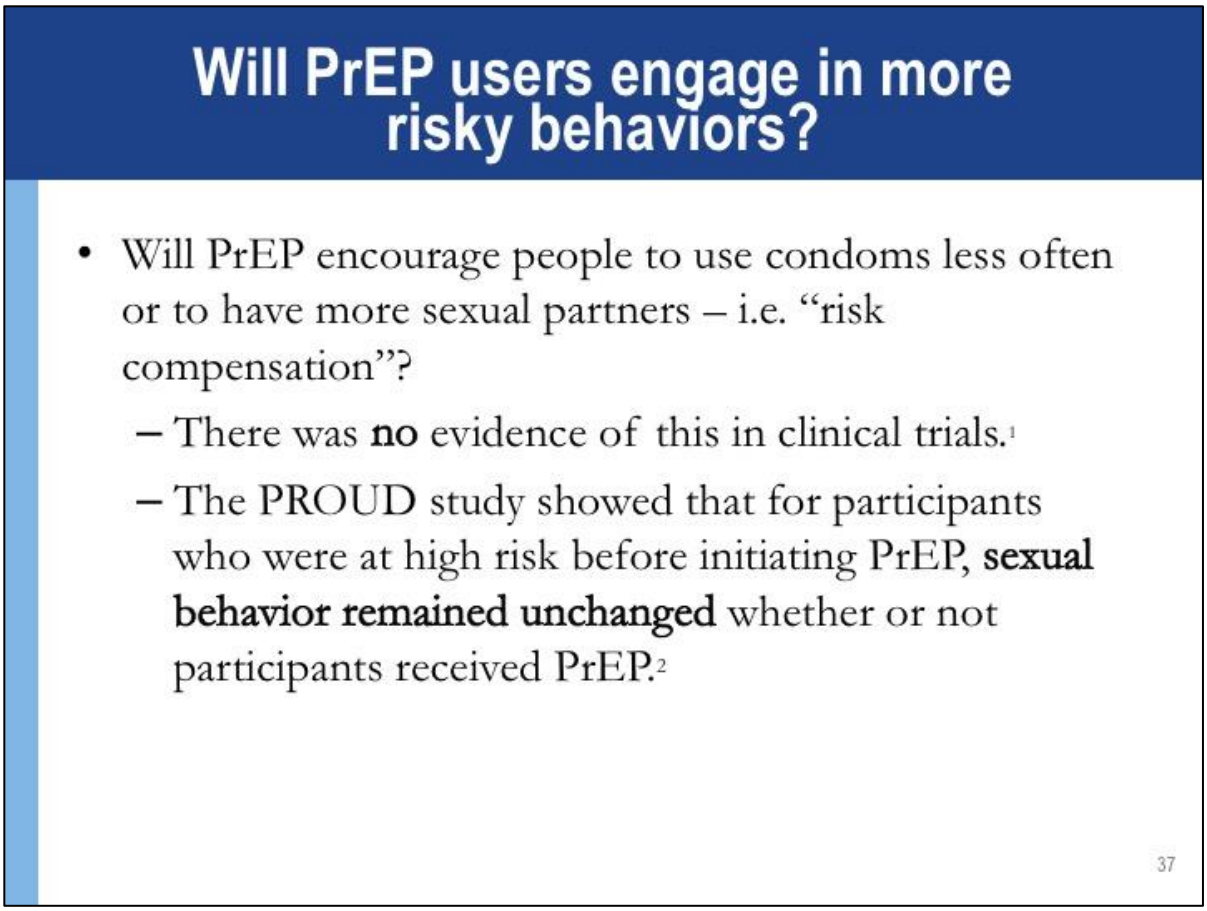
Speaker Notes:

- There have been some concerns about PrEP.
- One concern is around safety - Is PrEP safe?
- PrEP showed no evidence of increased proportion of adverse events. Analysis of results of many PrEP studies show that 90 percent of participants had no side-effects!
- PrEP is safe!
- Approximately 10 percent in clinical trials experienced mild, short-term side-effects like nausea, tiredness, gastrointestinal symptoms (flatulence) and headache.



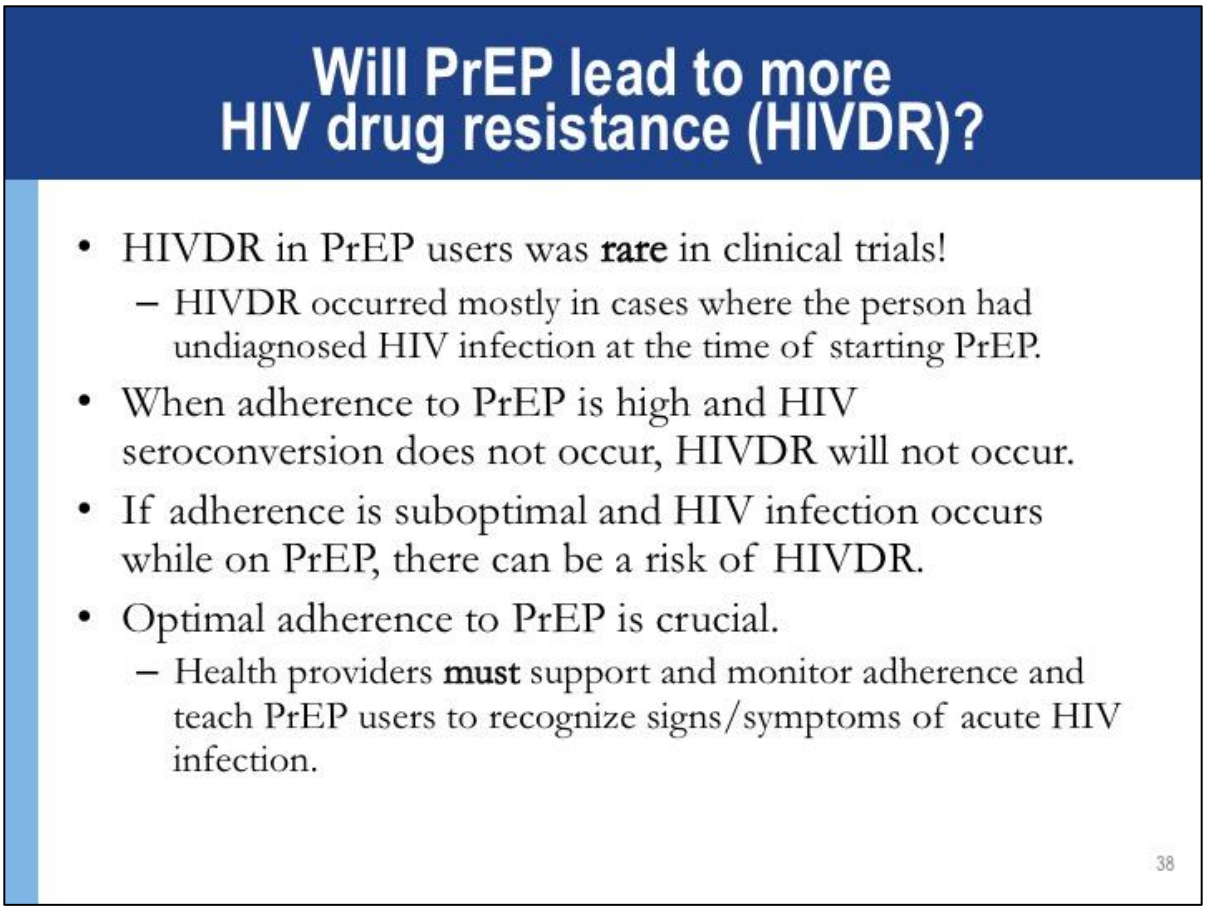
Speaker Notes:

- The Open-Label Extension (iPREX OLE) was an observational study, which is a term used to describe the situation when both the researcher and the participant in a research study know the treatment the participant is receiving.
- Participants in the study reported a "start syndrome" with GI symptoms, headaches and some skin problems. This start–up syndrome was TRANSIENT and it is important to counsel clients about this.



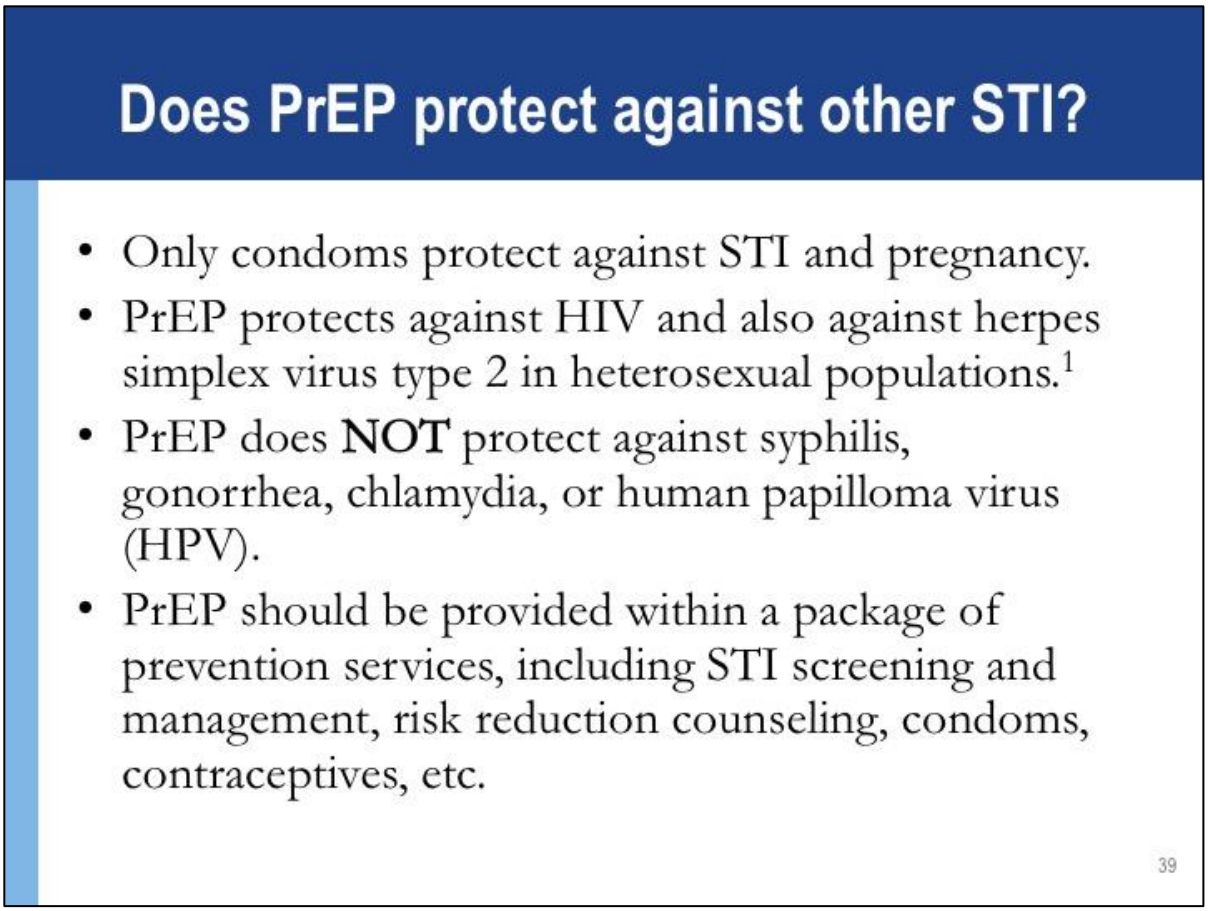
Speaker Notes:

- Another concern is risk-compensation.
- Will PrEP encourage people to use condoms less often than before, or to have more sexual partners - "risk compensation"?
- There was no evidence of risk compensation in clinical trials.
- PrEP users were people with high risk behaviors. The PROUD study showed that participants were at high risk before PrEP and sexual behavior remained unchanged whether or not participants received PrEP.



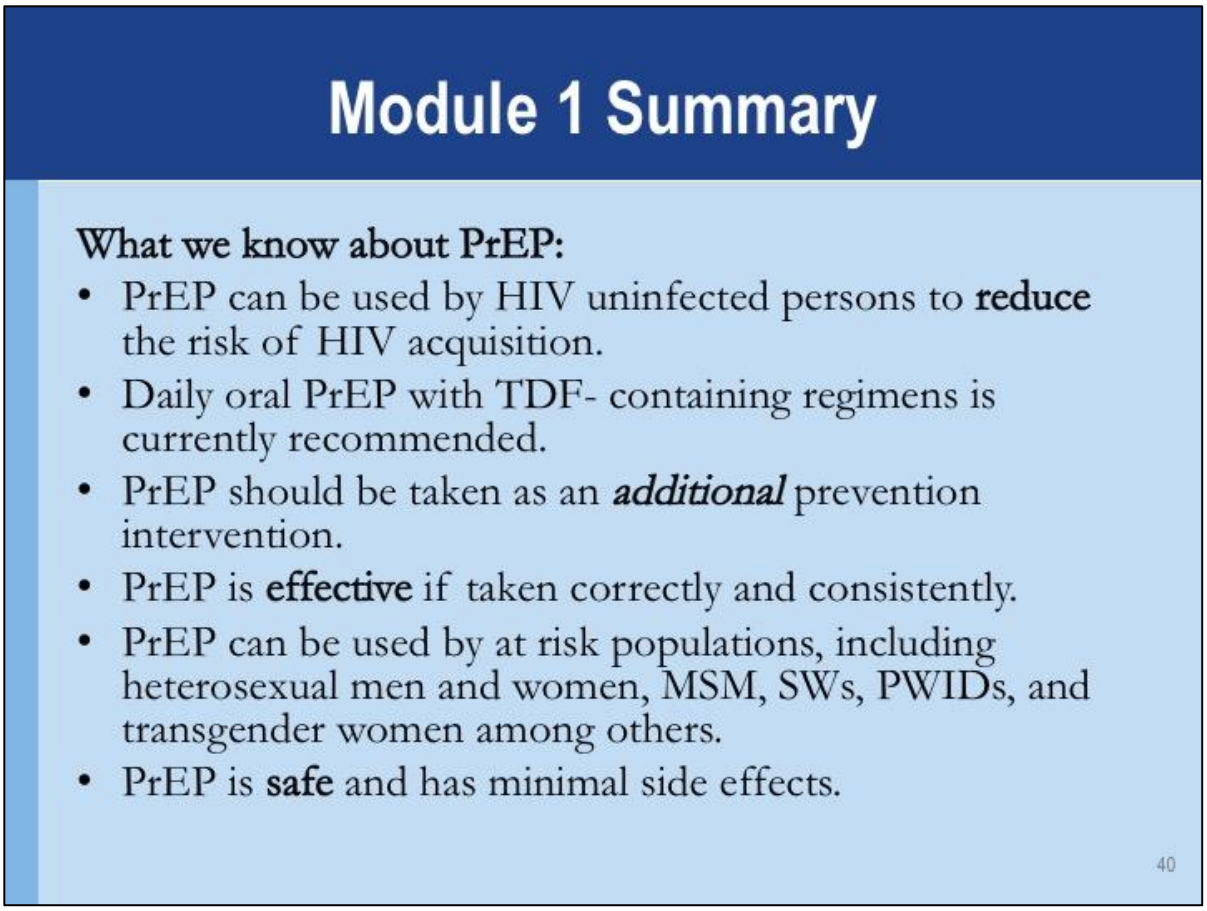
Speaker Notes:

- Will PrEP lead to more HIV drug resistance?
- When adherence to PrEP is good and HIV infection does not occur – there is no risk of HIVDR.
- If adherence is suboptimal and HIV infection occurs while on PrEP, there is a risk of HIVDR.
- However, HIVDR was rare in clinical trials.
- Optimal adherence to PrEP is crucial. Health providers must support and monitor adherence.



Speaker Notes:

- PrEP does **not** protect against most STIs, which is why PrEP should be provided within a package of prevention services including: STI screening and management, risk reduction counseling, condoms, and contraceptives.



Speaker Notes:

- In summary, what do we know about PrEP? We know…

MORNING BREAK

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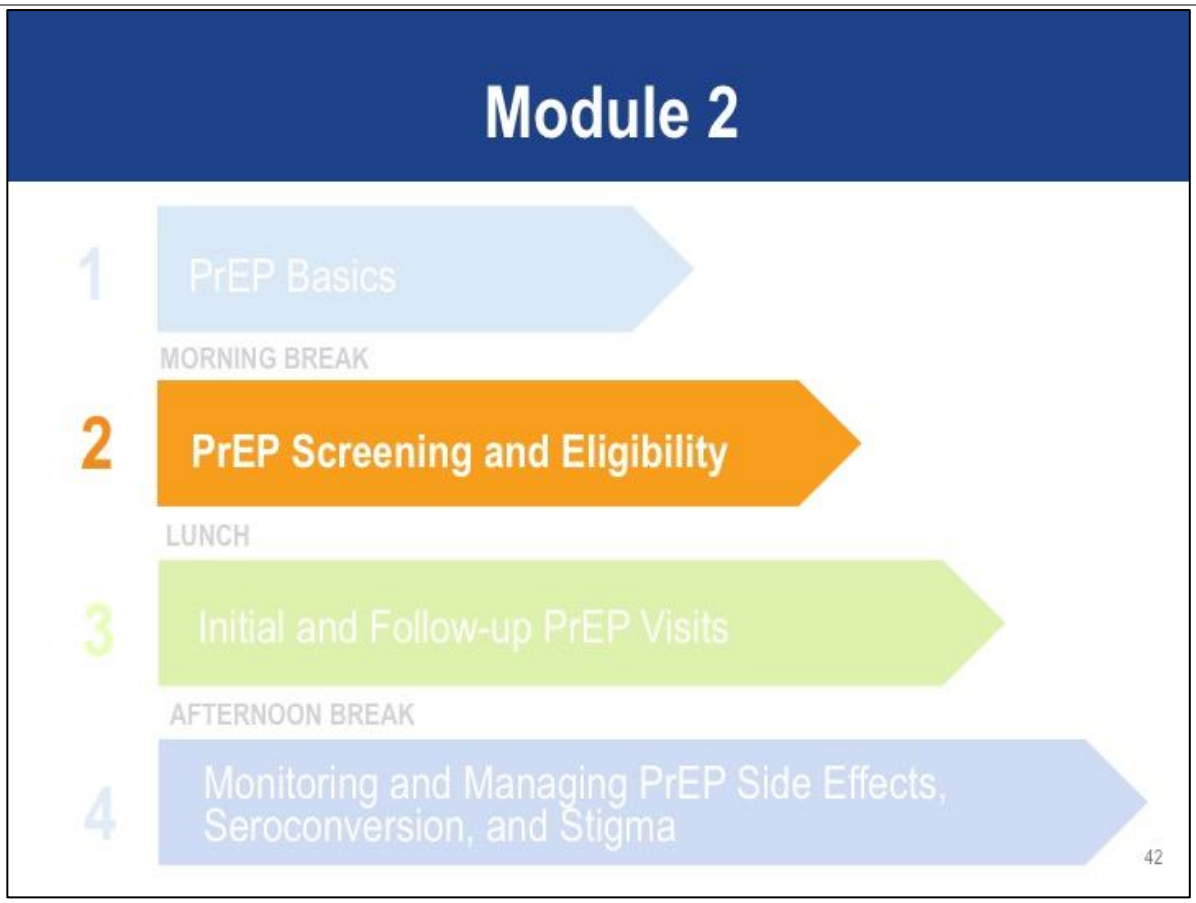
MODULE 2: PrEP Screening and Eligibility

DURATION: 105 MINUTES (1 HOUR, 45 MINUTES)



Module 2: Learning Objectives

After completing module 2, participants will be able to:

- List eligibility criteria for PrEP.
- Use the standard medical screening form for PrEP eligibility and substantial risk.
- Discuss the contraindications for PrEP.
- Explain how to exclude acute HIV infection.

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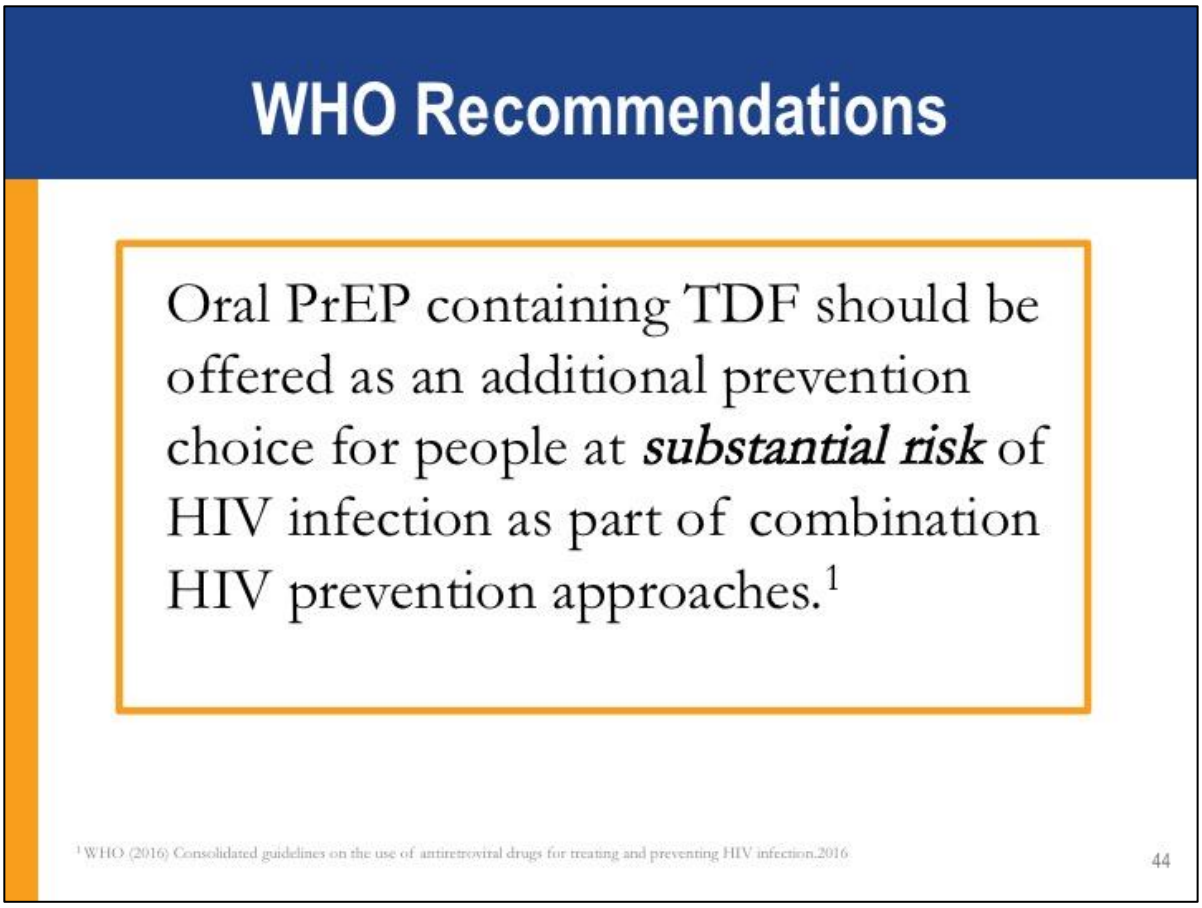

Speaker Notes:

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

Questions

- *Who should receive PrEP?*
- *What are the eligibility criteria for initiating PrEP?*

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Eligibility for PrEP

Eligibility criteria include:

- HIV seronegative
- No suspicion of acute HIV infection
- At substantial risk* of HIV infection
- Creatinine clearance (eGFR) >60ml/min**
- Willingness to use PrEP as prescribed

