

Providing PrEP to Pregnant and Breastfeeding Women: A Training Manual for Health Care Workers

LEARNER GUIDE



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Providing PrEP to Pregnant and Breastfeeding Women: Training Syllabus

INTRODUCTION

The purpose of this course is to help ministries of health, program managers, and providers expand access to high-quality pre-exposure prophylaxis (PrEP) for pregnant and breastfeeding women (PBFW) using a facility-based approach for training, capacity building, and mentorship.

COURSE DESCRIPTION

The course is designed as series of modules and includes a variety of activities for course delivery.

See **Table 1** for a summary of the modules and the estimated completion times for each module.

Table 1. Course Overview & Duration

Module Title	Duration
Module 1: Why Offer PrEP to Pregnant and Breastfeeding Women?	1.5 hours
Module 2: Before Starting PrEP	30 minutes
Module 3: Counseling on Use of PrEP for Pregnant and Breastfeeding Women	1 hour
Module 4: Laboratory Testing, Documentation, and Scheduling Follow-Up	1 hour
Module 5: After Starting PrEP	2 hours
Module 6: PrEP Use in Special Situations	1 hour
Module 7: Additional Health Services	30 minutes
Module 8: Intimate Partner Violence (IPV)	45 minutes
Module 9: Active Safety Surveillance	30 minutes
Module 10: Key Messages	1.5 hours

The training may take place over 1-2 days, or as a series of individual or paired modules over a series of days.

LEARNING OBJECTIVES

At the end of this session, learners will be able to state:

- The rationale for offering PrEP to PBFW
- Key actions to take before starting PrEP
- Counseling messages and techniques for PBFW
- How to address common PrEP side effects and monitor continued safety of PrEP
- Important additional services for PBFW taking PrEP

TEACHING AND LEARNING METHODS

Teaching/learning methods will include small group work, discussions, and case studies. Lecture will be used minimally; the course aims to support capacity building in the clinical

area.

If this course is delivered remotely, the facilitator can use the features in Zoom or other tools to assign small group activities or can change the small group and pair activities to large group discussion.

Day 1:

Module Title	Duration
Module 1: Why Offer PrEP to Pregnant and Breastfeeding Women?	1.5 hours
Module 2: Before Starting PrEP	30 minutes
Module 3: PrEP Use Counseling for Pregnant and Breastfeeding Women	1 hour
Module 4: Laboratory Testing, Documentation, and Scheduling Follow-Up	1 hour

Day 2:

Module Title	Duration
Module 5: After Starting PrEP	2 hours
Module 6: PrEP Use in Special Situations	1 hour
Module 7: Additional Health Services	30 minutes
Module 8: Intimate Partner Violence (IPV)	45 minutes
Module 9: Active Safety Surveillance	30 minutes
Module 10: Key Messages	1.5 hours

Module 1: Why Offer PrEP to Pregnant and Breastfeeding Women?

Module Objective

By the end of the module, learners will be able to state:

- The rationale for offering pre-exposure prophylaxis (PrEP) to pregnant and breastfeeding women (PBFW)

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
WHO Recommends PrEP!	The WHO recommends to provision PrEP to pregnant and breastfeeding women who are at continuing substantial risk of HIV infection.		WHO recommendations on antenatal care
Background	Reflection questions	Individual Reflection	Handout 1-1
PrEP Safety	PrEP appears safe for pregnant and breastfeeding women.	Group Discussion: Why might women be reluctant to begin PrEP?	
PrEP Medications	Lamivudine (3TC) is part of some PrEP regimens and also has a good safety record.	Small Group Activity	Handout 1-2

Handout 1-1: WHO Recommends PrEP!

WHO supports provision of PrEP to pregnant and breastfeeding women who are at continuing substantial risk of acquiring HIV.

“Oral pre-exposure prophylaxis (PrEP) containing tenofovir disoproxil fumarate (TDF) should be offered as an additional prevention choice for pregnant women at substantial risk of HIV infection as part of combination prevention approaches.”