* Defined later

** eGFR: estimated glomerular filtration rate. Waiting for creatinine result should not delay initiation of PrEP

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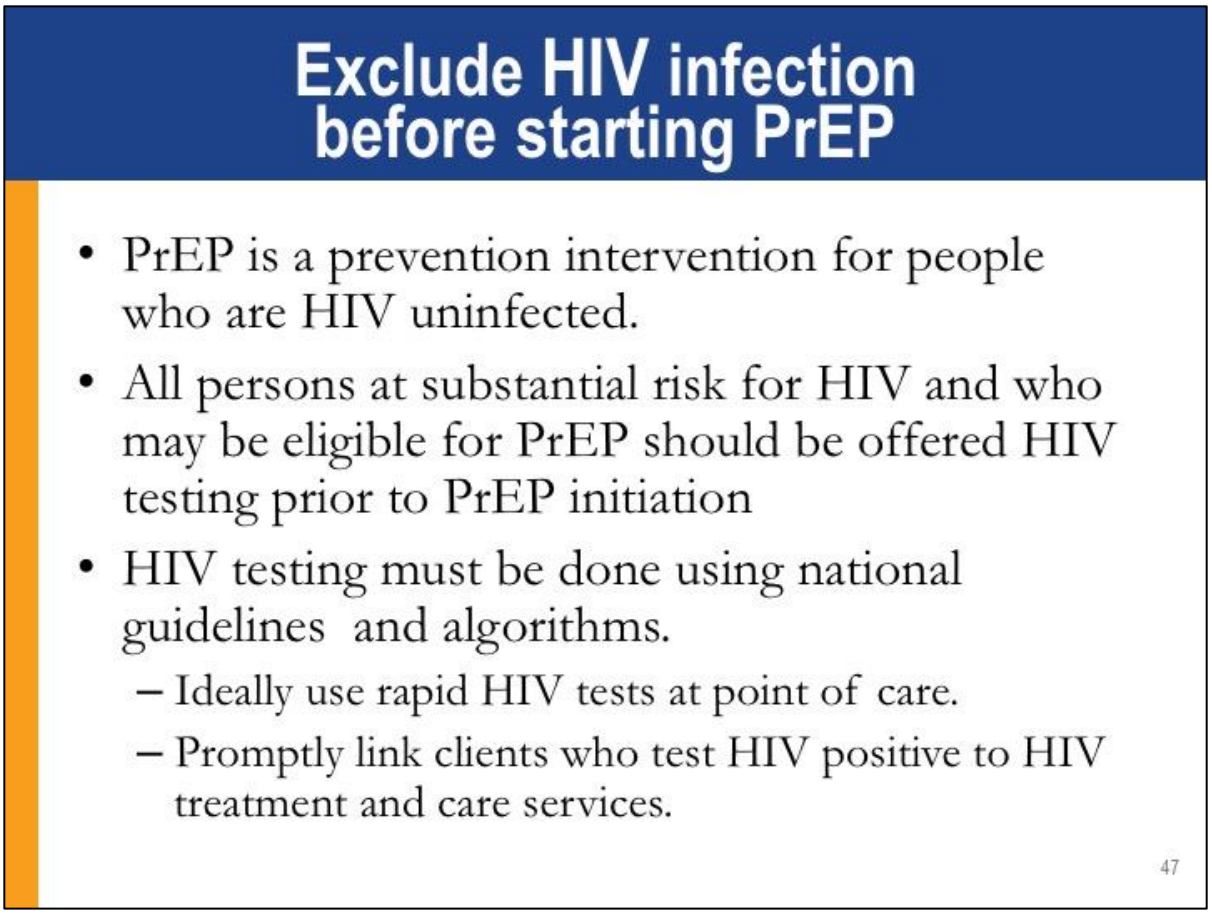
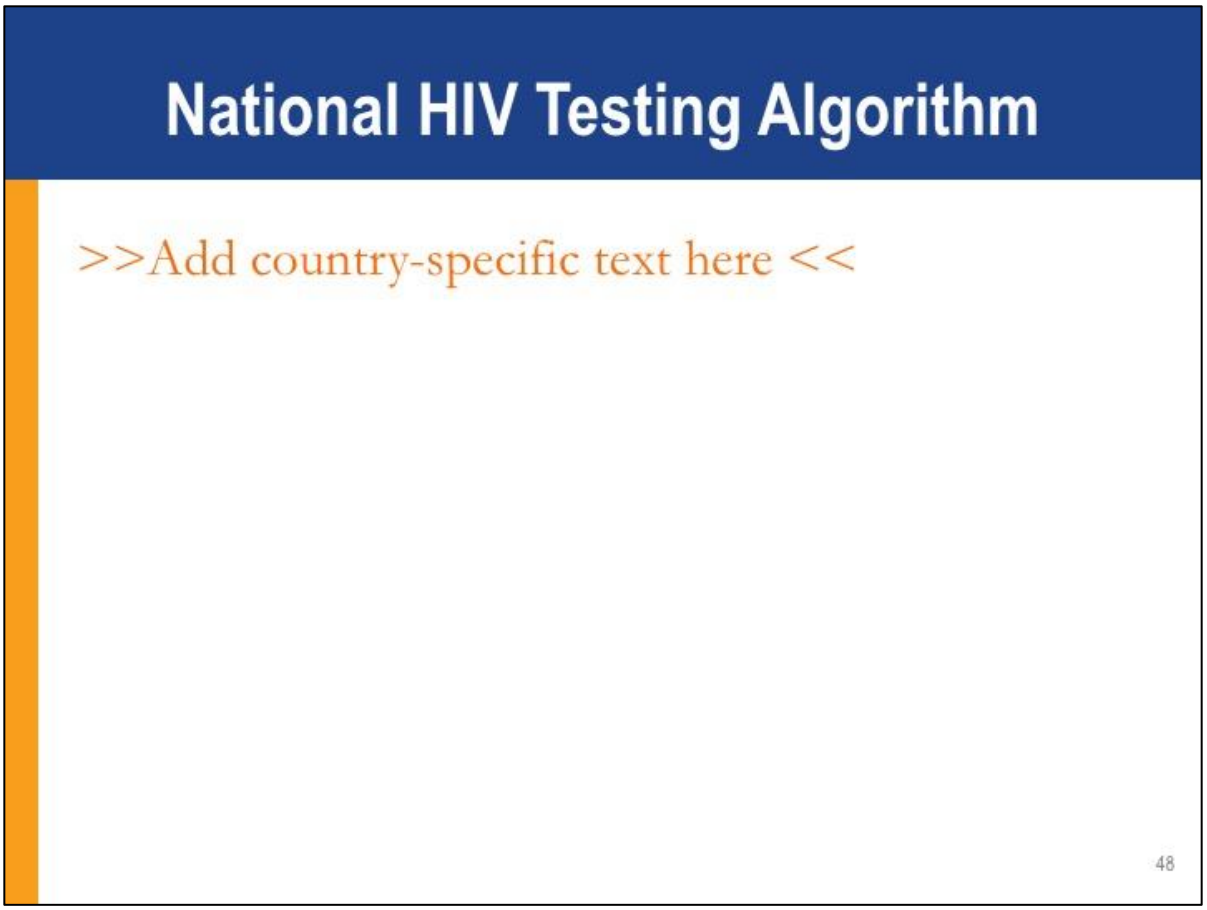


Speaker Notes:

- PrEP is a prevention intervention for people who are HIV-uninfected.
- All people at substantial risk for HIV and who may be eligible for PrEP should be offered HIV testing.
- HIV testing must be done using national algorithm and ideally rapid HIV tests at point of care should be used.
- Providers should counsel and promptly link clients who test HIV positive to treatment and care services.



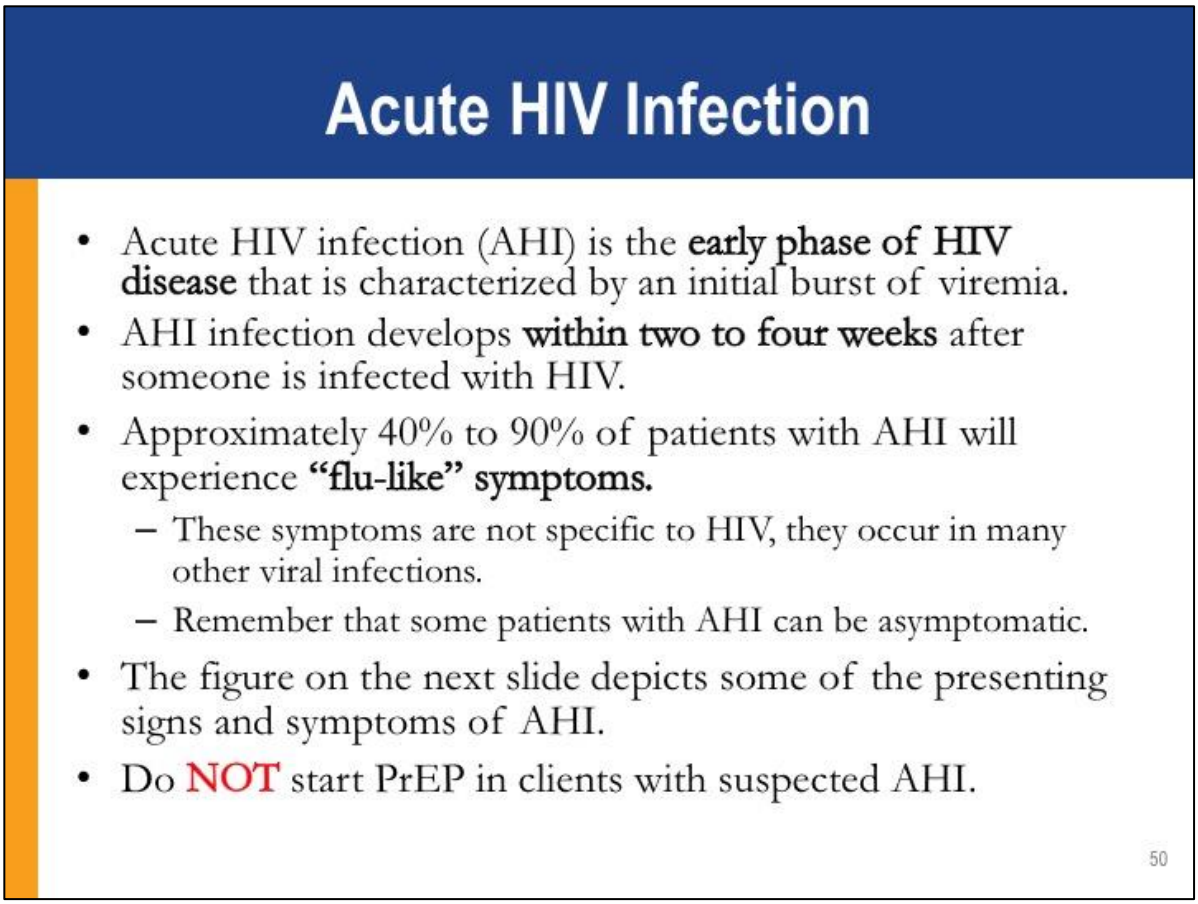
Speaker Notes:

- Countries should add their national HIV testing algorithm.

Question

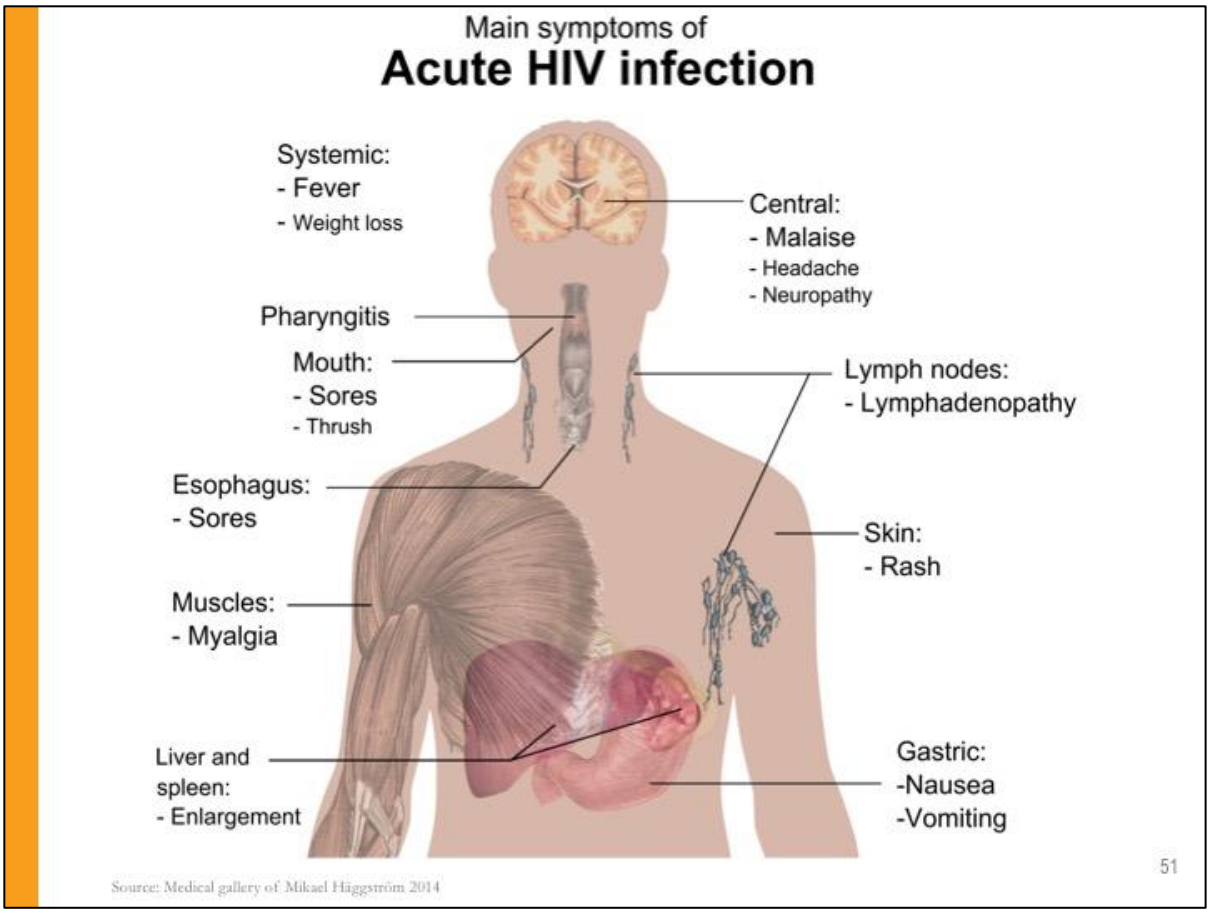
What is acute HIV infection?

49



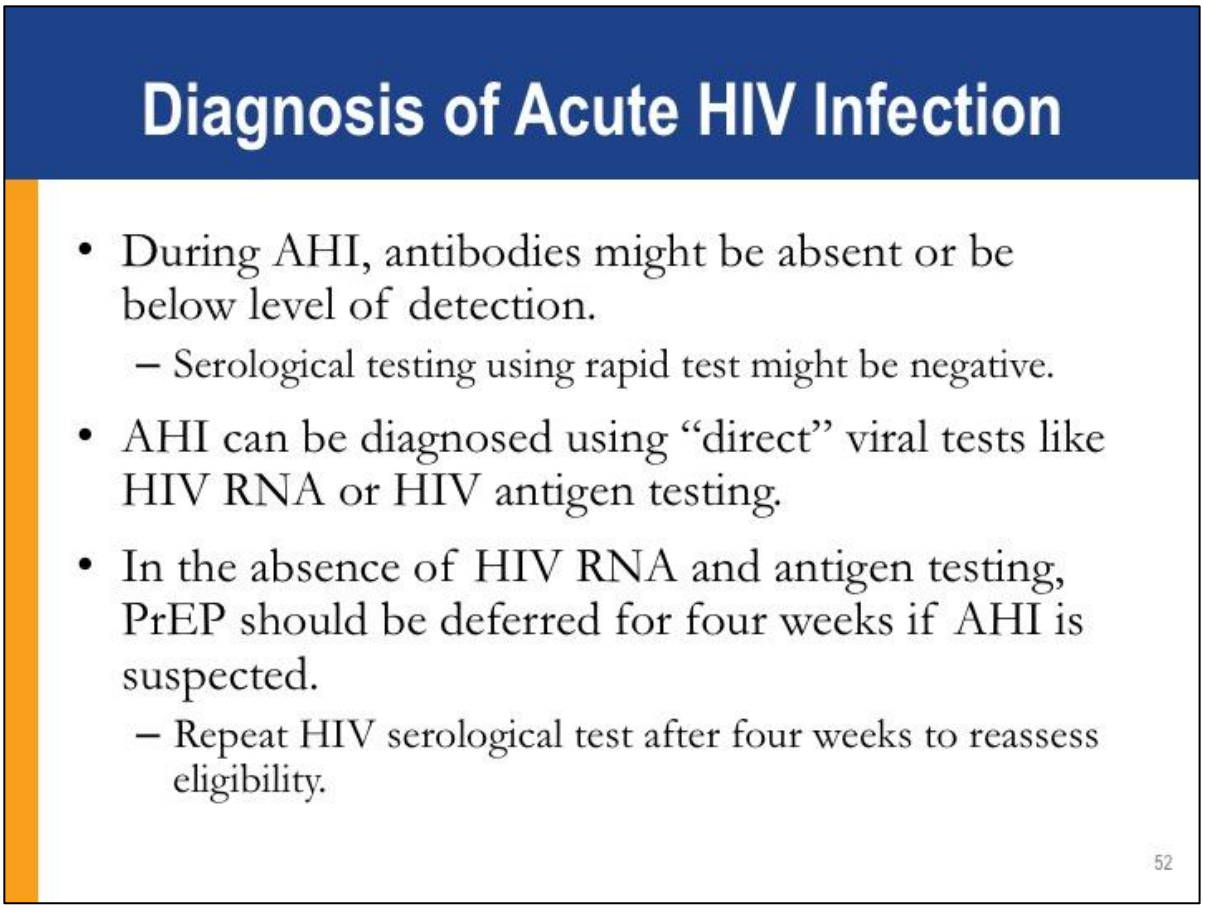
Speaker Notes:

- Acute HIV infection is the phase of HIV disease immediately after infection that is characterized by an initial burst of viremia.
- AHI infection usually develops within two to four weeks after someone is infected with HIV and is often characterized by "flu-like" symptoms.



Speaker Notes:

- 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:
    - Fever
    - Fatigue
    - Anorexia
    - Rash (often erythematous maculopapular)
    - Pharyngitis
    - Generalized lymphadenopathy
    - Mucocutaneous ulceration
    - Headache
    - Aseptic meningitis
    - Radiculitis, myelitis
    - 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.



Speaker Notes:

- During acute HIV infection antibodies might be absent or still be below the limit of detection – the HIV serological test will be negative
- Acute HIV infection can be diagnosed using "direct" viral tests like HIV RNA or antigen tests.
- In the absence of HIV RNA and antigen testing – PrEP should be deferred for four weeks if acute HIV infection is suspected.

Substantial risk for 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) PLUS reports *ANY* of the following in the past six months:
  - 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 past six months.

OR

- 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*

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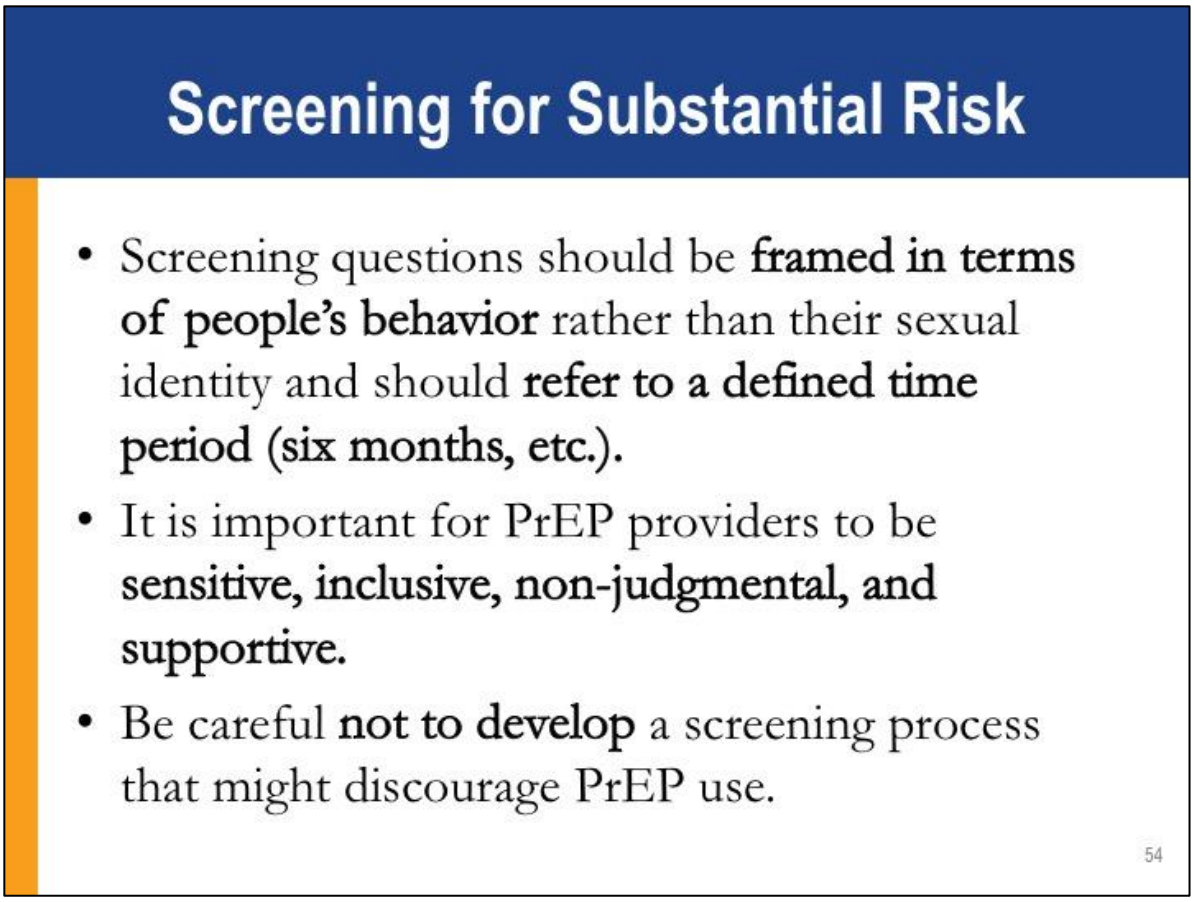

Speaker Notes:

- 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.

General Screening Questions

Consider PrEP if a client from a high prevalence population or in a high prevalence setting answers yes to any of the following questions:

"In the past six months,":

- "Have you had sex with more than one sexual partner?"
- "Have you had sex without a condom?"
- "Have you had sex with people whose HIV status you do not know?"
- "Are any of your partners at risk of HIV?"
- "Have you had sex with a person who has HIV?"

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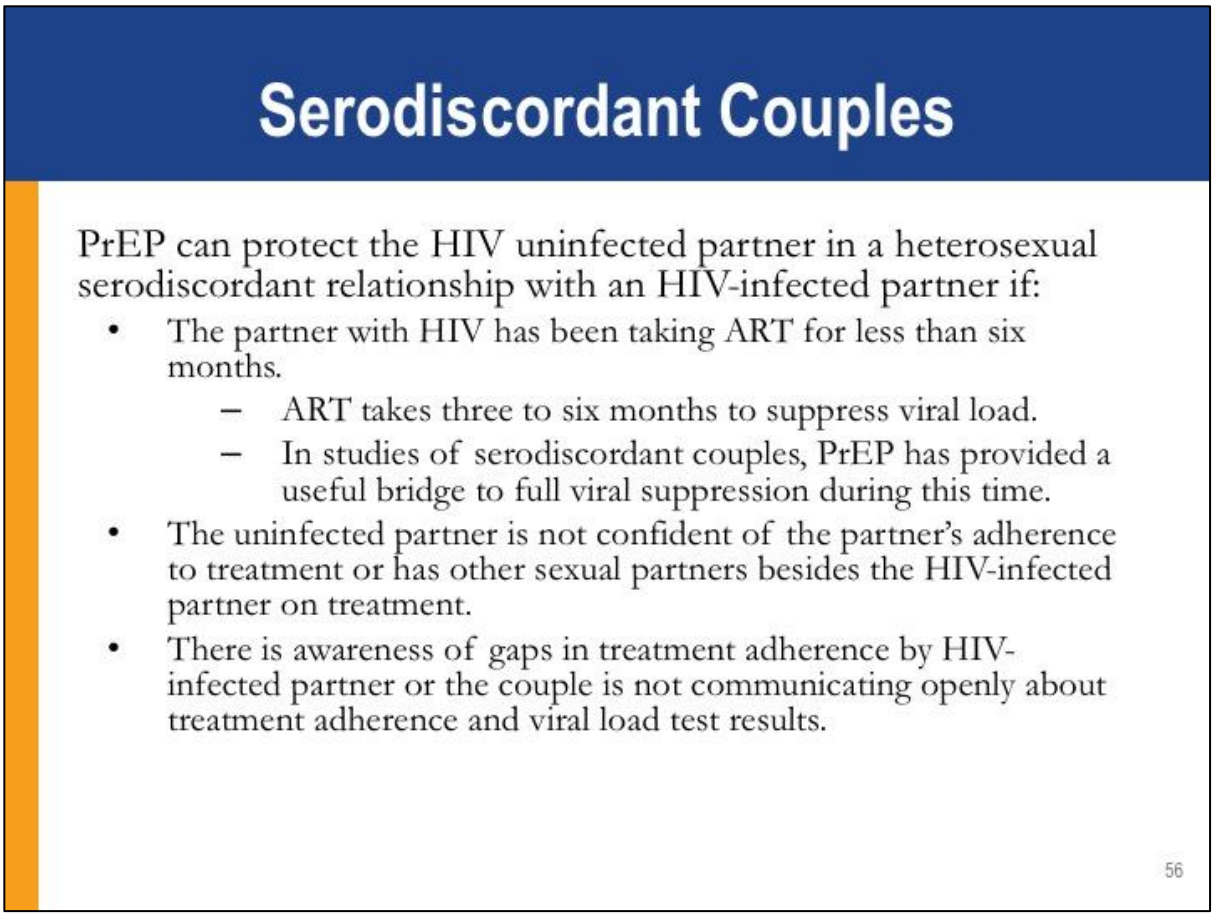

Speaker Notes:

- 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 behaviour, or anger or fear in response to questions about HIV treatment should prompt discussion about PrEP as a way to control risk for HIV.

For a Person Who Has a Partner with HIV:

The following questions will help to ascertain whether that person would be a good candidate for PrEP:

- "Is your partner taking ART for HIV?"
- "Has your partner been on ART for more than six months?"
- "Do you discuss your partner's adherence to HIV treatment every month?"
- "Do you know your partner's last viral load? What was the result? And when was it done?
- "Do you desire having a child with your partner?"
- "Are you and your partner consistently using condoms?"

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Additional Factors to Ask About:

"Are there aspects of your situation that may indicate higher risk for HIV? Have you…":

- "Received money, housing, food or gifts in exchange for sex?"
- "Been forced to have sex against your will?"
- "Been physically assaulted, including assault by a sex partner?"
- "Taken PEP to prevent HIV infection?"
- "Had a sexually transmitted infection (STI)?"
- "Injected drugs or hormones using shared equipment?"
- "Used recreational/psychoactive drugs?"
- "Been required to leave your home?"
- "Moved to a new place?"
- "Lost your job?"
- "Had less than 12 years schooling or left school early?"

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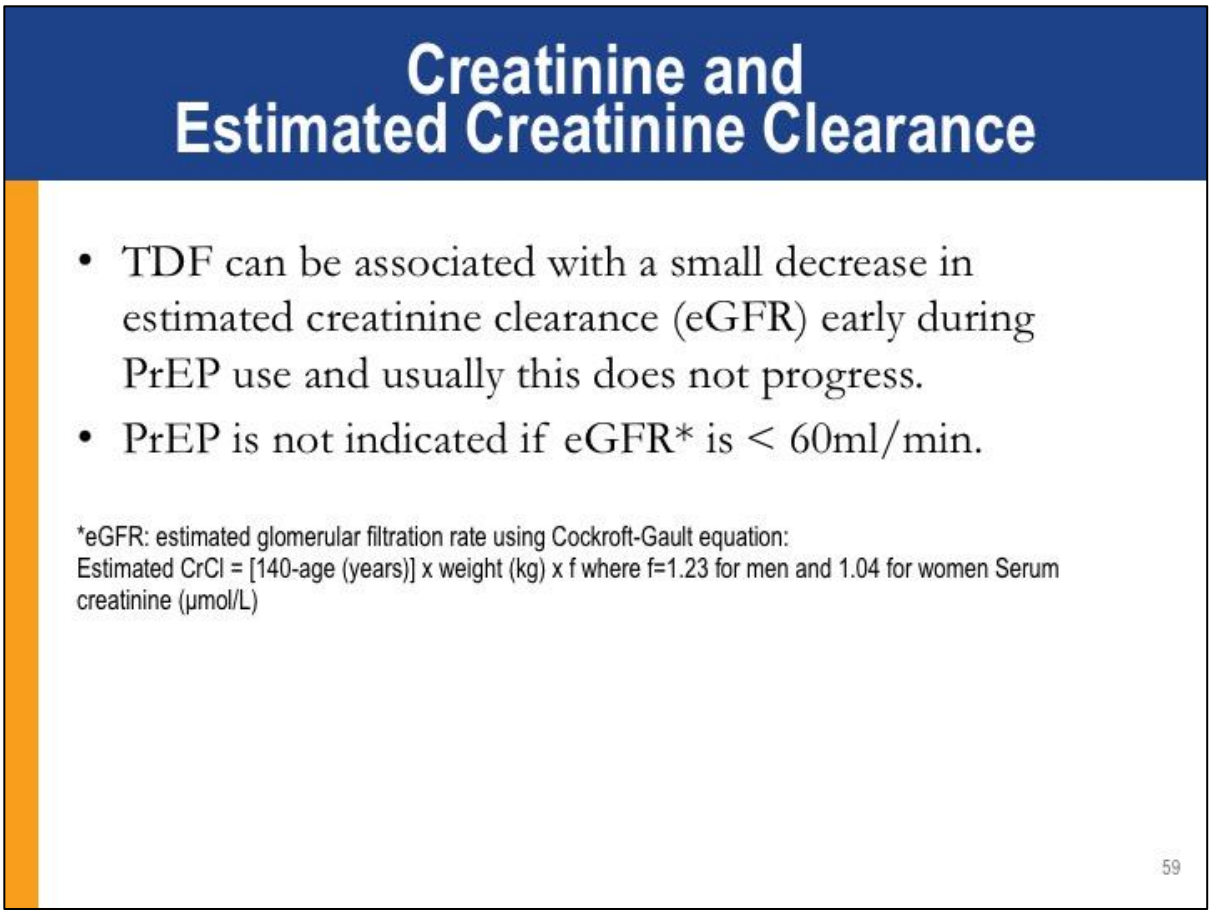
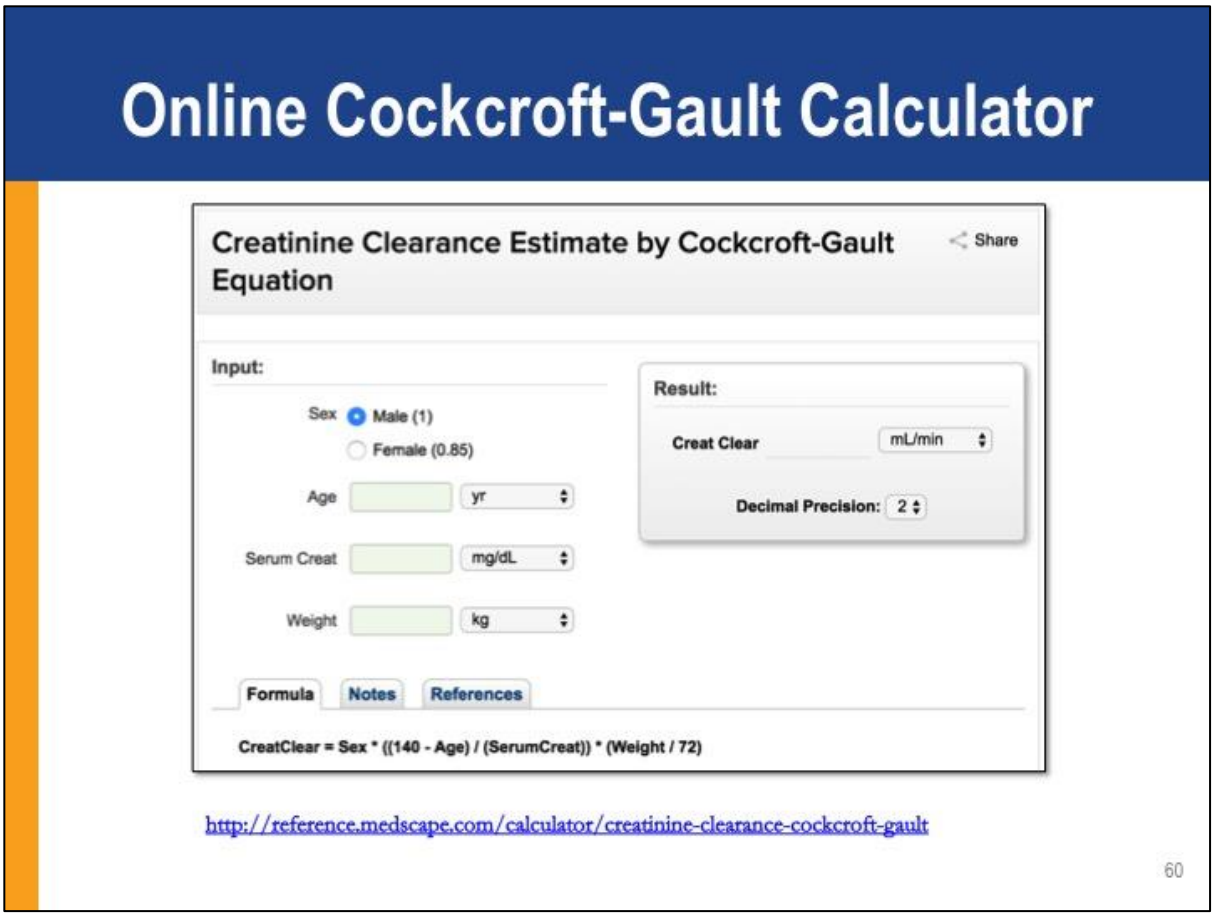


Speaker Notes:

- TDF can be associated with a small decrease in estimated creatinine clearance (eGFR) early during PrEP use and usually this does not progress.
- PrEP is not indicated if eGFR is <60ml/min.
- You can calculate eGFR by using the Cockcroft-Gault equation. All of you should be familiar with this equation.



Speaker Notes:

- You can also use an online calculator to calculate the eGFR
- Use example of a 26 year old woman with a weight of 55Kg and serum creatinine is 6.9 umol/L

Question

Is PrEP safe during pregnancy ?

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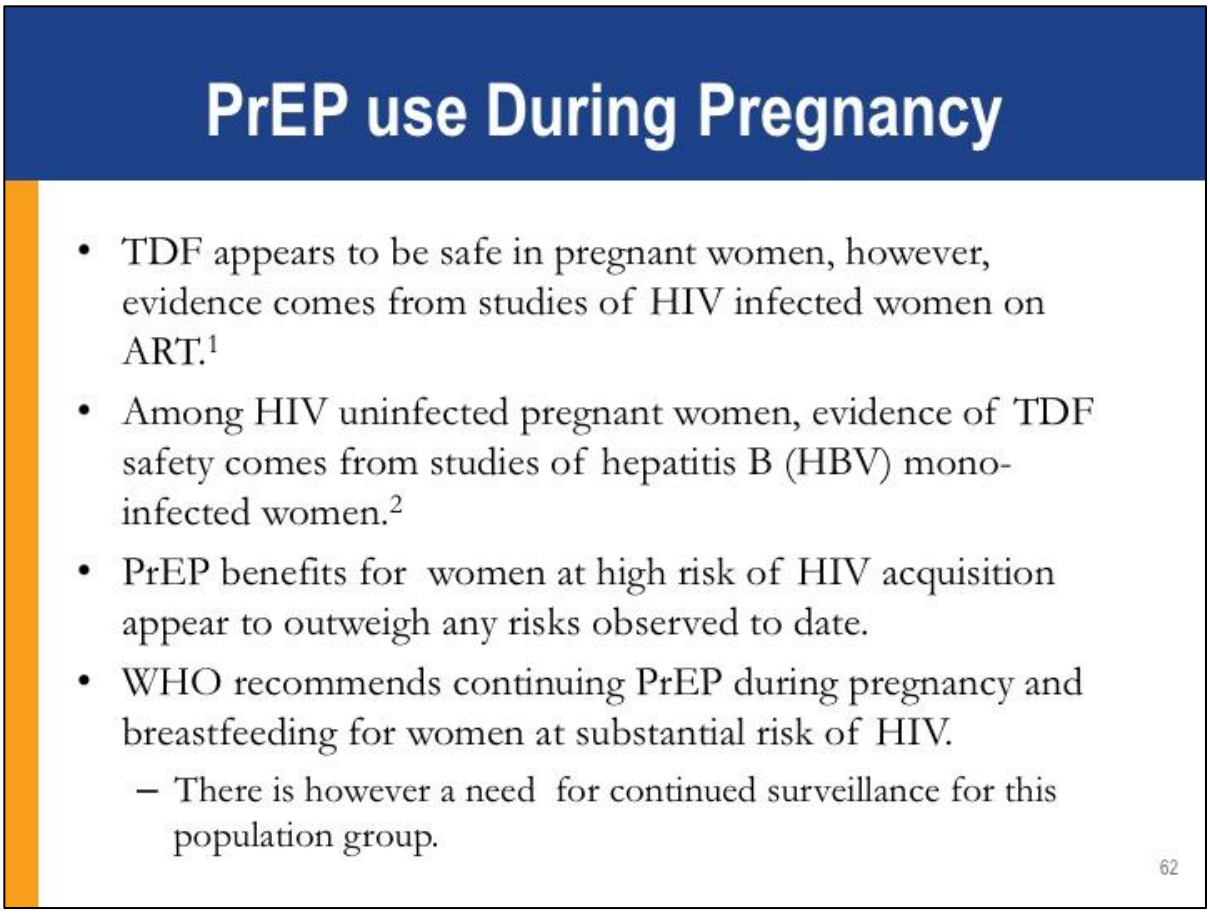
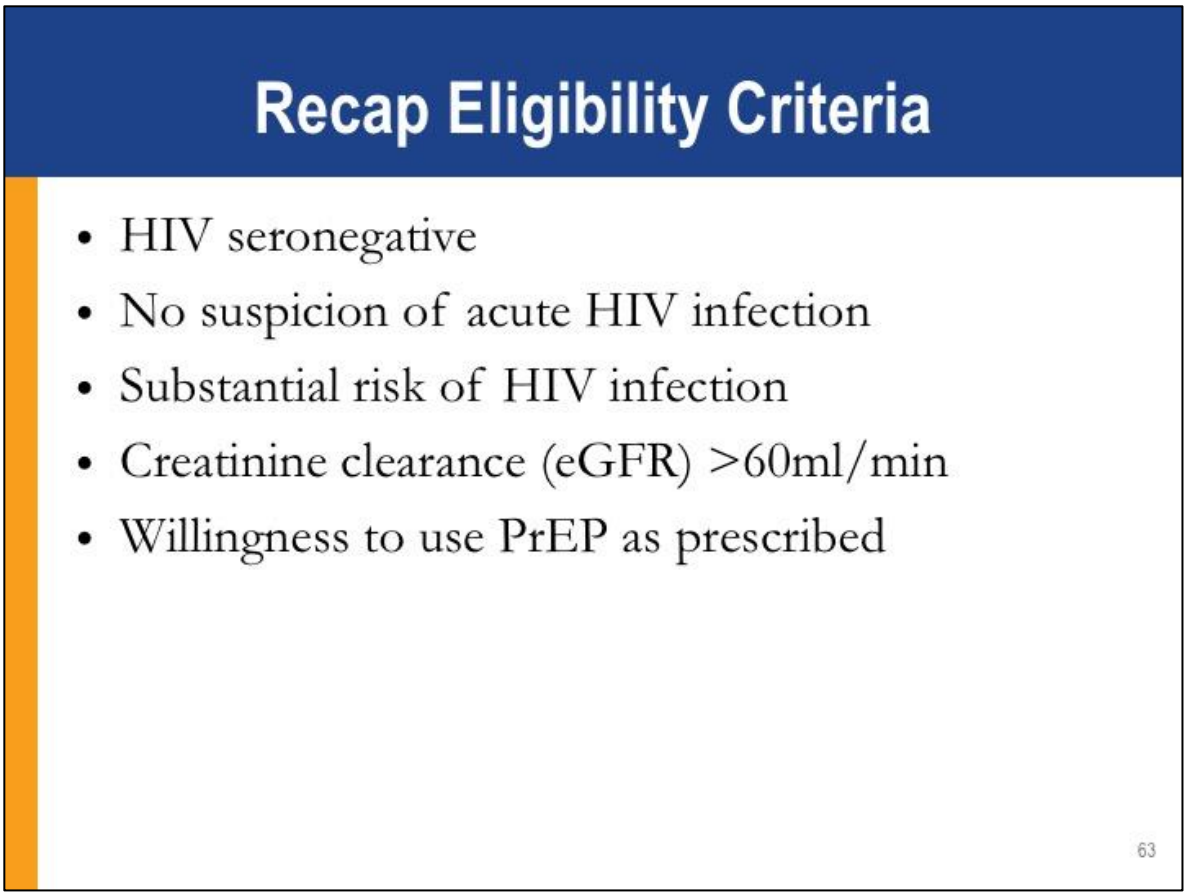


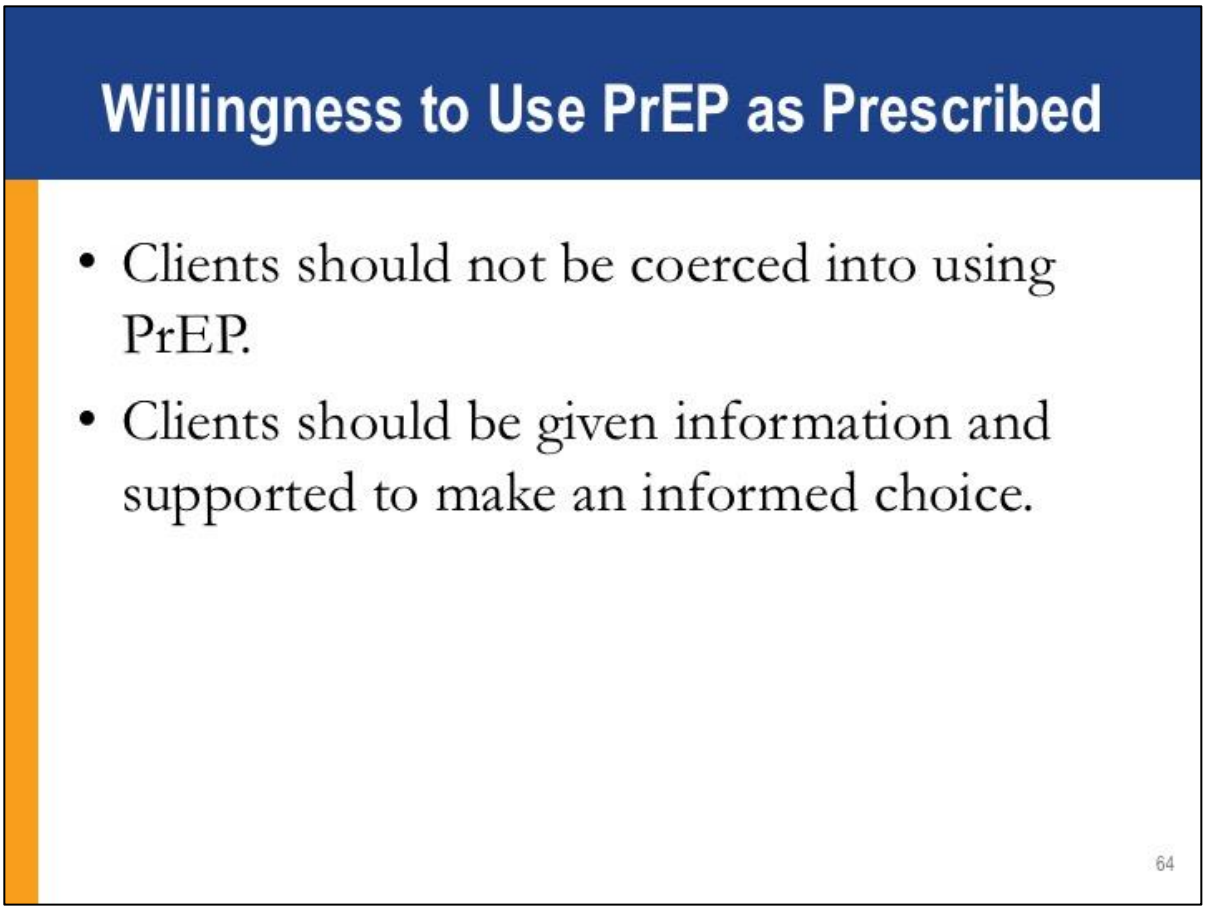
Speaker Notes:

- 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 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.



Speaker Notes:

- Let's quickly recap eligibility criteria.



Speaker Notes:

- After education and counseling, clients should be willing to use PrEP.
- Clients should not be coerced into using PrEP.
- Clients should be supported to make an informed choice.

Sample of PrEP Screening Form

- Use of a standard form can ensure that screening is done in a consistent manner and is well documented.
- Please refer to the tool Pre-exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility in your participant folder that can be adapted for use to record key elements in the sexual history needed to screen for PrEP eligibility.

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

**See PrEP M&E Tool Package for full document*

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

1. Facility Information	
Facility Name	
Date of initial client visit (dd/mm/yy) __ __ / __ __ / __ __	Person Completing Form

2. Client Information		
First Name	Middle Name	Surname
Address	Telephone #	
Unique Client ID number	Client clinic ID number	

3. Client Demographics	
What was your sex at birth?	☐ Male ☐ Female ☐ Other: _____
What is your current gender?	☐ Male ☐ Female ☐ Transgender (male to female) ☐ Transgender (female to male) ☐ Other: _____
What is your age?	_____ *Enter number of years*

4. Screening for Substantial Risk for HIV infection	
Clients are at substantial risk if they belong to any of the these categories below:	**Question prompts for providers:**
1) If they are sexually active in a high HIV prevalence population PLUS report ANY one of the below in the last six months	Have you been sexually active in the last six months?
☐ Report vaginal or anal intercourse without condoms with more than one partner	With how many people did you have vaginal or anal sex in the last six months? Did you use condoms consistently during sex in the last six months?
☐ Have a sex partner with one or more HIV risk	Have you had a sex partner in the last six months who: • Is living with HIV? • Injects drugs? • Has sex with men? • Is a transgender person? • Is a sex worker? • Has sex with multiple partners without condoms?
☐ History of a sexually transmitted infection (STI) (based on self-report, lab test, syndromic STI treatment)	Have you had an STI in the last six months?
☐ History of use of post-exposure prophylaxis (PEP)	Have you taken post-exposure prophylaxis (PEP) following a potential exposure to HIV in the last six months?