Reflection Questions

- When do you think women are at higher risk of HIV acquisition and of transmitting HIV to their infants?
- How does the information presented differ from what you initially thought?

Handout 1-2: PrEP regimens

Lamivudine (3TC) is part of some PrEP regimens and also has good safety record.

Lamivudine (3TC) is a medication (nucleoside analog) used for HIV treatment, in combination with other antiretroviral drugs.

Studies have not shown adverse effects in infants exposed in utero:

- 3TC exposure during pregnancy was not associated with adverse outcomes in **growth, hearing, language, neurodevelopment, metabolic, hematologic/clinical chemistry, or blood lactate**
- Fewer spontaneous abortions and preterm births with use of lamivudine-containing regimens in the context of HIV treatment
- It is important to note that hepatitis B virus flare may occur if 3TC is stopped in a person who has acquired HBV

PrEP use has been shown to be generally safe across a range of different countries and populations, based on data gathered so far.

The medications used in PrEP have **no known drug interactions** with the medications most commonly prescribed during pregnancy or the postnatal period.

Discussion Questions

- Identify common medications that women may be taking.
- Brainstorm how to respond to concerns about starting PrEP in addition to taking those medications.

Module 2: Before Starting PrEP

Module Objective

By the end of the module, learners will be able to identify good candidates for PrEP.

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
Topic	Topic Instruction/Overview		Materials by topic
Who is a good candidate for PrEP?	In settings of high HIV incidence, all HIV-negative pregnant and breastfeeding woman should be considered candidates for PrEP.	Group Discussion: How does this differ from what you may have previously believed or from what you hear from others? Group Discussion: work in small groups to list the range of clients for whom you should consider PrEP.	WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection
Contraindications	Review the PPT for the contraindications.		PPT Review.

Module 3: Counseling on Use of PrEP for Pregnant and Breastfeeding Women

Module Objective

By the end of the module, learners will be able to state:

- Counseling messages and techniques for PBFW

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
Importance	Counseling and communication are important in maternity care.		
Contexts	PrEP may be introduced in a variety of different community and facility-based contexts.		
Additional Counseling Messages	Counseling messages in addition to standard PrEP counseling messages for pregnant and breastfeeding women are important	Role Play	Handout 3-1
Case Study	Case Study and Group Discussion	Case Study: Review the Case Study in your group and be prepared to report your answers to one of the discussion questions.	Handout 3-2

Handout 3-1: Key Additional Counseling Messages

1. In general, women are at higher risk for acquiring HIV when they are pregnant or breastfeeding compared to times when they are not.
2. For most women who live in areas where HIV is common, the potential benefits of PrEP for mothers outweigh potential risks. Taking PrEP is generally safer for you and your baby, compared to acquiring HIV.
3. There is no evidence that PrEP increases the chance of birth defects, miscarriage, or other complications during pregnancy, birth, or after the birth.
4. PrEP does not have any known negative interactions with the medications and supplements most commonly prescribed for women in pregnancy and during breastfeeding.
5. The amount of PrEP drug that may pass to the baby during pregnancy and breastfeeding is very small and has not been shown to cause any serious health problems for babies.
6. PrEP use during pregnancy and breastfeeding has not been shown to cause your baby to be too big or too small.
7. PrEP has not been shown to have any impact on your ability to become pregnant in the future.
8. Some people taking PrEP experience side effects, but they are generally mild, not dangerous, and resolve quickly.
9. Please keep your PrEP supply in a safe place where children cannot reach it.
10. Exclusive breastfeeding for the first six months of life is the recommended way of feeding infants, followed by continued breastfeeding with appropriate complementary foods for up to two years or beyond.
11. PrEP has not been shown to affect a mother's milk production or the taste or quality of breast milk.
12. If you are experiencing violence in your life, you can tell me about it and we will talk about ways to help you and your baby stay safe.