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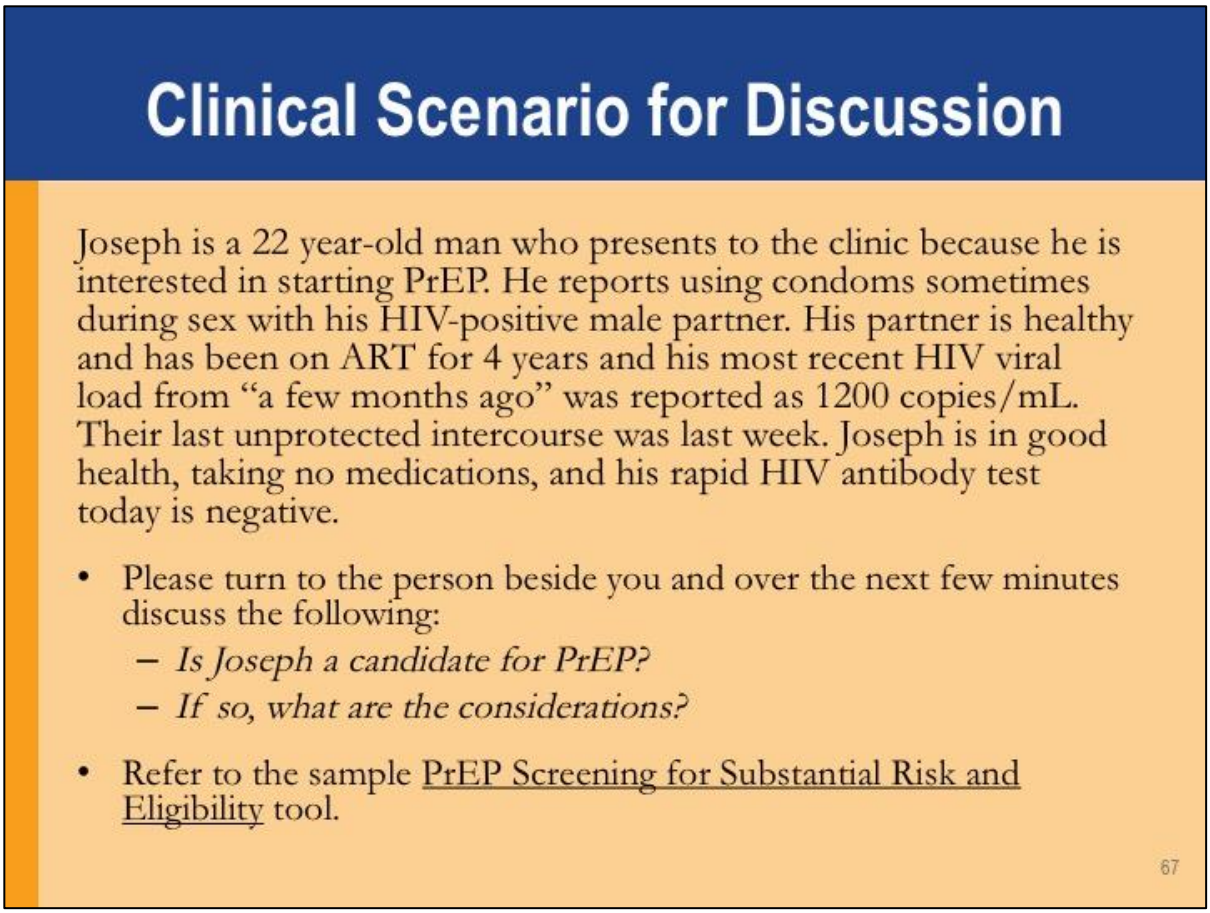
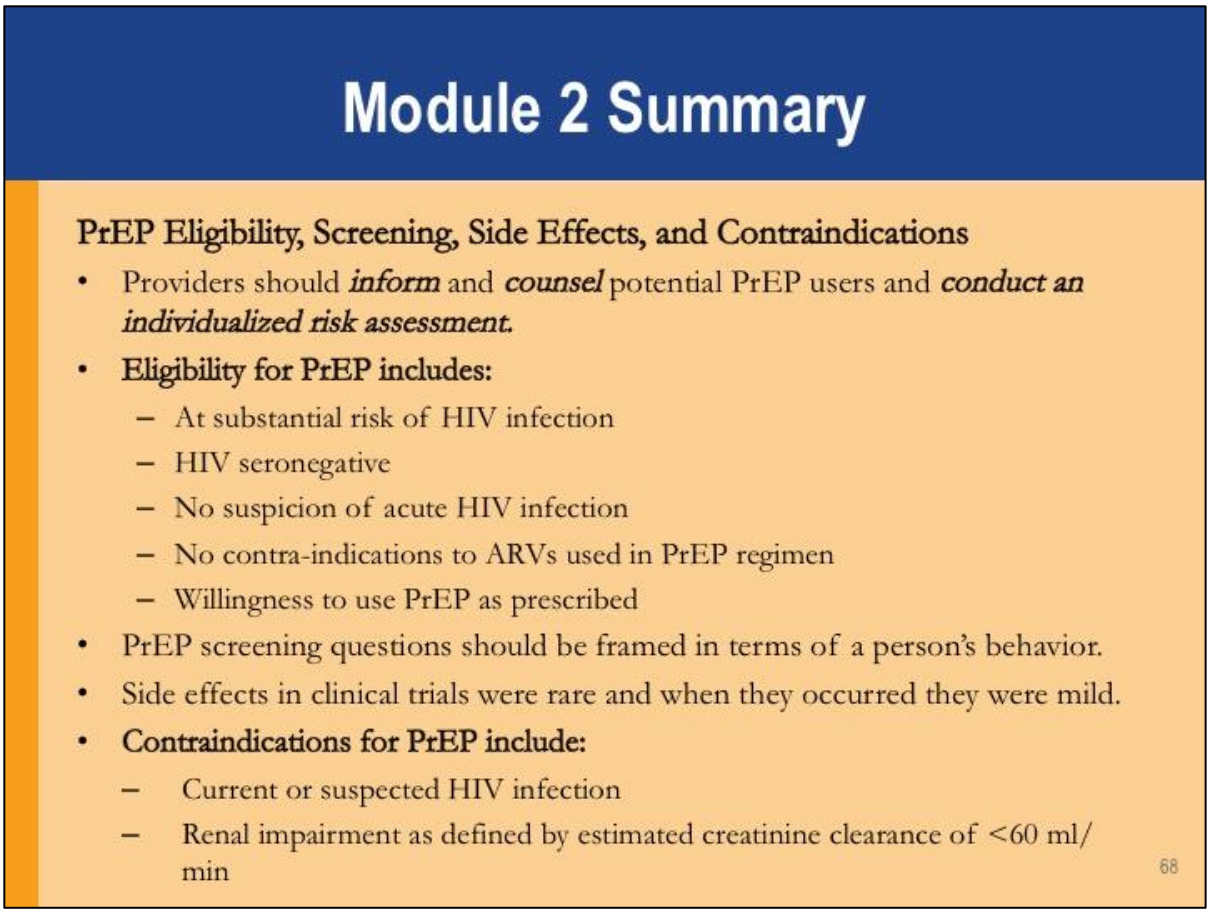


Speaker Notes:

- Instruct participants to refer to the PrEP Screening for Substantial Risk and Eligibility tool in their participant folder. Ask them to turn to the person beside them and while referring to the tool, discuss the following over the next few minutes:
    - *Is Joseph a candidate for PrEP?*
    - *If yes, what are the considerations?*
- After a few minutes, ask for a show of hands as to who thinks Joseph is a candidate for PrEP. Then ask for a show of hands as to who thinks Joseph is not a candidate for PrEP. Ask each group what they considered in making their determination.
- Examples of things they should have considered were:
    - *Joseph's substantial risk and eligibility*
    - *Joseph's partner viral load*
    - *Rapid HIV antibody test window period*
    - *Other issues*



Speaker Notes:

- In summary, what do we know about PrEP?

LUNCH

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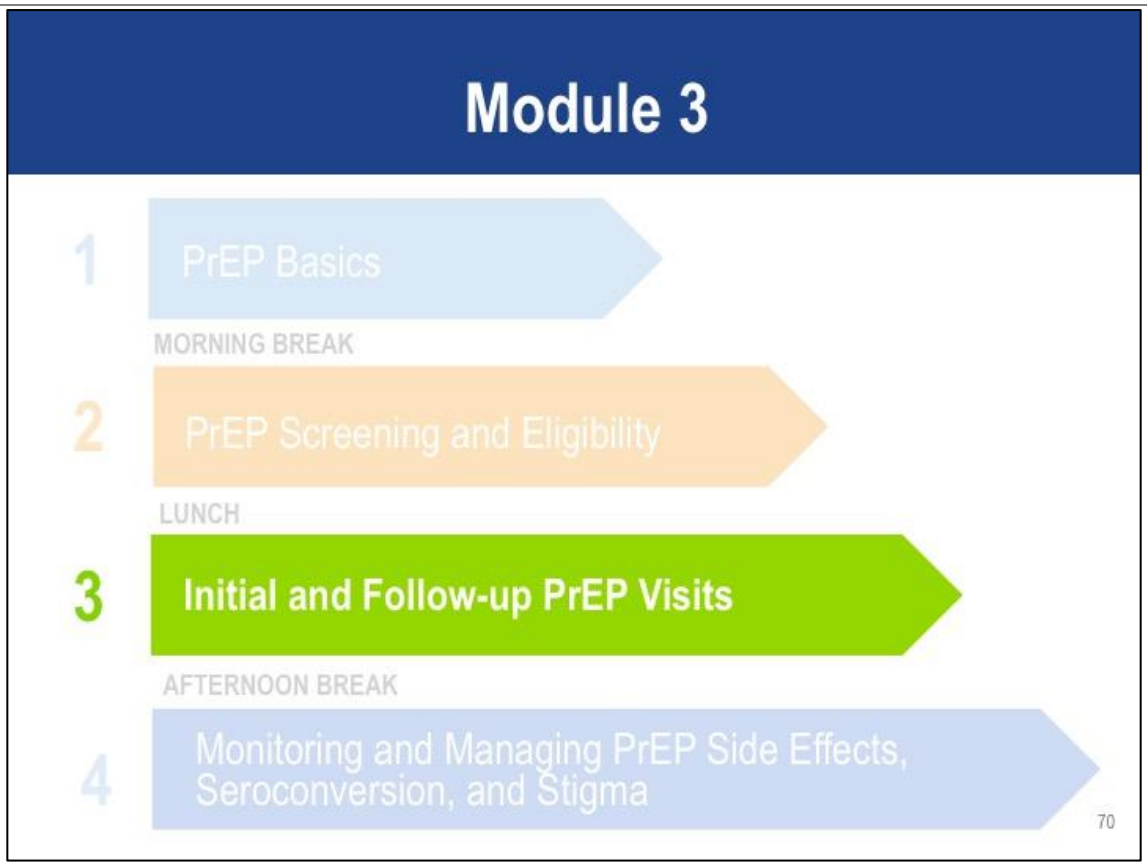
MODULE 3: Initial and Follow-Up PrEP Visits

DURATION: 120 MINUTES (2 HOURS)



Module 3: Learning Objectives

By the end of 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/first PrEP visit.
- Practice using the Integrated Next Step Counseling (iNSC) process to counsel clients on sexual health and PrEP adherence.
- Specify the suggested procedures for follow-up PrEP visits.
- Describe the rationale and content for follow-up counseling at each visit.

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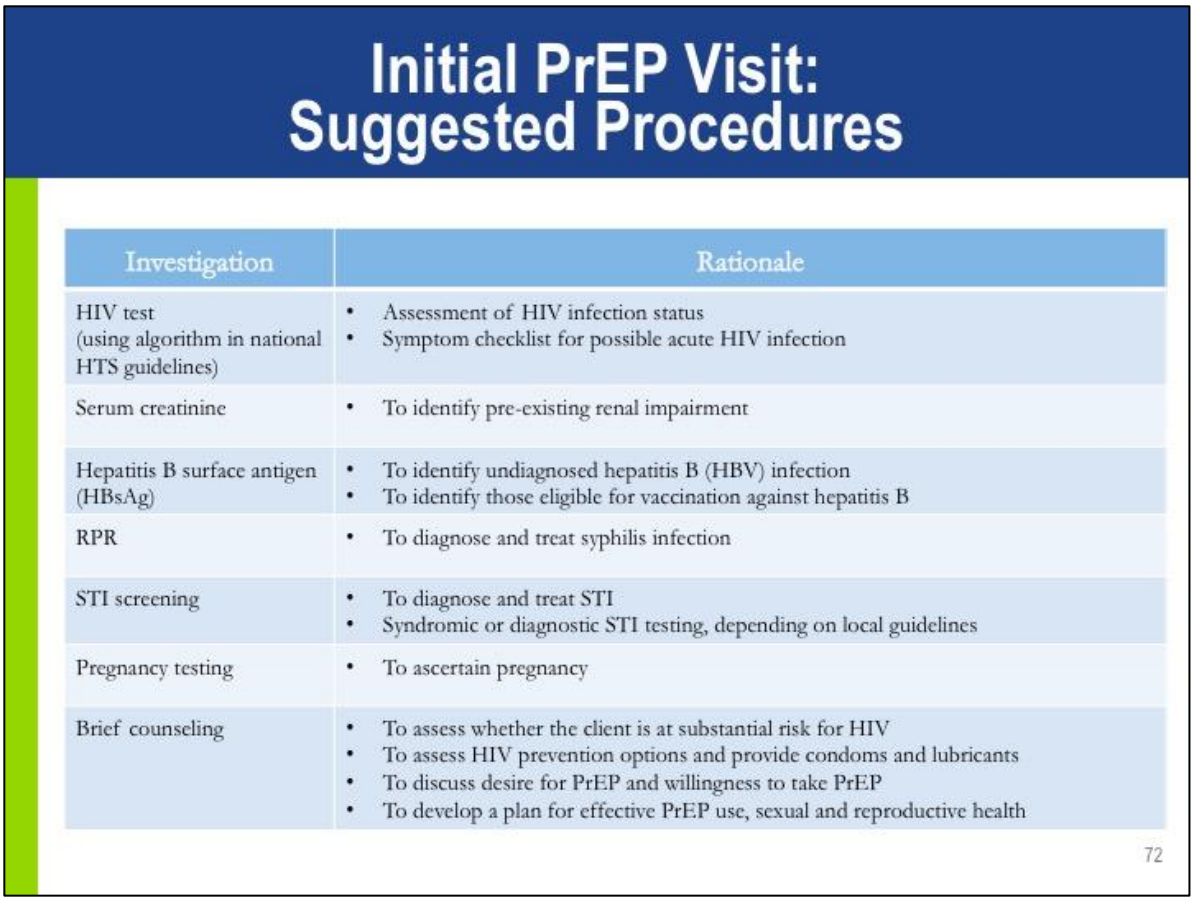
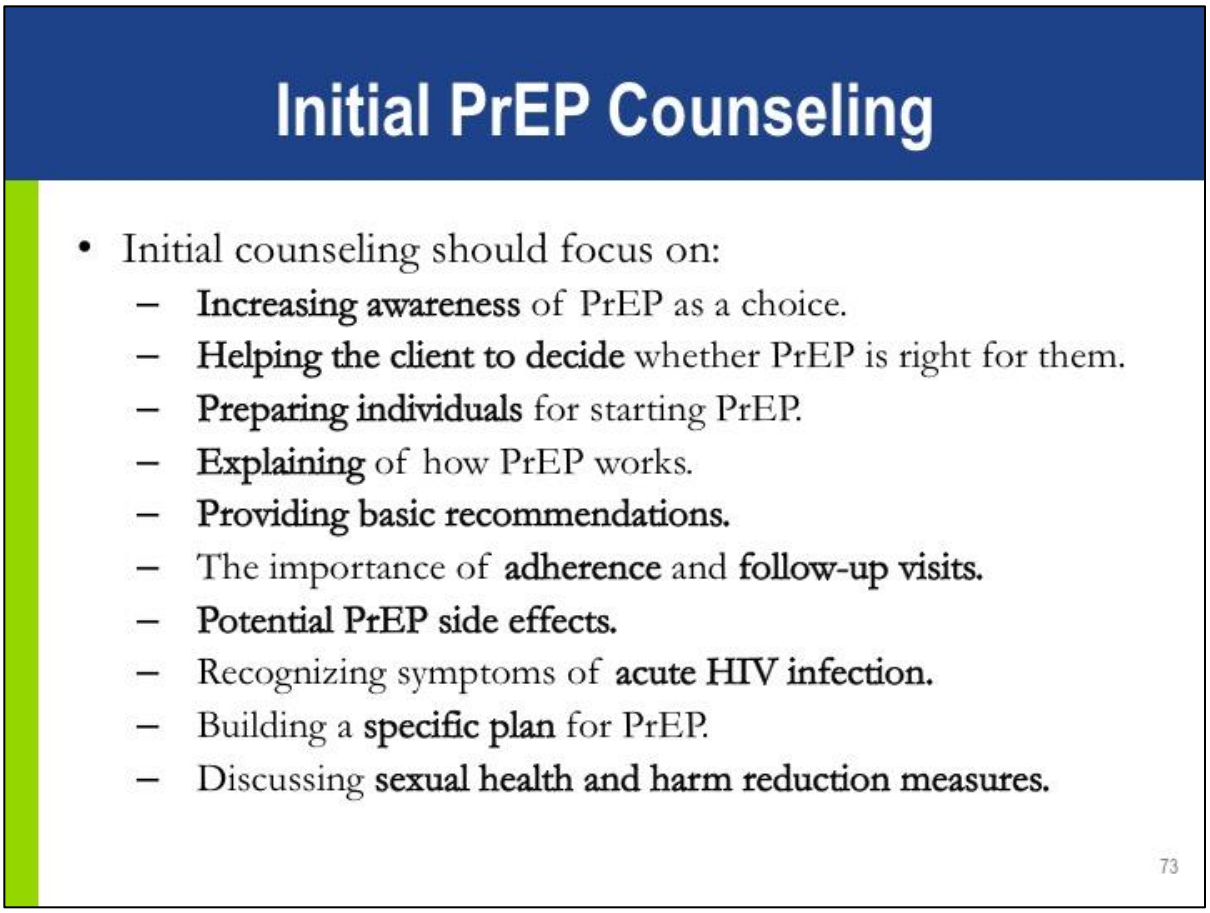


Speaker Notes:

- Here are the suggested procedures for the initial PrEP visit.



Speaker Notes:

- Before starting PrEP, the client should be counseled and the initial counseling session should focus on:

Initial PrEP counseling (cont.)

- Assess client's understanding that the protection provided by PrEP is not 100%.
- Explain need for repeat clinic visits and repeat blood tests.
- Additional information for women:
  - PrEP does not affect the efficacy of hormonal contraceptives.
  - PrEP does not protect against pregnancy.
  - PrEP can be continued during pregnancy and breastfeeding.

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PrEP Counseling

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

(Source: From the Southern African Clinician Society Guidelines for Provision of PrEP)

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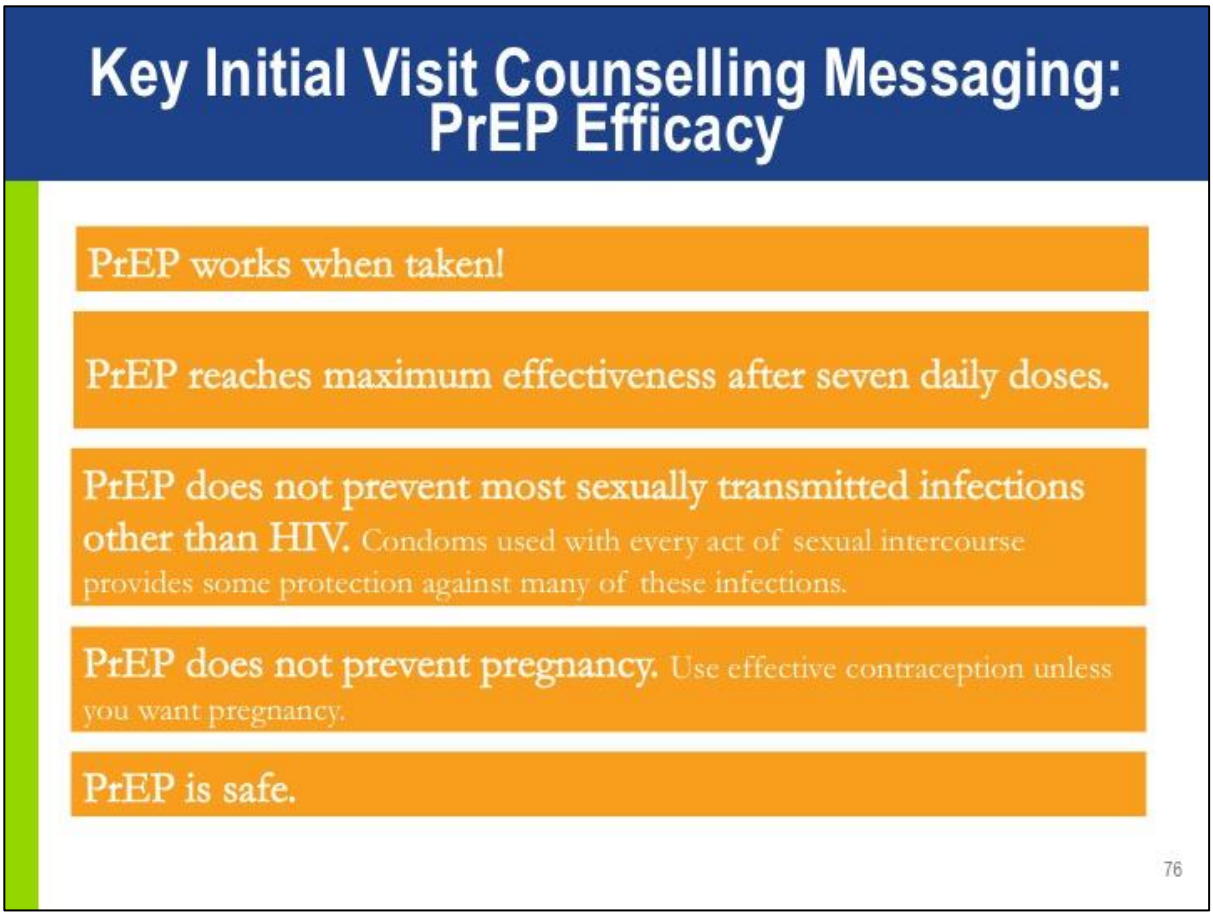
Key Initial Visit Counselling Messaging: PrEP Efficacy
PrEP works when taken!
PrEP reaches maximum effectiveness after seven daily doses.
PrEP does not prevent most sexually transmitted infections other than HIV. Condoms used with every act of sexual intercourse provides some protection against many of these infections.
PrEP does not prevent pregnancy. Use effective contraception unless you want pregnancy.
PrEP is safe.
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Key Initial Visit Counselling Messaging: Supporting Adherence

Taking PrEP each day is easiest if you make taking the tablets a daily habit, linked to something else that you do every day without fail.

If you forget to take a tablet, take it as soon as you remember.

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

PrEP is safe and effective even if you are taking hormonal contraceptives, sex hormones or non-prescription drugs.

- Drinking alcohol will not affect the safety or effectiveness of PrEP. But drinking alcohol could make you forget to take the PrEP tablets.

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Question

What are some common reasons for poor adherence?

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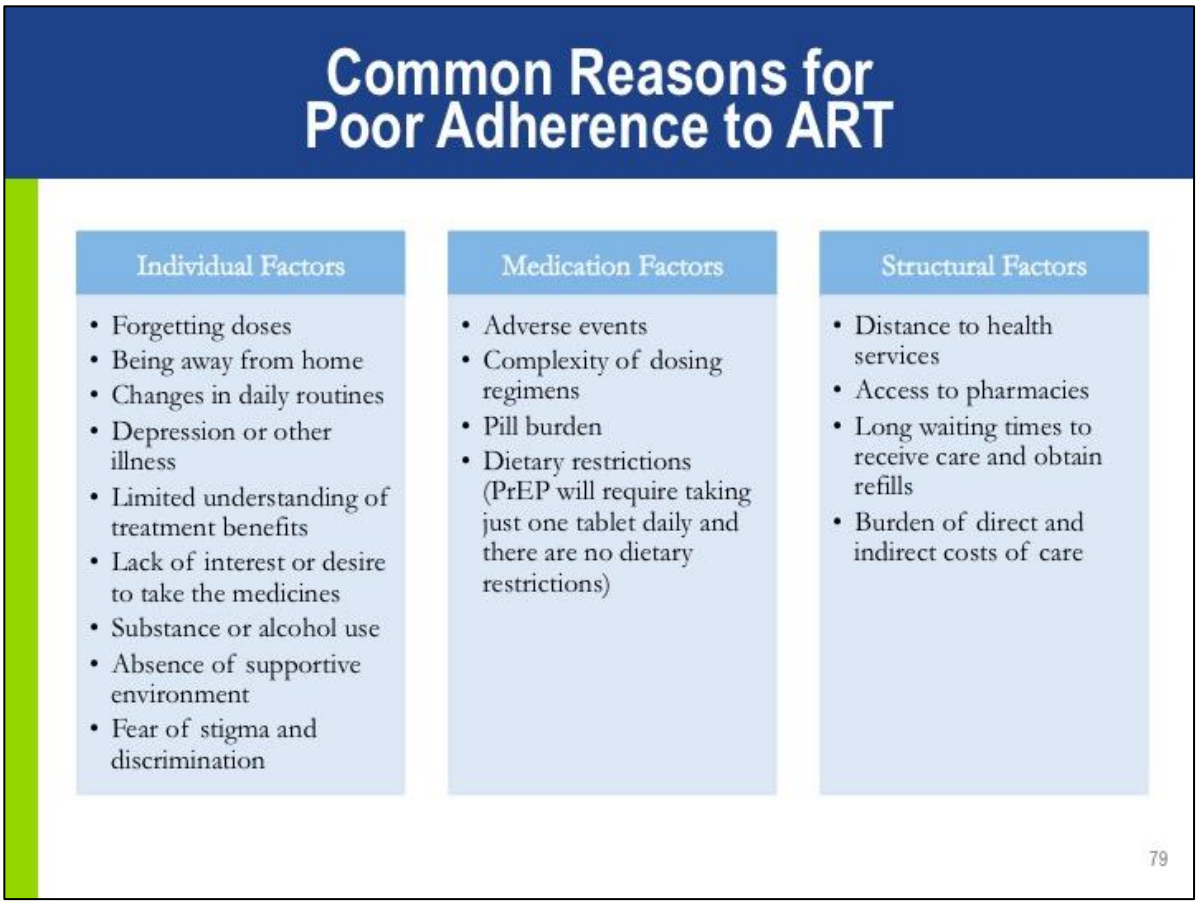
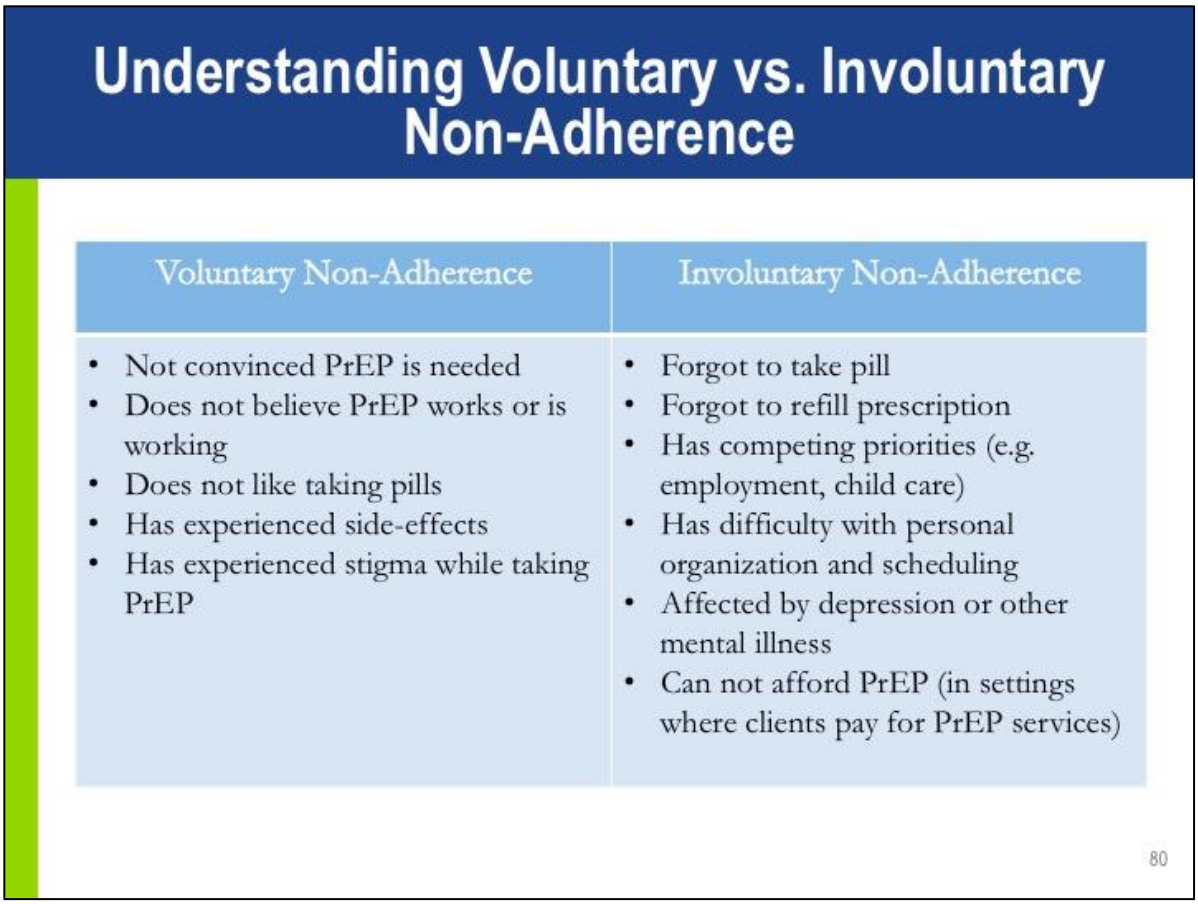


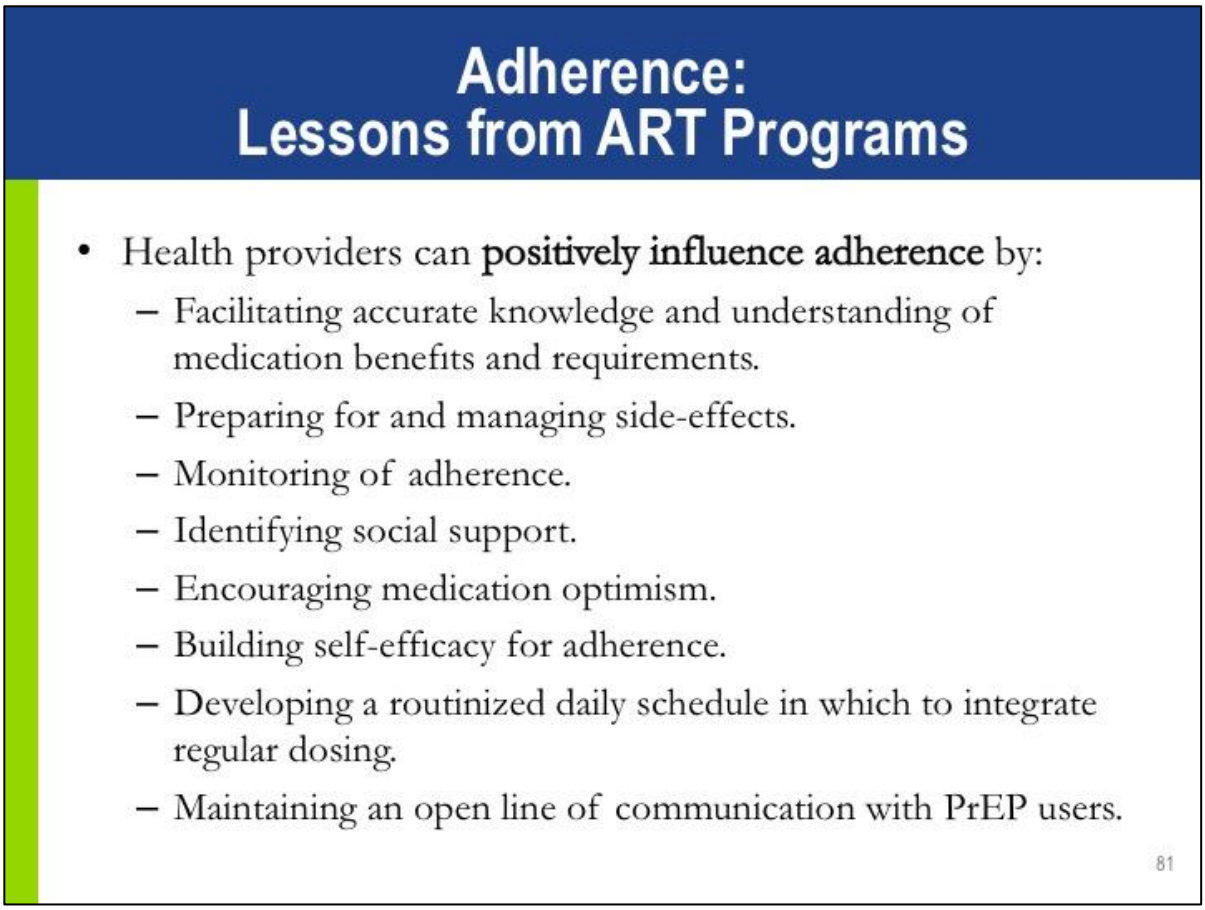
Speaker Notes:

- Reasons for poor adherence can be related to the client, the ARV drug regimen, or the health system.



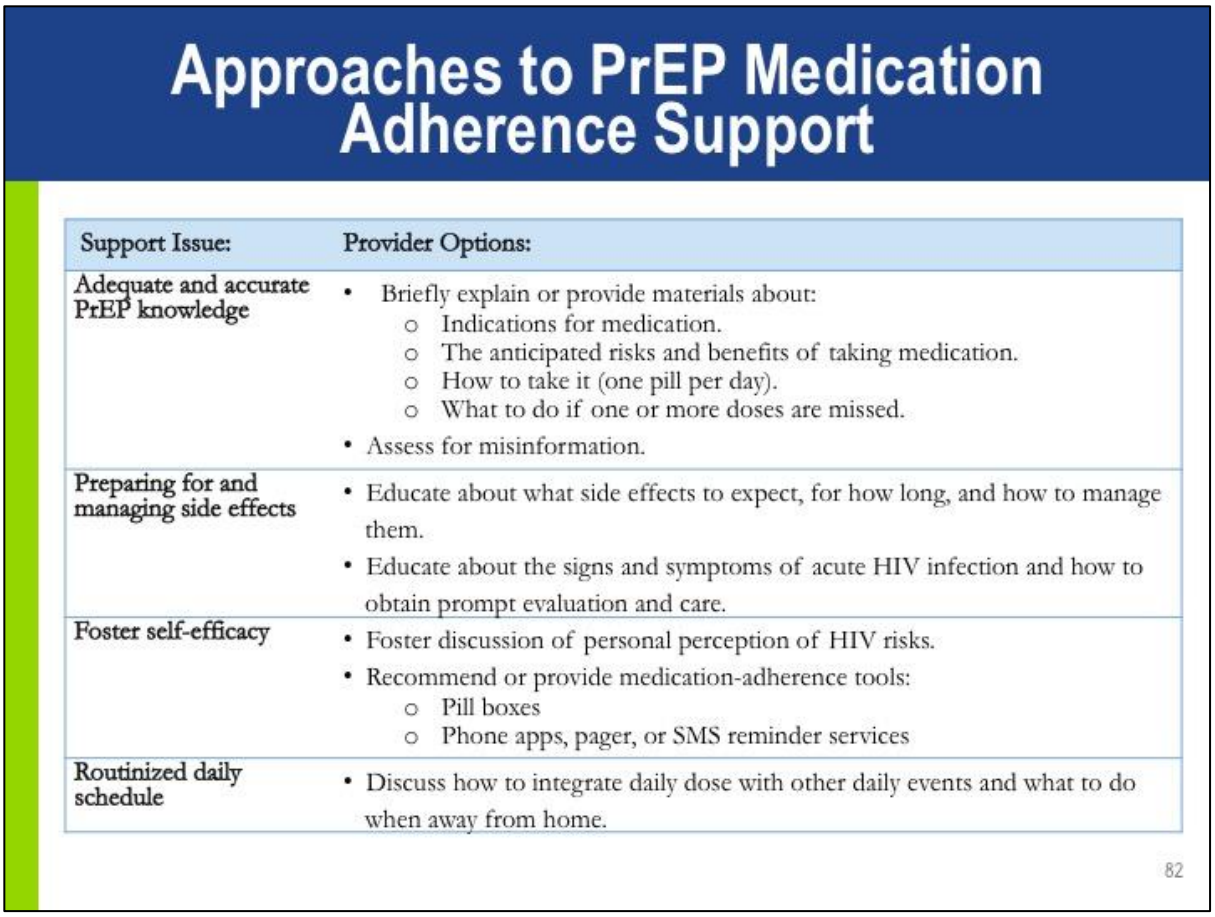
Speaker Notes:

- It is helpful to think about non-adherence in relation to voluntary and involuntary non-adherence in order to better target adherence support strategies.



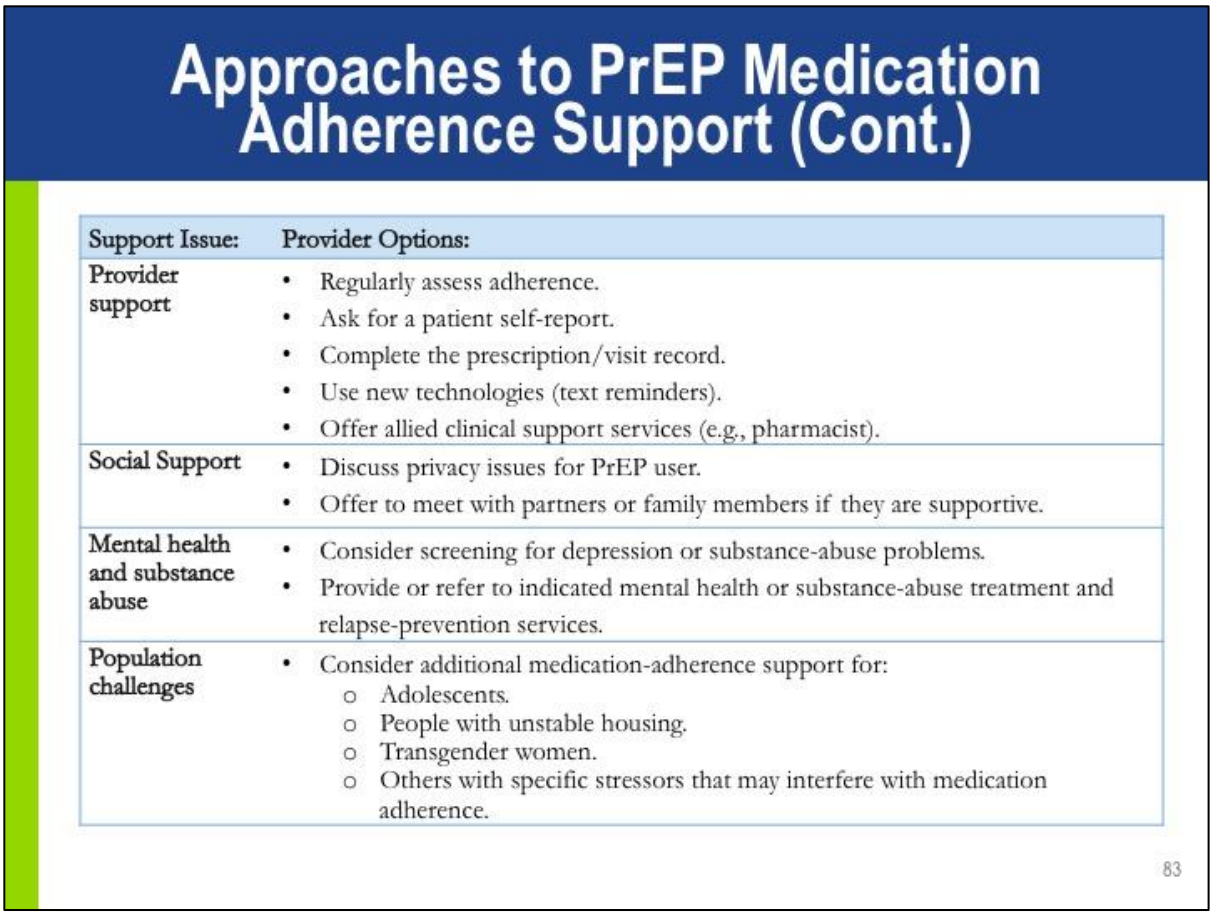
Speaker Notes:

- The health provider can help support adherence by learning from ART programs in order to use some of the general strategies that have been shown to positively influence adherence including (see slide).



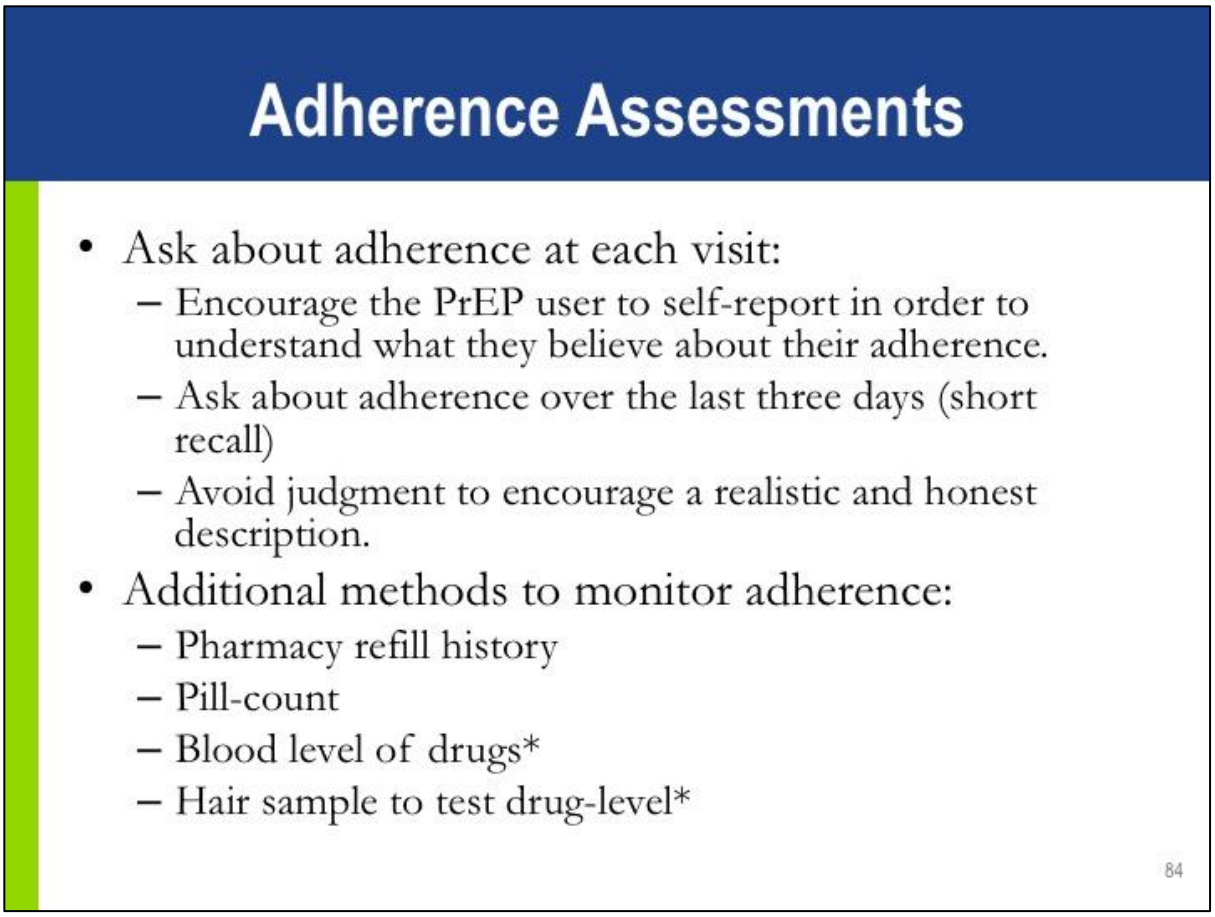
Speaker Notes:

- Related to PrEP medication adherence, 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. For example…



Speaker Notes:

- Here are additional options/strategies that the provider can use to address additional PrEP specific medication adherence support issues listed on the left side of the table. Examples of these options include…



Speaker Notes:

- At each visit health providers should ask about adherence. There is no gold standard for adherence measurement, the provider can use:
    - Self-report (easy, cheap but not always reliable)
    - Pharmacy refills
    - Pill-count
- More expensive options: measuring drug level in blood and hair sample.

Promoting Adherence

- Several approaches can be used to promote adherence:
  - Motivational interviewing
  - Informed Choice Counselling (ICC)
  - Next Step Counseling (see next slides)
  - And others

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Integrated Next Step Counseling (iNSC)

- Integrated next step counseling (**iNSC**) was used in the iPrEx OLE study to counsel individuals on sexual health promotion more generally, **with specific emphasis on PrEP adherence for individuals on PrEP.**
- Implementation of iNSC is positioned with delivery of negative HIV test results and serves as pre/post-test HIV counseling as well as adherence counseling in **one brief, targeted, tailored conversation.**

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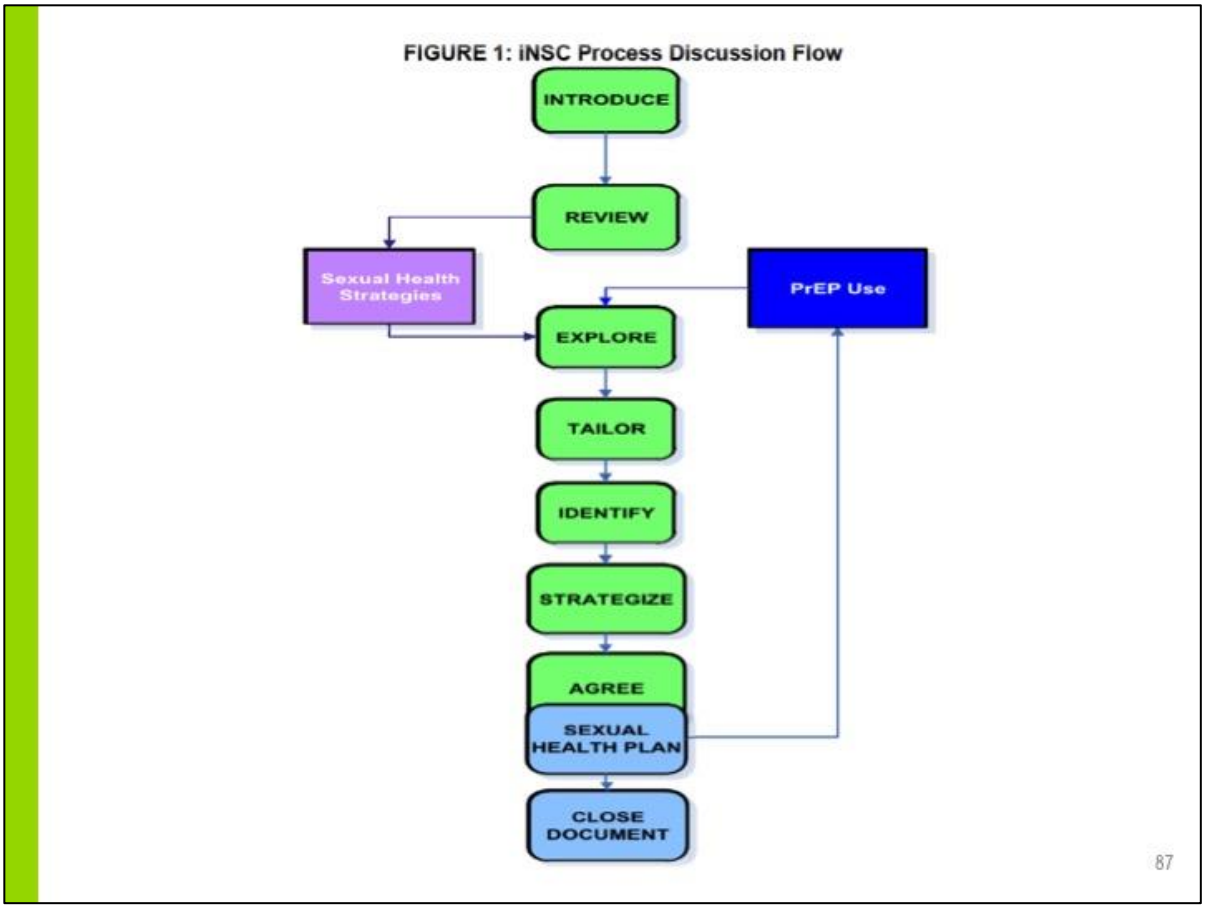

Speaker Notes:

- 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.

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

K RA, McMahan V, Goicochea P, et al. Supporting study product use and accuracy in self-report in the iPrEx study: next step counseling and neutral assessment. AIDS and behavior. Jul 2012;16(5):1243-1259

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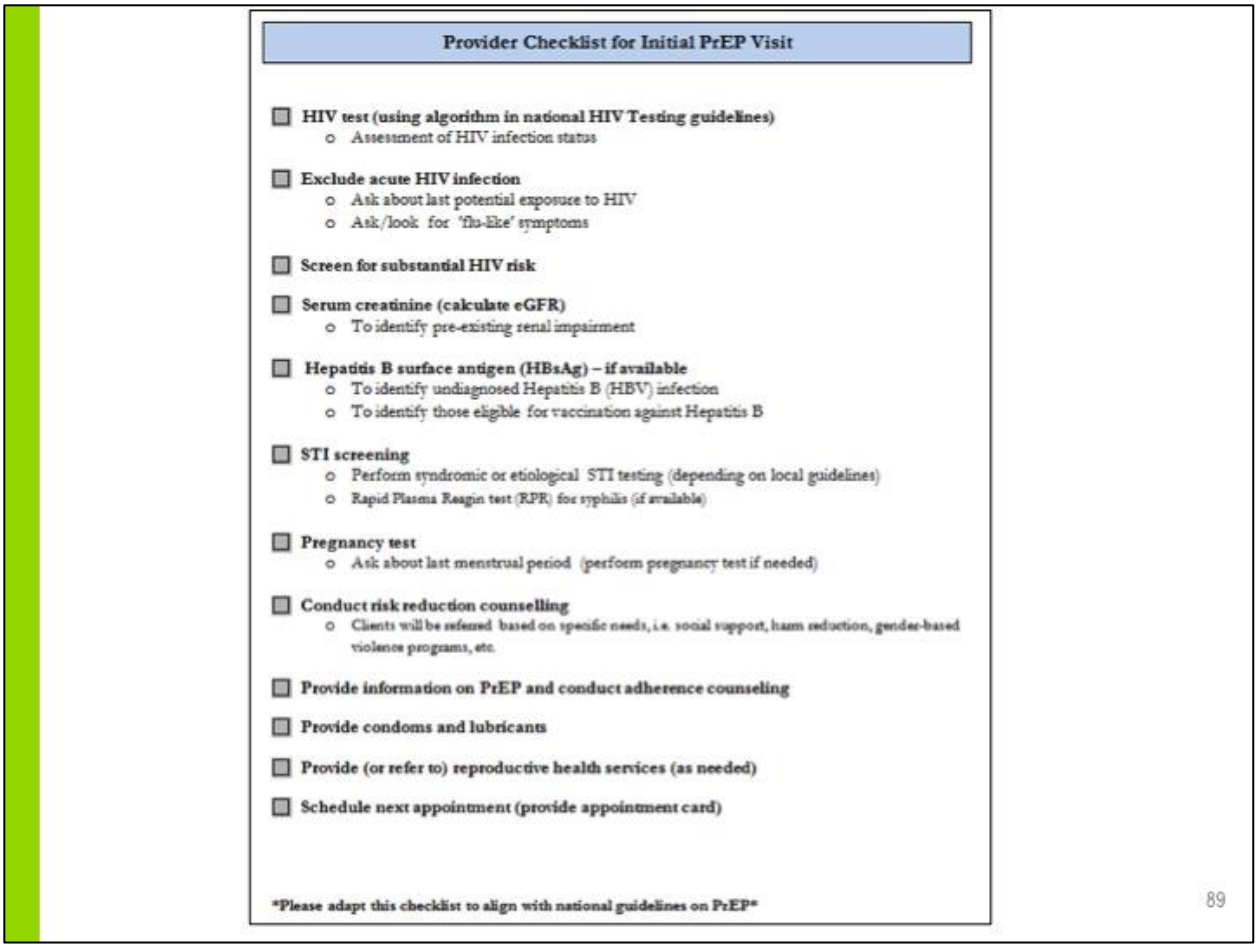
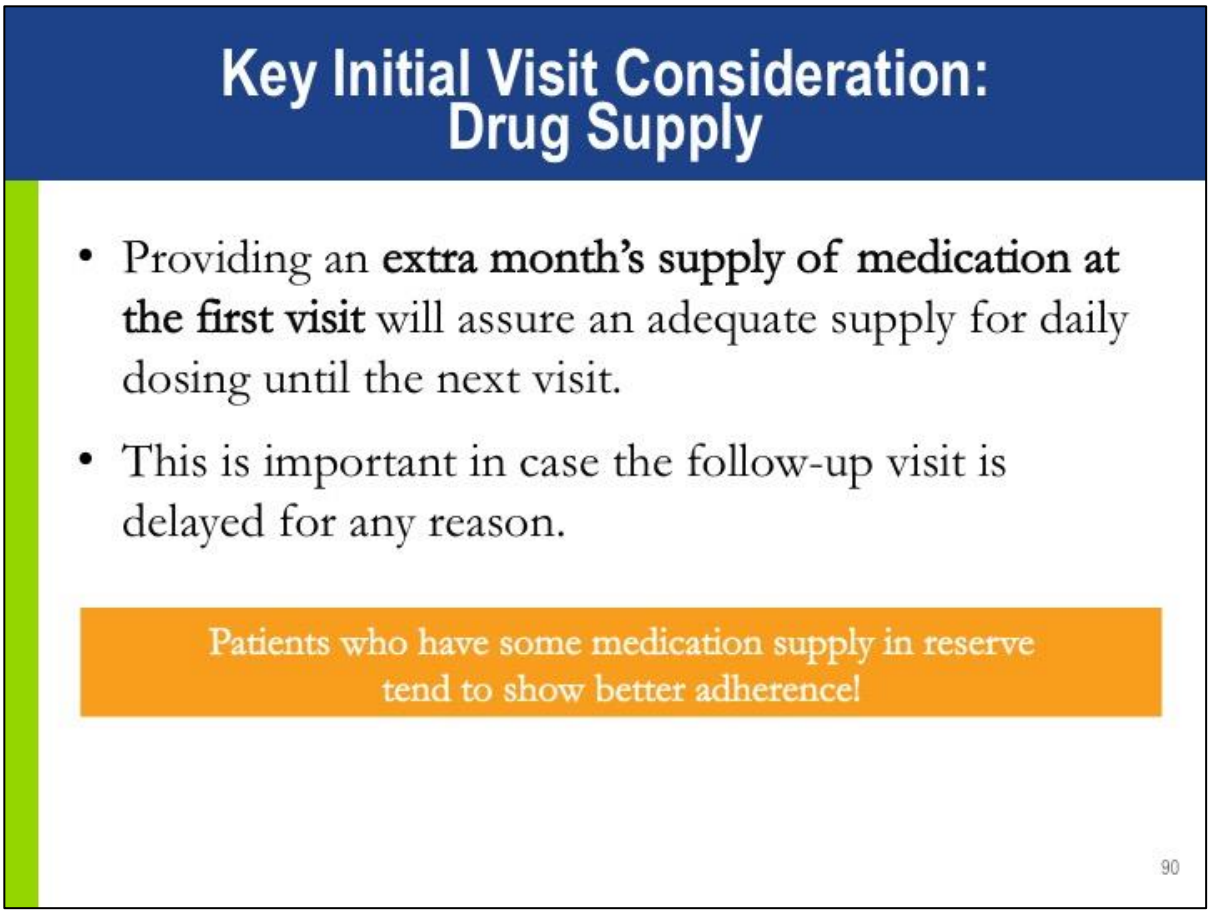


Speaker Notes:

- Please look in the participant folder for this checklist. Countries can customize this checklist to align with national guidelines.



Speaker Notes:

- Ensure that PrEP users have an adequate supply of drugs.

Clinical Scenario for Role Play

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 baby in the coming year. She is using injectable hormonal contraceptive as she used to forget to take oral contraceptives on a daily basis.

- *Think about how would you use the iNSC to have a client-centered conversation to focus on PrEP adherence.*
- *Please observe the following role play and use the copy of the previous slide in your participant folder to check off the iNSC steps that are being addressed and specific example prompts that are being used.*

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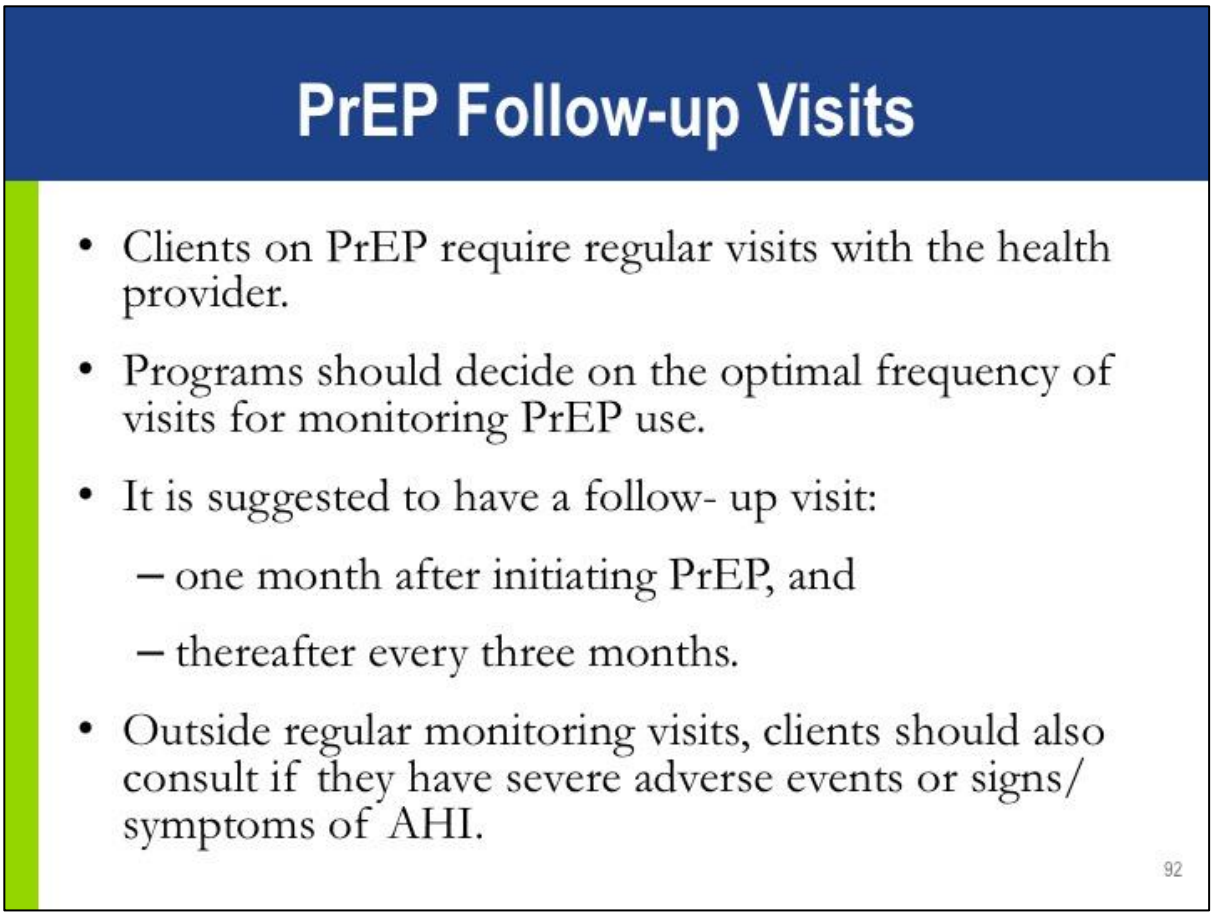
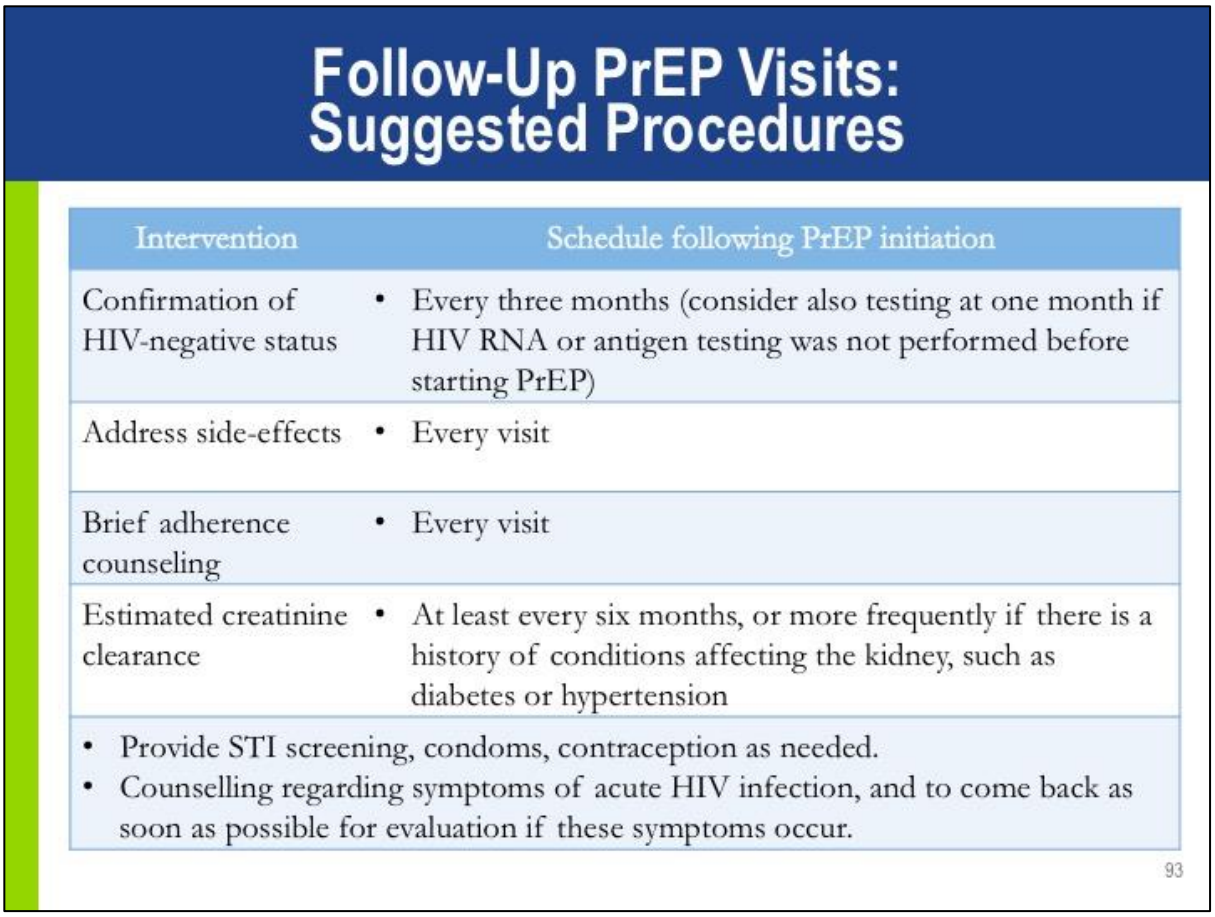


Speaker Notes:

- PrEP requires frequent follow up visits.
- Programs should decide on the optimal frequency of visits for monitoring PrEP use.
- It is suggested to have a follow- up visit:
    - 1 month after initiating PrEP
    - Thereafter, every three months



Speaker Notes:

- During the follow-up visit repeat the HIV test to confirm HIV-negative status. We need repeat HIV testing to inform decisions on whether to continue or discontinue PrEP.
- Repeat HIV testing:
    - One month after starting PrEP
    - Every three months thereafter
- Countries should use HIV testing algorithms in line with their national guidelines.
- It is useful to remember that the limitation of serological tests is the window period (time from HIV infection to detection of antibodies), also exposure to ARVs can decrease sensitivity of serological tests.

Repeat HIV Testing

- Repeat HIV testing is needed to inform decisions on whether to continue or discontinue PrEP.
- Repeat HIV testing (using national guidelines):
  - One month after starting PrEP.
  - Every three months thereafter.
- Remember the limitation of serological tests during AHI in the window period (time from HIV infection to detection of antibodies), and also that exposure to ARVs can decrease sensitivity of serological tests.
- Stop PrEP if AHI is suspected.

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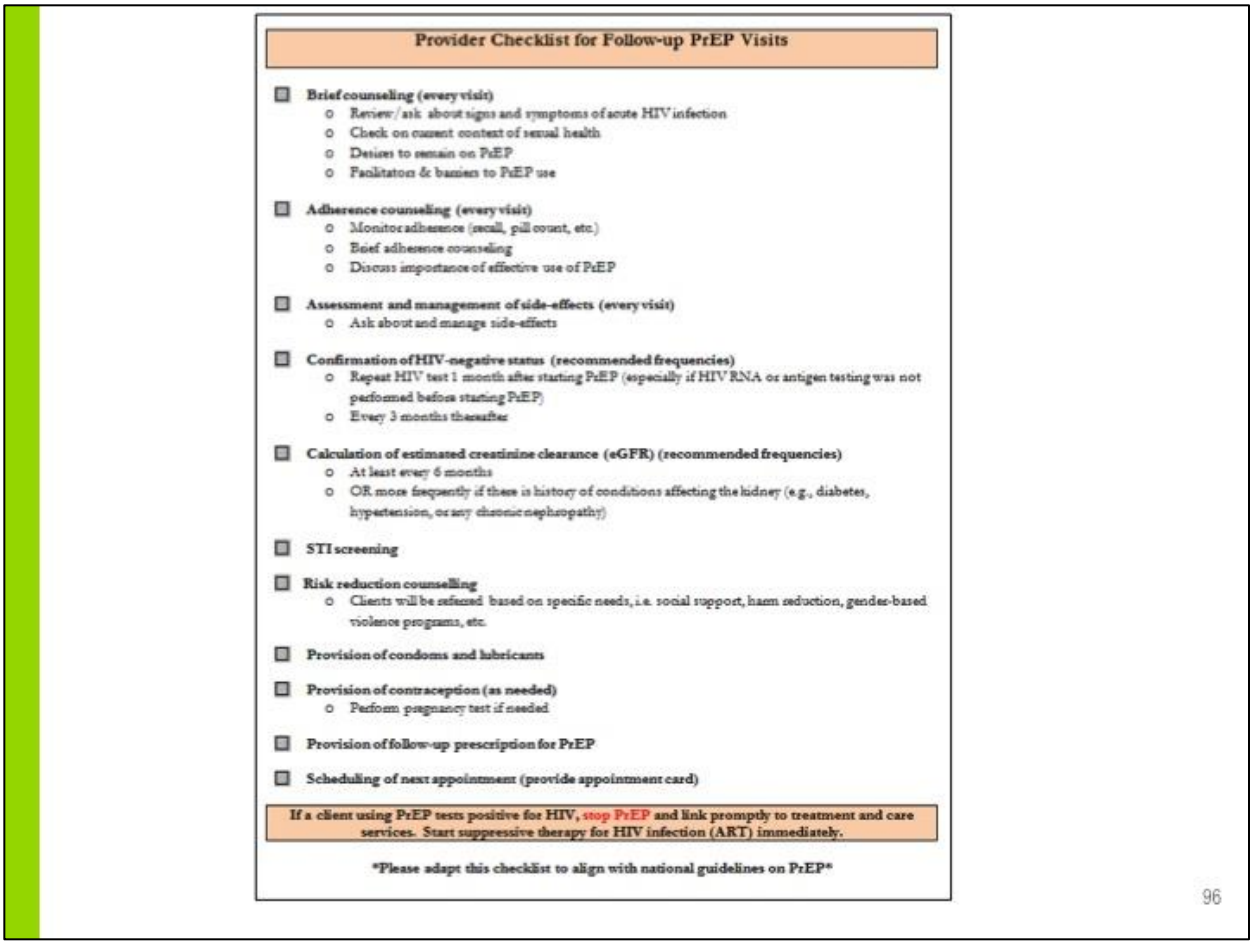
Follow-Up PrEP Counseling

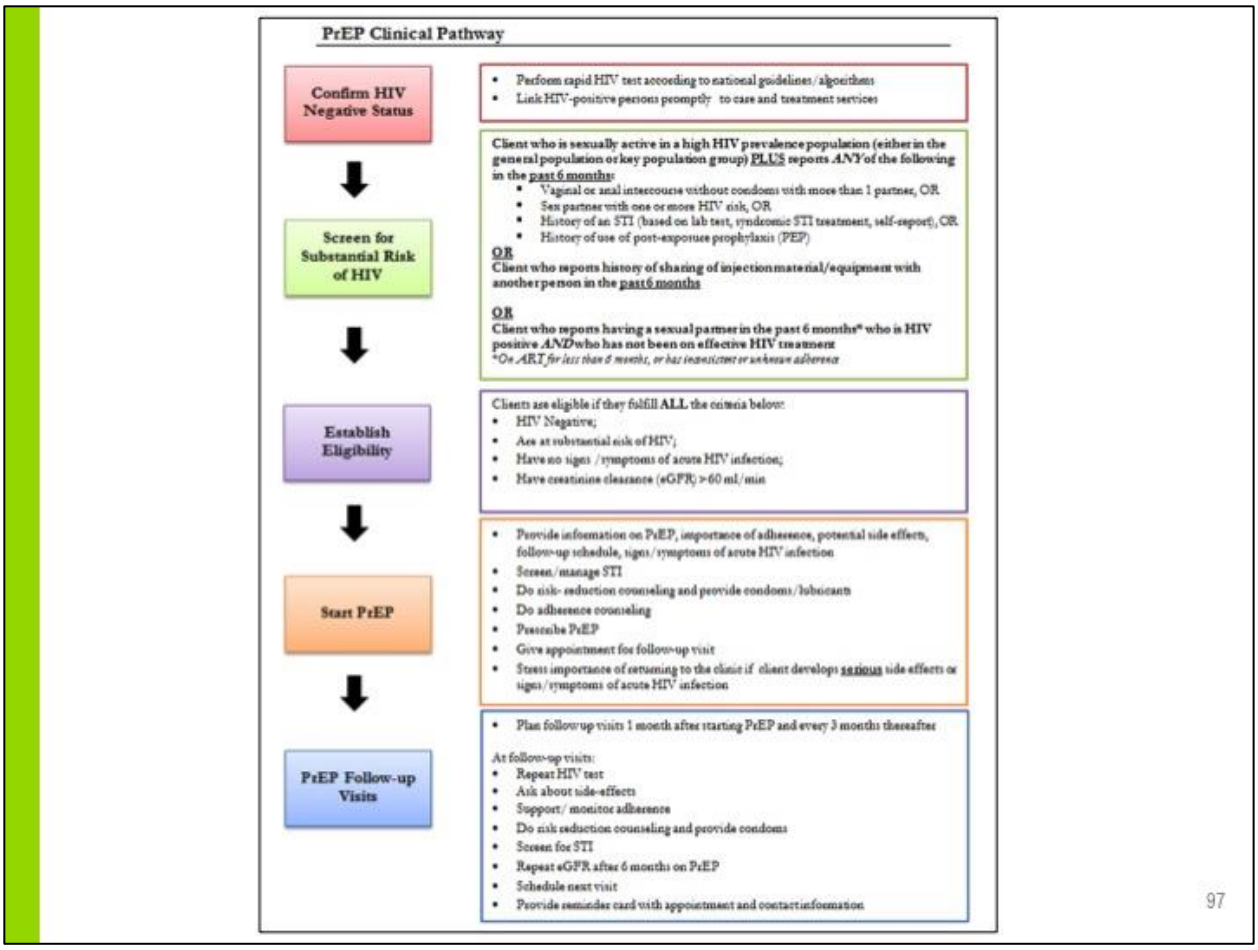
- Follow-up counseling should focus on:
  - Checking in on the **current context** of sexual health.
  - The patient's **desire to remain on and assessment of continued risk** of PrEP.
  - **Facilitators** & **barriers** to PrEP use.
  - Additional **non-PrEP related sexual health protection** strategies (condoms, etc.).
  - **Dosing requirements** for highest protection.
  - What to do **if a dose is missed.**
  - Common **adherence strategies.**
  - Reasons for **ongoing monitoring** while on PrEP.
  - How to recognize symptoms of **acute HIV infection.**
  - **Side-effects** & **side-effects management.**
  - How to **safely discontinue** and **restart** PrEP as appropriate.

95



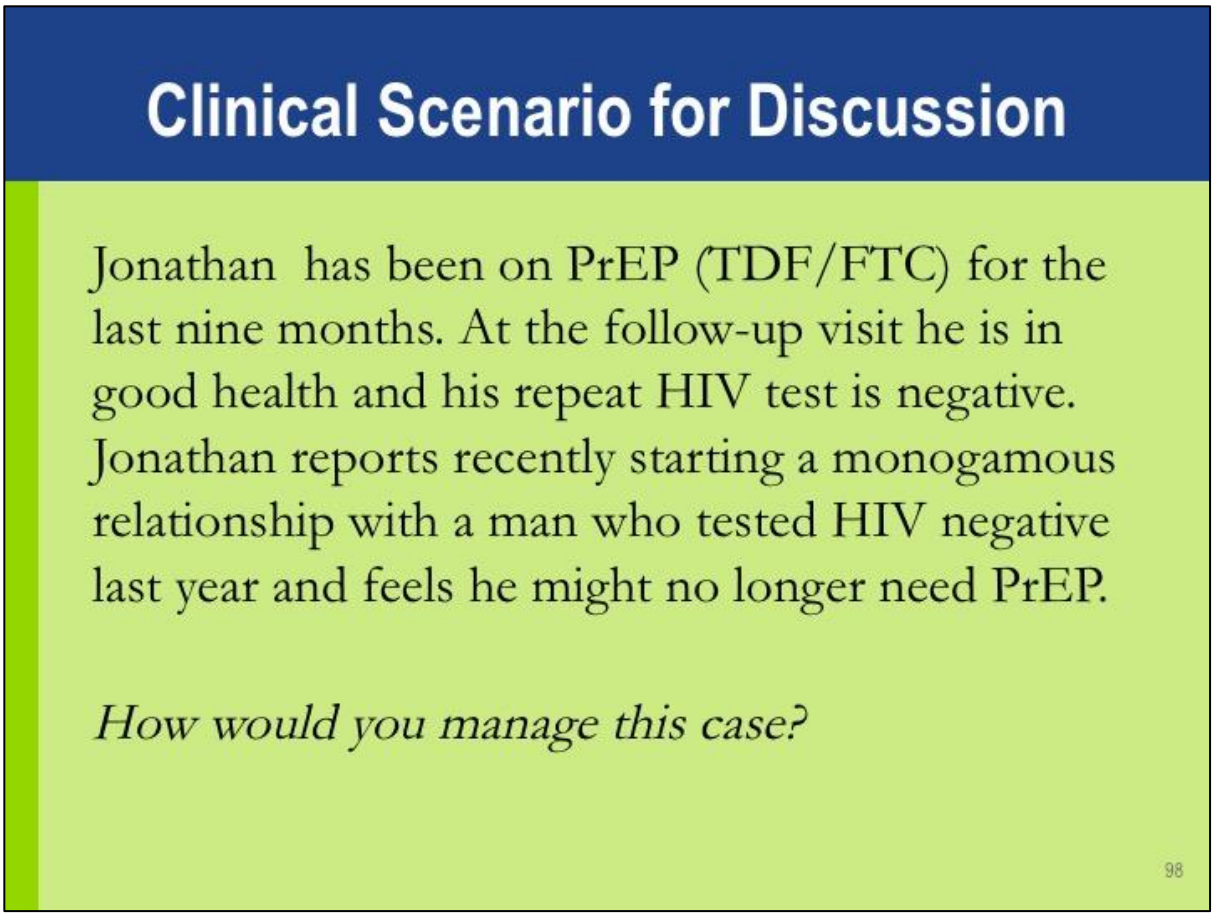
Speaker Notes:

- Please look for this checklist in the participant folder. Countries can modify the checklist to align with national guidelines.



Speaker Notes:

- You will see this in the participant folder. You can customize it to reflect local practices.



Speaker Notes:

- PrEP can be started and stopped as needed.
- People can move through periods of substantial risk (change in sexual practices, change in relationship status…).
    - Clients can choose to discontinue PrEP if they are no longer at substantial risk of HIV:
    - Clients should inform the provider of their wish to stop PrEP.
    - Provider should document HIV test result at the time of stopping PrEP.
    - Providers should counsel about other prevention methods.
    - Clients wishing to restart PrEP later should undergo HIV testing and other baseline tests (see Module 2).
- Please note that PrEP is also discontinued if:
    - Client tests HIV positive (in which case you would refer for treatment and care).
    - There is suspicion of acute HIV infection.
    - 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).

Module 3 Summary

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

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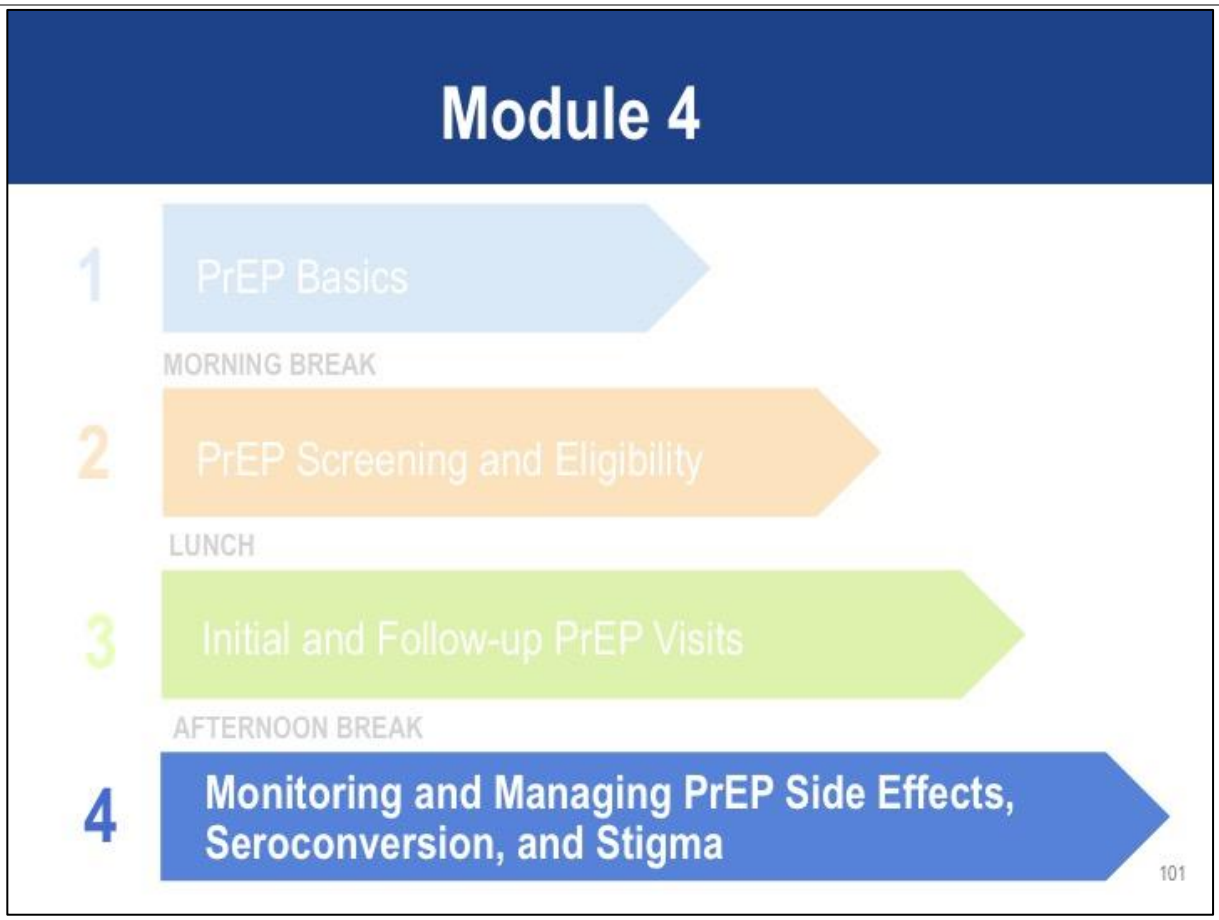
AFTERNOON BREAK

100

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

DURATION: 105 MINUTES (1 HOUR, 45 MINUTES)



Module 4: Learning Objectives

By the end of 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.
- Think about how M&E tools can be adapted for local use.

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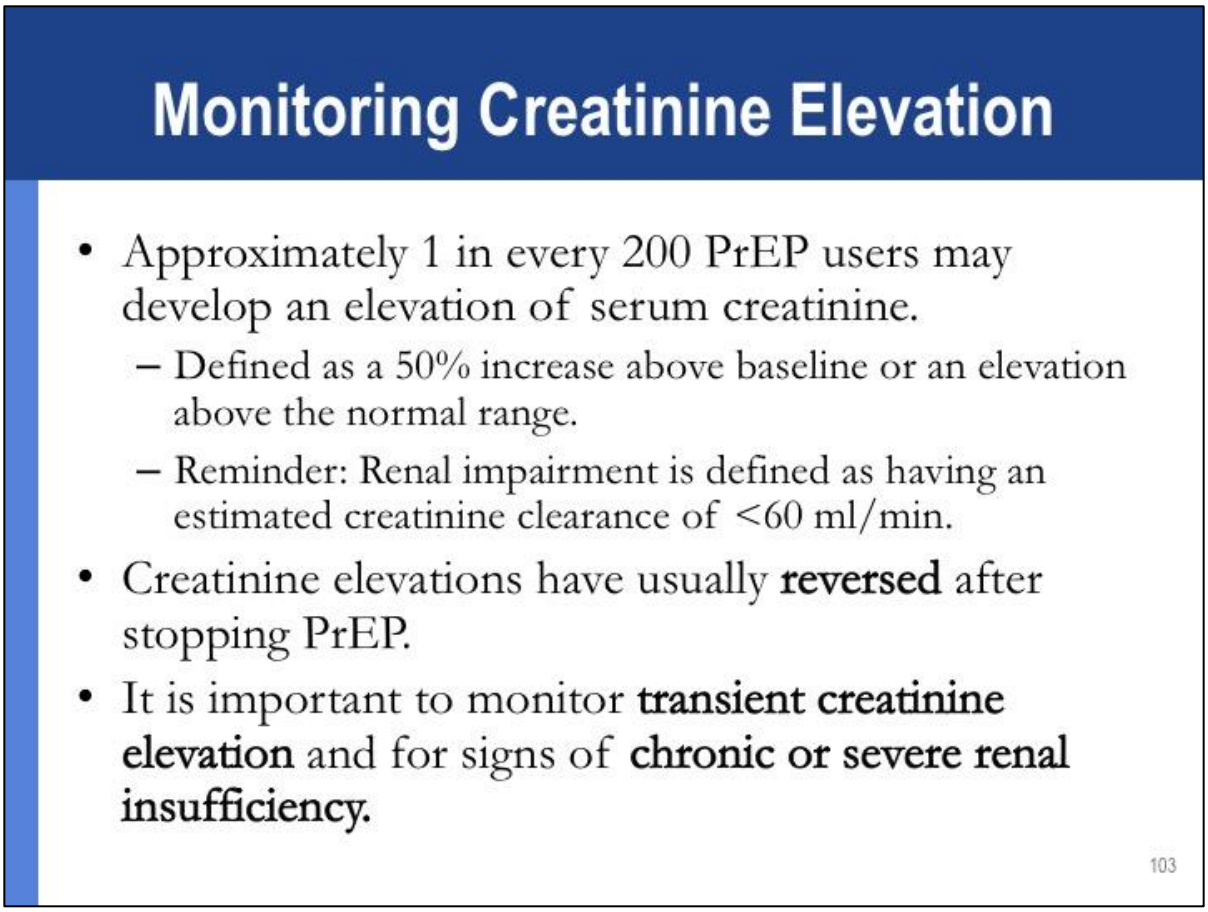

Speaker Notes:

- Ideally, clients should have eGFR measured at baseline and after six months of PrEP.

Question

How would you manage increase in creatinine clearance?

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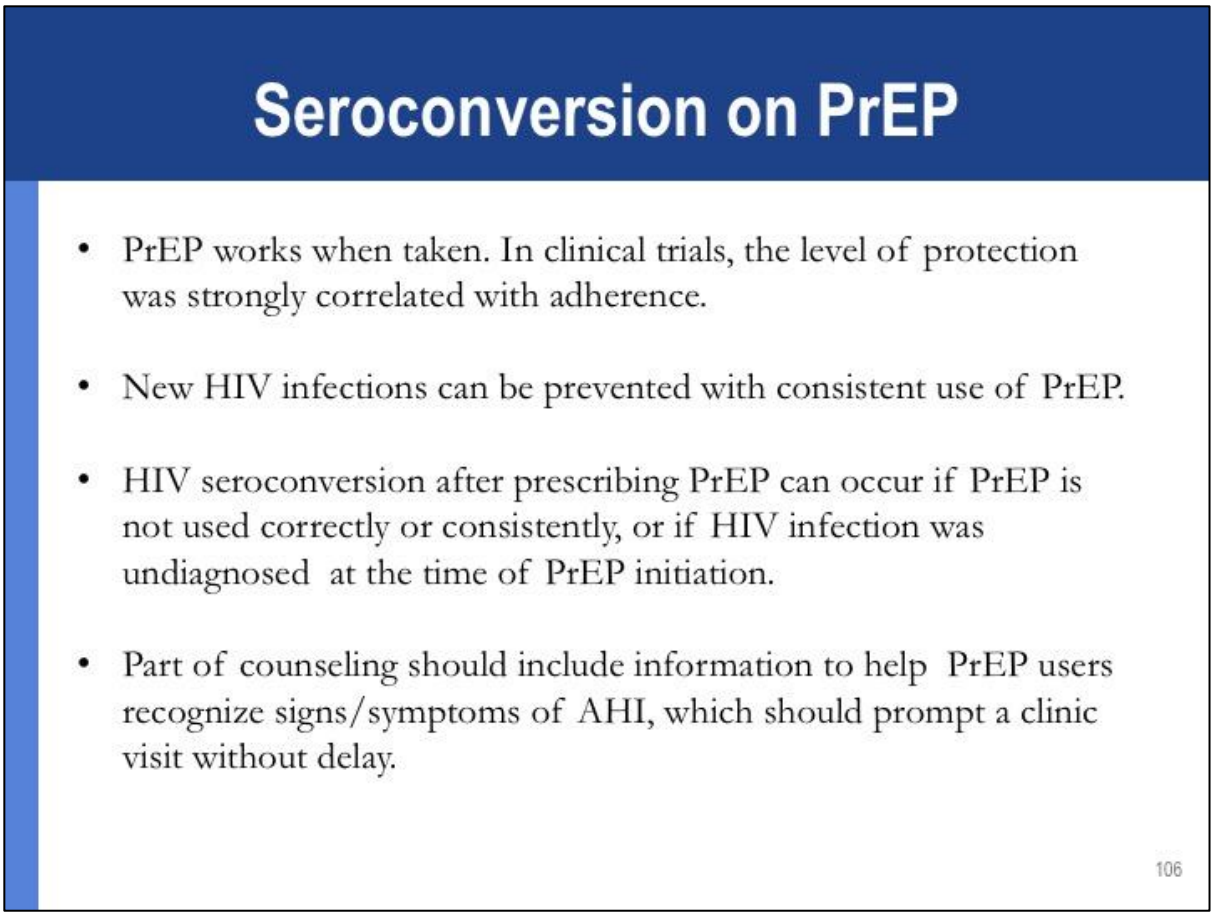
Managing Creatinine Elevation

- Discontinue PrEP if creatinine elevation is confirmed on a separate specimen and if estimated creatinine clearance decreases to <60 ml/min.
- After PrEP is stopped, creatinine should be checked for another one to three months and PrEP restarted if eGFR returns to > 60 ml/min.
- Additional causes and management of creatinine elevations should be considered if:
  - Creatinine elevations are more than 3x the baseline.
  - Renal function or creatinine elevations do not return to normal levels within three months after stopping PrEP.
  - Creatinine elevations progress at one month or more after stopping PrEP.
- Common causes of chronic or severe renal insufficiency include: diabetes mellitus, uncontrolled systemic hypertension, hepatitis C infection, liver failure, and pre-eclampsia during pregnancy.

105



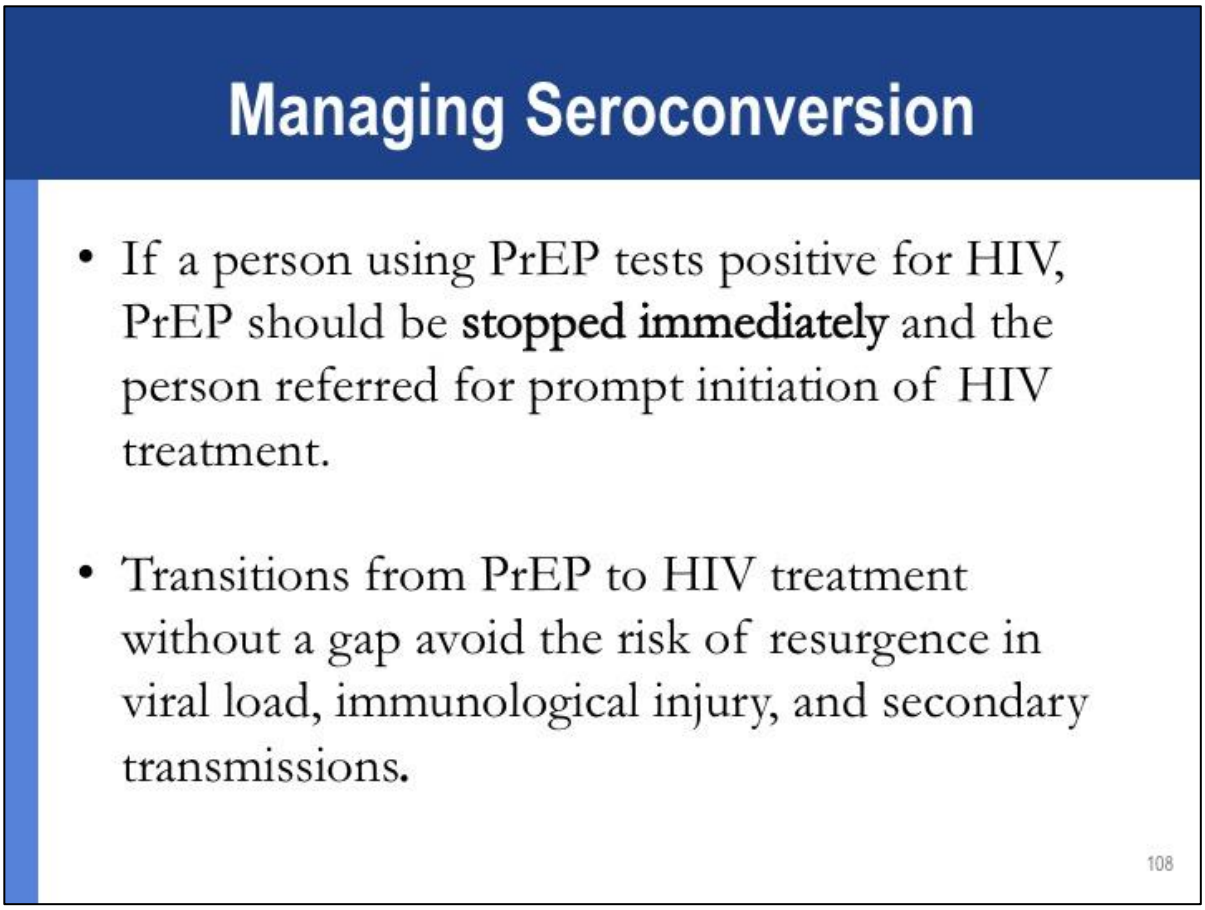
Speaker Notes:

- In clinical trials there were very few cases of seroconversion on PrEP.

Question

How would you manage seroconversion on PrEP?

107



Speaker Notes:

- How would you manage seroconversion on PrEP?

PrEP "Special Situations"

Situation	Recommendation/Follow-Up
Hormonal Contraception	• PrEP does not affect the efficacy of hormonal contraceptives and hormonal contraceptives do not affect PrEP efficacy.
Pregnancy and breastfeeding	• PrEP may be continued during breastfeeding in women who are at substantial risk for HIV acquisition.
Hepatitis B infection	• Hepatitis B vaccination is appropriate for people at substantial risk for HBV or HIV infection.
Management of Recent HIV Exposure with PEP	• People who have been exposed to HIV in the past 72 hours should be offered post-exposure prophylaxis (PEP). • WHO recommends PEP consisting of TDF/3TC (or FTC), preferably combined with a boosted protease inhibitor, for 28 days (use national guidelines). • PEP should be transitioned to PrEP after 28 days if the HIV test remains negative and there is substantial ongoing risk of HIV acquisition.

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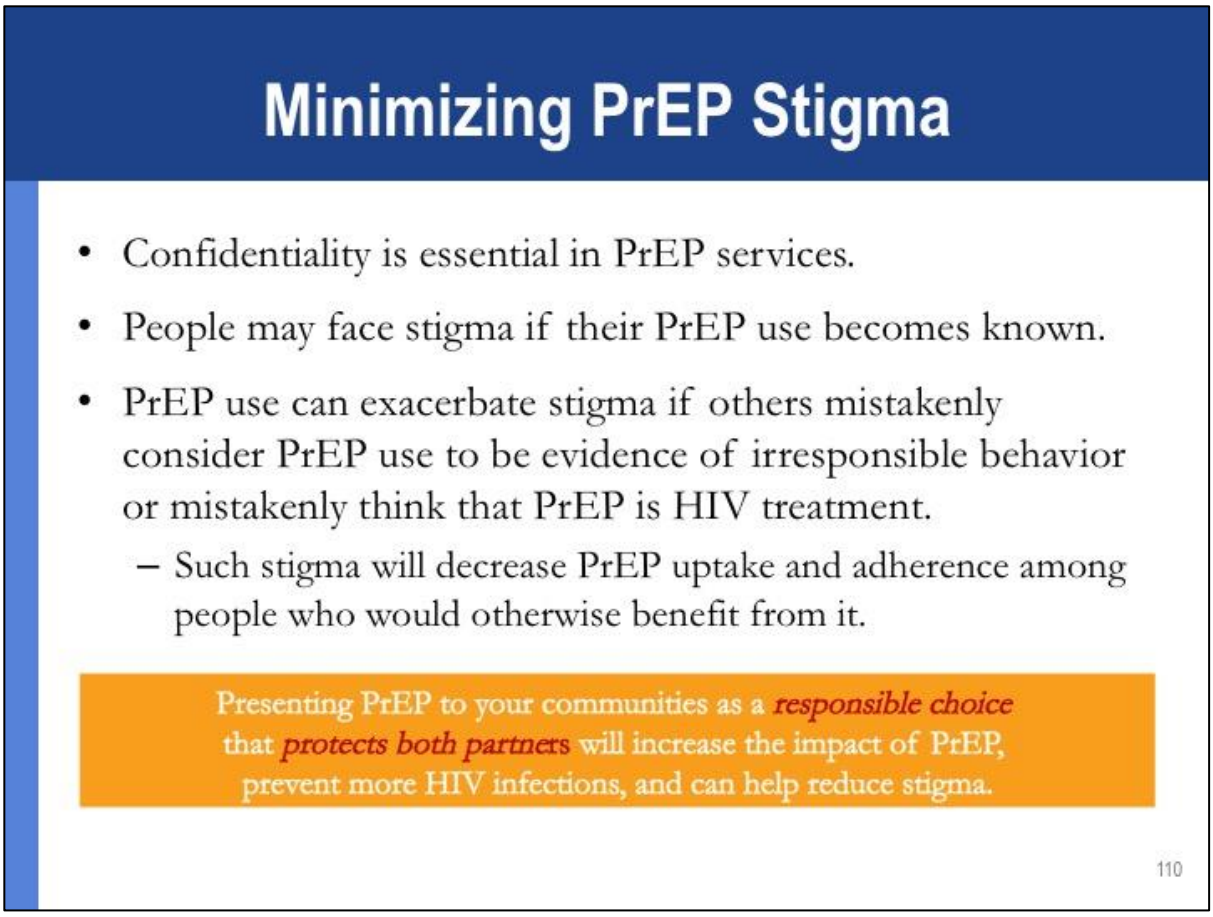
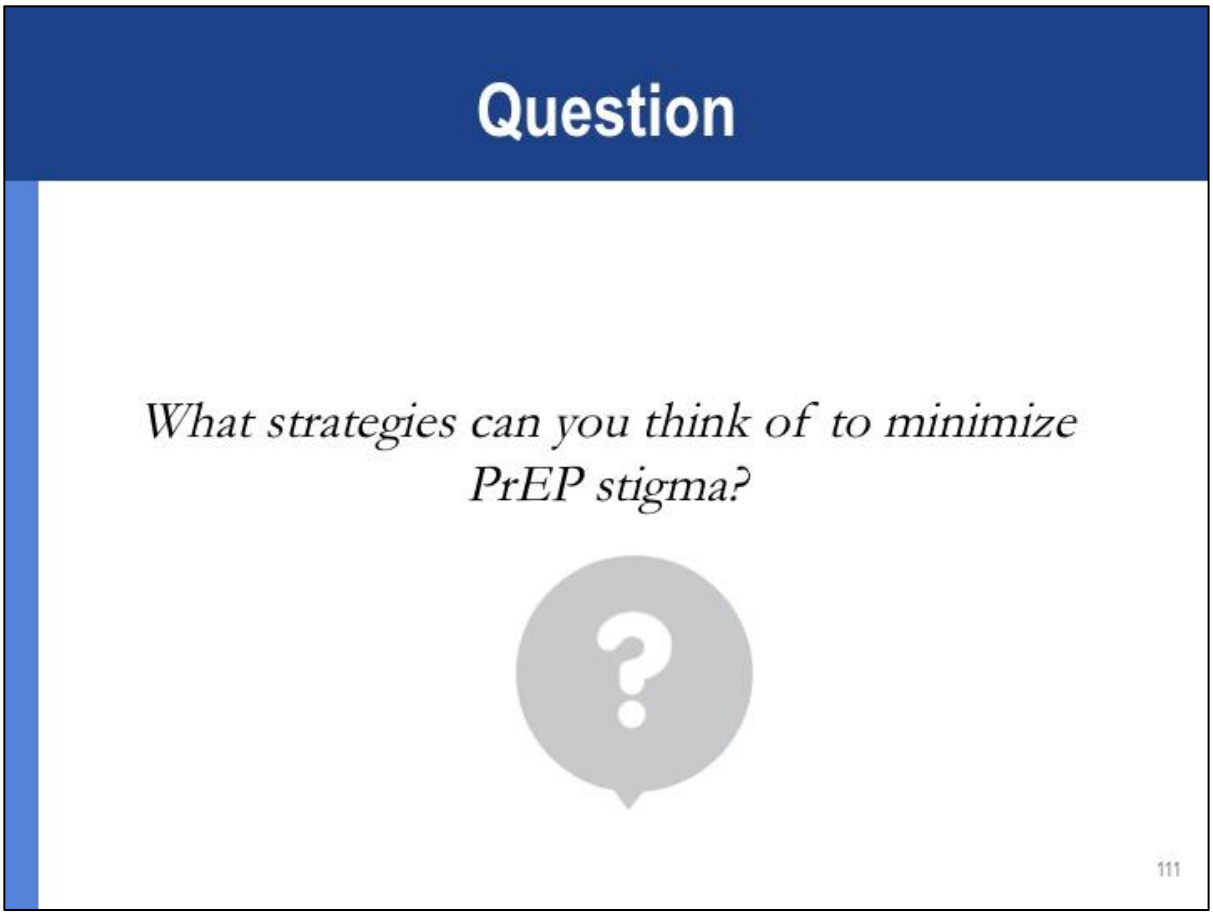


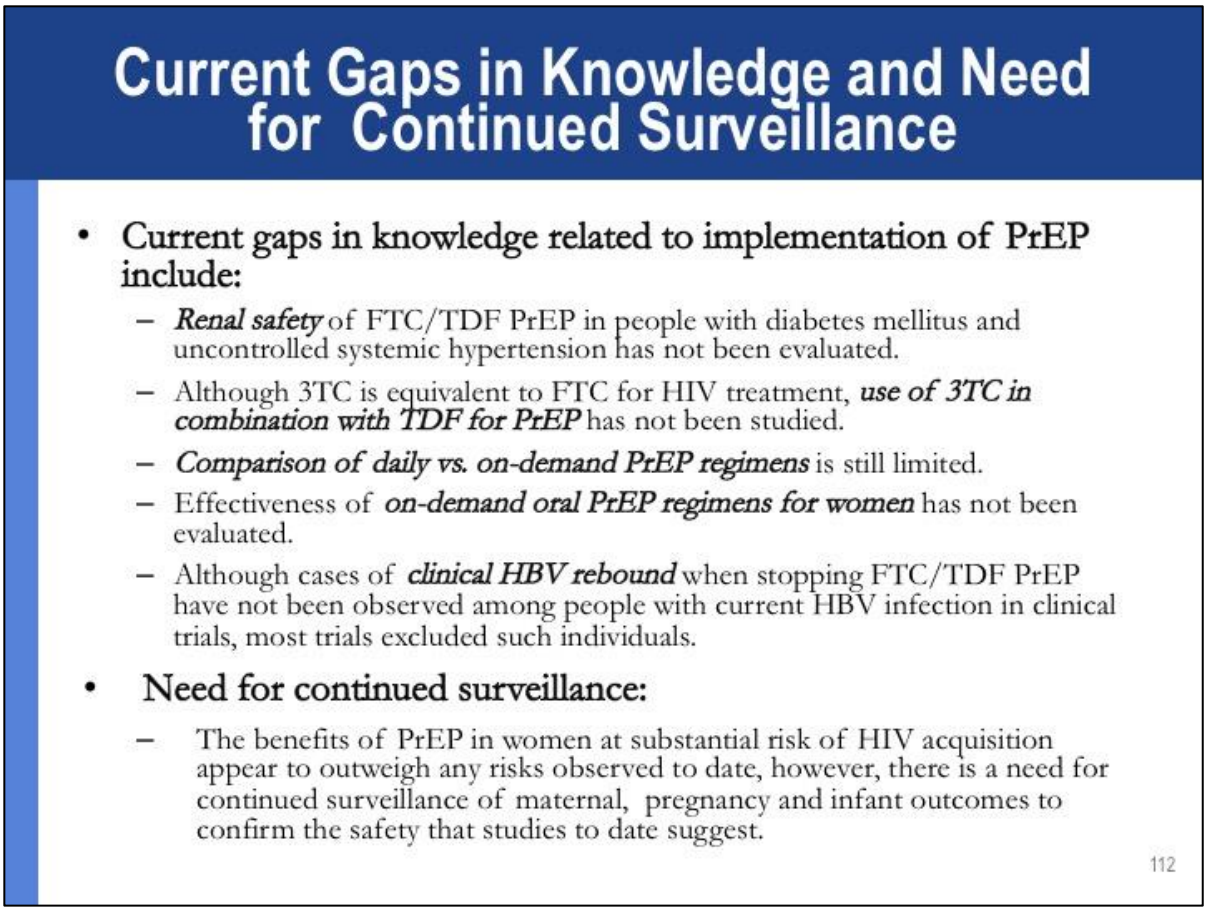
Speaker Notes:

- Key populations usually face stigma and discrimination. Will use of PrEP add more stigma?



Speaker Notes:

- This could be turned into a group exercise with a report-back component, depending upon time.



Speaker Notes:

- The evidence for PrEP efficacy and safety presented in theses slides are 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.

PrEP M&E Tools

- Refer to your participant folder for a:
  - Facility-held card
  - PrEP register
  - PrEP monthly report form
  - Substantial Risk and Eligibility Assessment
- *Begin to think* about how these M&E tools can be adapted for your country/facility.
- **Additional onsite training will be provided for adapting M&E tools.**

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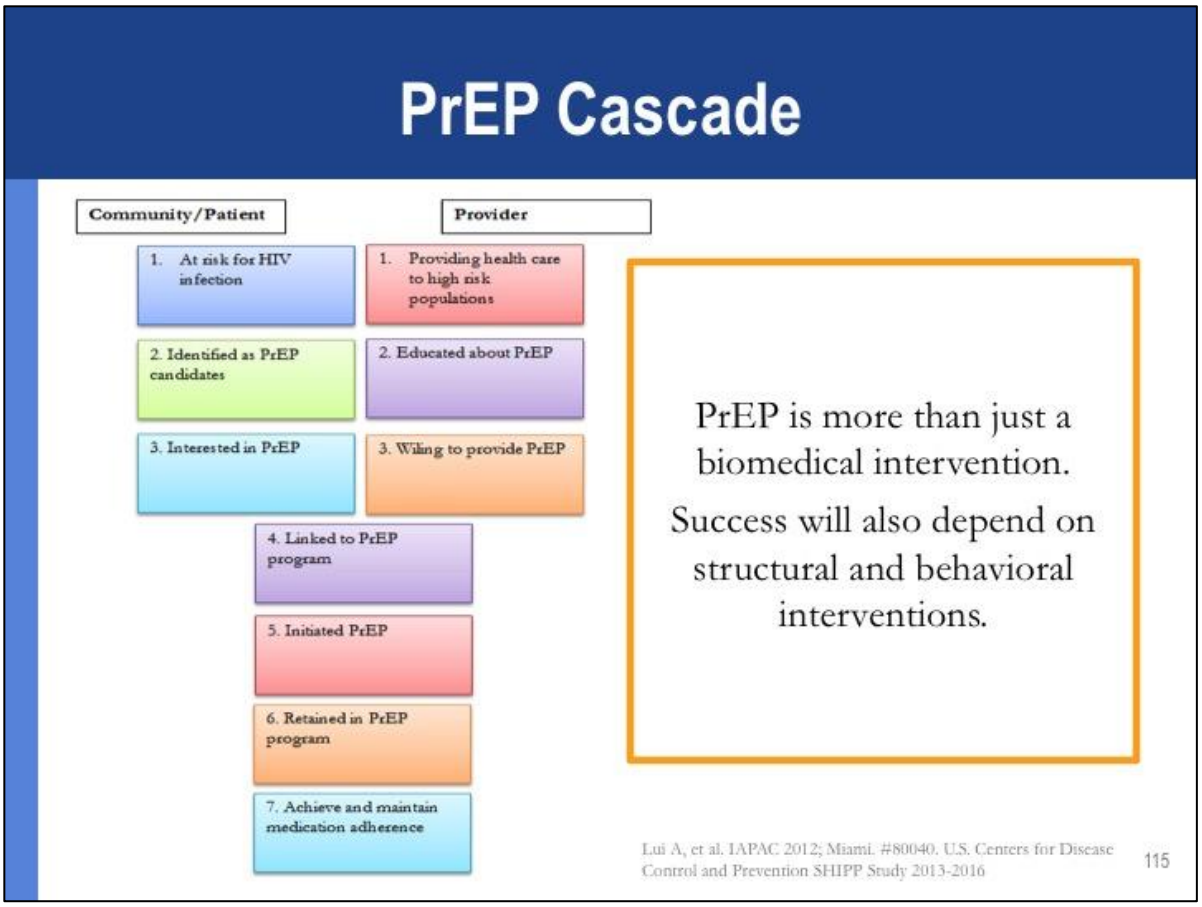
Module 4 Summary

- PrEP users should be informed about how to recognize signs and symptoms of acute HIV infection.
- If person using PrEP tests positive for HIV, stop PrEP immediately and start ART as soon as possible, without a gap after PrEP is discontinued.
- If confirmation of positive HIV test result is delayed for more than a few hours, transition to fully suppressive ART (three ARVs as per national treatment guidelines).
- Ideally, blood creatinine (eGFR) should be measured before starting PrEP and *at least every six months* after PrEP is started.
  - Initiation of PrEP should not be delayed while waiting for creatinine result.

114



Speaker Notes:

- PrEP is a biomedical intervention but it is more than just prescribing a pill. Success will also depend on the implementation of structural and behavioral interventions.
- There is a need for concerted efforts at each step of the cascade in:
    - Creating demand for PrEP
    - Linking potential PrEP clients to services
    - Starting PrEP
    - Retaining clients on PrEP
    - Achieving and maintaining good adherence

Question

What are concerns you have about implementing PrEP?

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PrEP Resources for Providers

- http://www.who.int/hiv/pub/arv/arv-2016/en/
- http://www.who.int/hiv/topics/prep/en/
- http://www.unaids.org/sites/default/files/media_asset/UNAIDS_JC2764_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. http://emtct-iatt.org/wp-content/uploads/2016/08/WHO-TDF-pregnancy-Lynne-Mofenson.August-21-2016.pdf . Accessed October 5, 2016.

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PrEP Resources for PrEP Users

- http://www.whatisprep.org
- http://www.PleasePrEPMe.org/resources
- http://www.iwantprepnow.co.uk
- http://www.cdc.gov/hiv/pdf/risk_PrEP_TalkingtoDr_FINALcleared.pdf
- https://www.facebook.com/groups/PrEPFacts/

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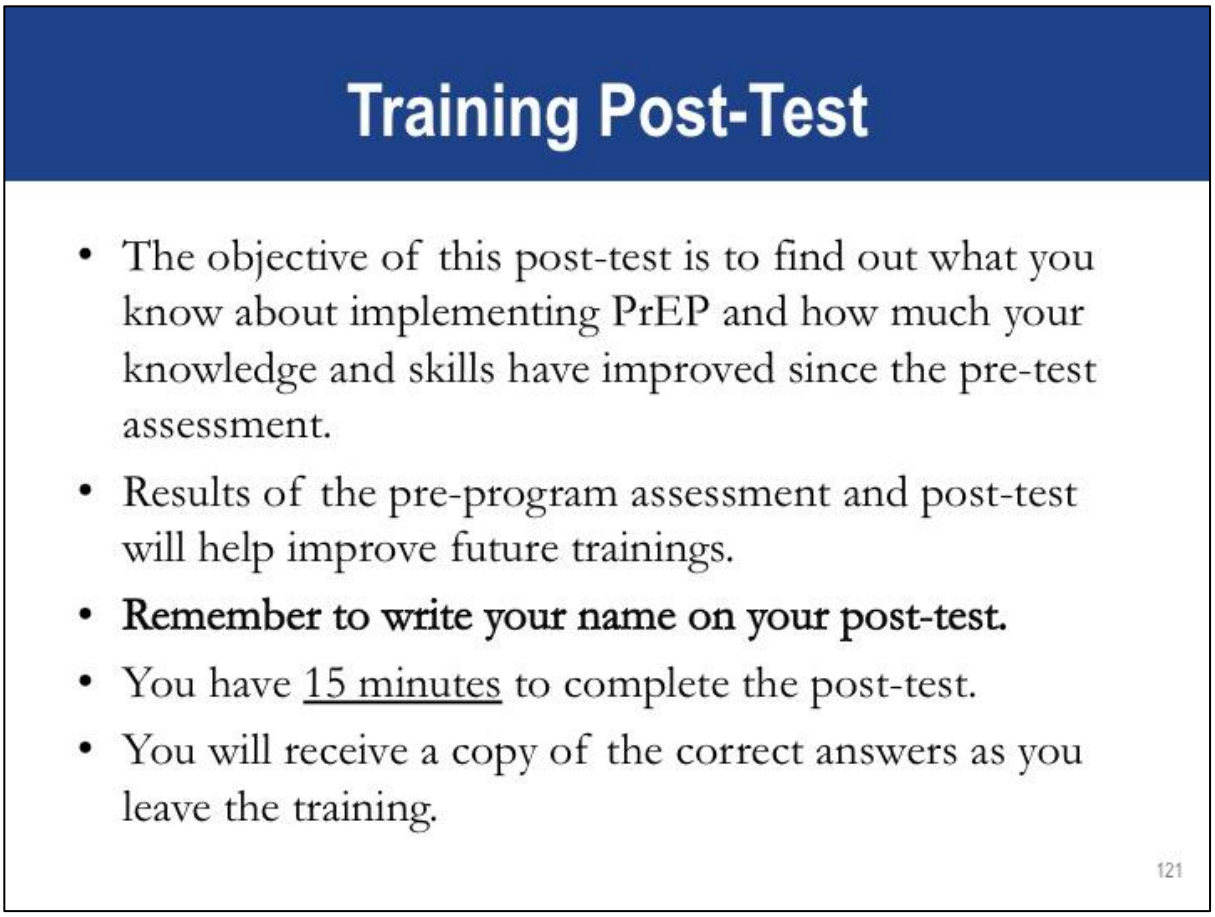
Post-Test,
Training Evaluation,
and Closing
119

PrEP Specific Competencies

After completing today's training program, participants will be able to:

- Identify eligible candidates for PrEP.
- Conduct an individualized risk assessment.
- Educate and counsel PrEP candidates and users.
- Conduct clinical and laboratory assessments during the initial PrEP visit.
- Prescribe PrEP.
- Conduct clinical and laboratory assessments during follow-up PrEP visits.
- Review PrEP M&E tools.

120



Speaker Notes:

- Distribute copies of the post-test to all participants.

Training Evaluation Form

Training Evaluation Form

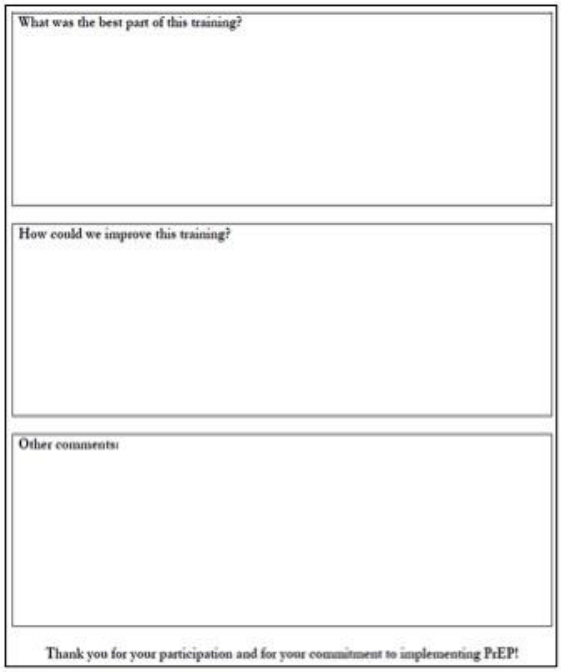
Name (optional): _____
Your position (optional): _____
Health facility where you work (optional): _____

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

	① Strongly Disagree	Disagree	Neither agree nor disagree	Agree	⑤ 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

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.

	① Not helpful				⑤ Very helpful
Module 1: PrEP Basics	1	2	3	4	5
Module 2: PrEP Eligibility, Screening & Contraindications	1	2	3	4	5
Module 3: Initial PrEP Visit & Follow-Up Visits	1	2	3	4	5
Module 4: Monitoring & Counselling PrEP: Side Effects, Seroconversion, and Stigma	1	2	3	4	5



What was the best part of this training?

How could we improve this training?

Other comments:

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

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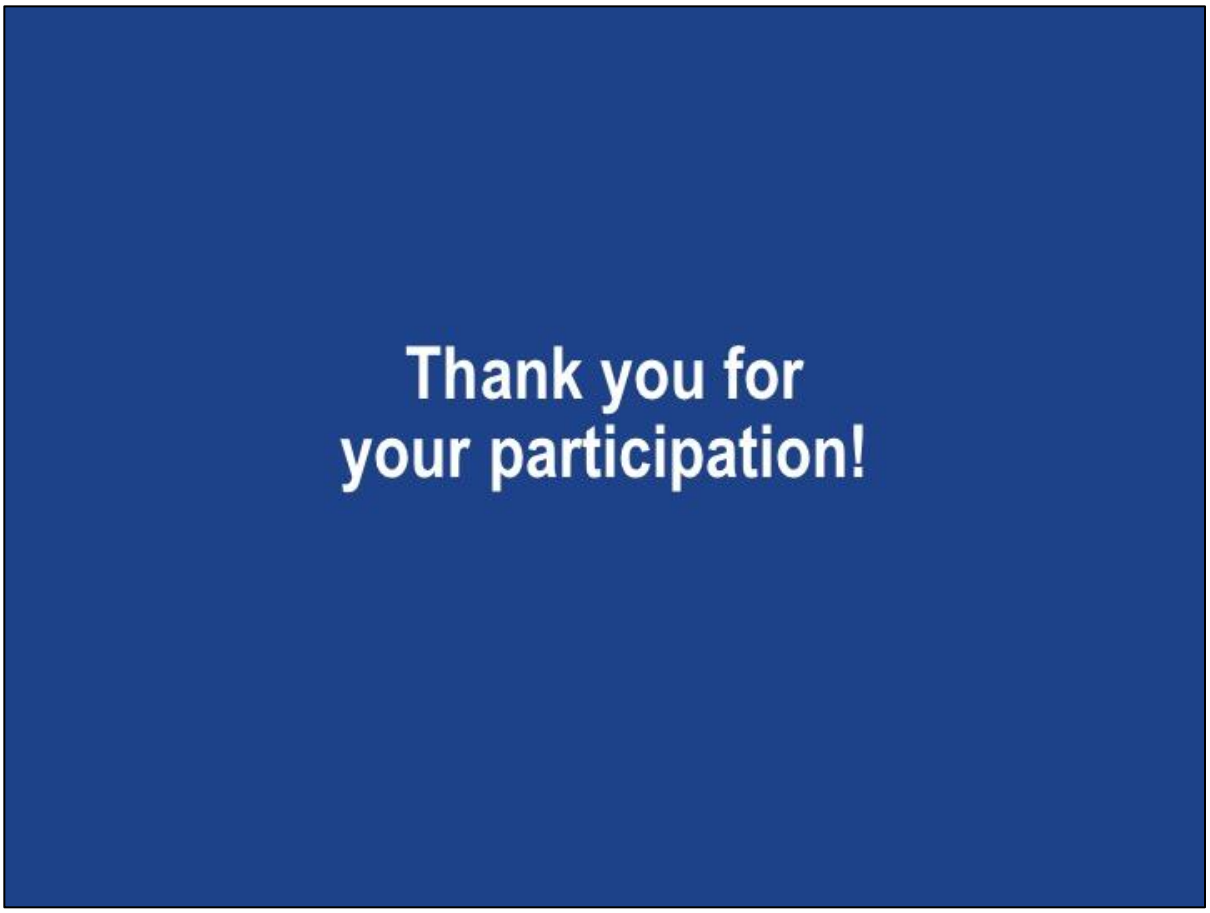
Training Evaluation

(See Participant Folder*: Training Evaluation Form.)*

- We welcome your honest feedback to improve future trainings.
- Your evaluations are confidential — you do not have to include your name.

123


Thank you for
your participation!

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 was the best part of this training?

How could we improve this training?

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. **Copy of the *PrEP Training for Providers in Clinical Settings* PowerPoint slide set**
2. **Pre-Test Assessment**
3. **Post-Test Assessment**
4. **Training Evaluation Form**
5. **PrEP Clinical Pathway**
6. **Screening for Substantial Risk of HIV Infection Chart**
7. **Provider Checklist for Initial PrEP Visits**
8. **Provider Checklist for Follow-up PrEP Visits**
9. **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)

G. PrEP Clinical Pathway

Confirm HIV Negative Status

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

Screen for Substantial Risk of HIV

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

- 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 past six months

OR

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*

Establish Eligibility

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

Start PrEP

- 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 **serious** side effects or signs/symptoms of acute HIV infection

PrEP Follow-up Visits

- 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

H. 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) PLUS reports *ANY* of the following in the past 6 months:**
  - 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)

OR

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

OR

- **Client who reports having a sexual partner in the past 6 months* who is HIV positive *AND* who has not been on effective HIV treatment**

  **On ART for less than 6 months, or has inconsistent or unknown adherence*

I. Provider Checklist for Initial PrEP Visit

Provider Checklist for Initial PrEP Visit

- ☐ **HIV test (using algorithm in national HIV Testing guidelines)**
  - Assessment of HIV infection status

- ☐ **Exclude acute HIV infection**
  - Ask about last potential exposure to HIV
  - Ask/look for 'flu-like' symptoms

- ☐ **Screen for substantial HIV risk**

- ☐ **Serum creatinine (calculate eGFR)**
  - 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**
  - Perform syndromic or etiological STI testing (depending on local guidelines)
  - Rapid Plasma Reagin test (RPR) for syphilis (if available)

- ☐ **Pregnancy test**
  - 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, gender-based 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

J. 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)**
- Monitor adherence (recall, pill count, etc.)
- 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)**
- 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 and care services. Start suppressive therapy for HIV infection (ART) immediately.

Please adapt this checklist to align with national guidelines on PrEP