Role Play

- Work in pairs to role play how you would deliver these messages to pregnant and breastfeeding women.
- One partner plays the role of the provider and one the women.
 - The "provider" should provide counseling messages and the "women" should identify concerns to be addressed through counseling messages.
- Then, switch roles.

Handout 3-2: Case Study

Case Study

Aaliyah is pregnant with her third child and comes to your clinic. During the exam and discussion, she mentions that her sister, who lives close by, has HIV. Aaliyah is concerned about her personal risk and is unsure about her partner's HIV status and ongoing risk. Aaliyah tested negative for HIV and you recommend that she start PrEP and continue throughout her pregnancy and while breastfeeding.

Aaliyah immediately closes up and does not want to discuss it. She says that she is already taking enough medication with her iron and folic acid tablets and she worries about her partner finding PrEP in their home. She doesn't want to put her unborn baby at risk and is afraid the side effects will make it challenging to take care of her other children.

Discussion Questions

- What are the key messages you should tell Aaliyah about taking PrEP with other medications?
- What should you tell Aaliyah about the safety of PrEP while pregnant?
- How can you address her concerns about putting her unborn baby at risk?
- How would you respond to her concerns about side effects and not being able to care for her other children?
- What concerns might Aaliyah have that she didn't feel comfortable sharing with you (e.g., potential concerns about intimate partner violence [IPV])?
 - What additional questions can you ask to uncover those concerns?
 - How would you address those concerns?

Module 4: Laboratory Testing, Documentation, and Scheduling Follow-Up

Module Objective

By the end of the module, learners will be able to state:

- Key actions to take before starting PrEP

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
Rule Out Infection	It is important to rule out HIV infection before starting treatment.	Group Discussion: How should you discuss/approach this with a woman who is reluctant to get tested?	
Testing Before Starting PrEP	Testing must be performed prior to starting PrEP		
Documenting Clinical Care	Requirements for documenting care in clinical records.		
Scheduling Follow-Up	Requirement to schedule follow-up.	Work in pairs to develop a list of questions to ask and techniques to use in order to optimize chances for PrEP continuation.	Handout 4-1

Handout 4-1: Case Study

Pair Activity

Develop a list of questions to ask and techniques to use to optimize chances for PrEP continuation.

Module 5: After Starting PrEP

Module Objective

By the end of the module, learners will be able to state:

- How to address common PrEP side effects and monitor continued safety of PrEP

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
Integration of PrEP Care into ANC and PNC	The provider should provide continuing care.	Group Discussion: How do you provide continuing care? How do you work with other providers to provide continuing care?	
Managing PrEP Side Effects	Ways to identify and manage side effects.	Small Group Activity	Handout 5-1
Deciding Whether to Pause or Stop PrEP for PBFW	Before deciding to pause or stop PrEP use, it is important to consider whether or not there is reasonable suspicion that a complaint was caused by PrEP use.	Group Discussion	Handout 5-2
		Reference Table	Handout 5-3
Kidney Function	Where capacity allows, serum creatinine is recommended to monitor kidney function for PrEP users who are pregnant, with a repeat test performed every three months.		
Stopping PrEP Due to HIV Seroconversion	It is possible that a pregnant or breastfeeding client who has been prescribed PrEP will experience HIV seroconversion. In the event that this occurs, it's important for the health provider to take several actions		
Evaluating Potential Problems in Breastfeeding Infants	PrEP use in mothers has not been associated with significant safety concerns among their breastfeeding infants.		
Determining the Best	There is no single best place to manage PrEP use for PBFW that are transitioning from one	Group Discussion	Handout 5-4

Location for Clients	care setting to another, or who may be eligible to receive services from multiple settings at once.		
Helping Clients Change PrEP Delivery Settings	Clients should be supported to continue PrEP as they transition between different clinical contexts and service delivery settings.	Individual Activity	Handout 5-5
Case Study		Case Study: Read the case study. Discuss the case study questions with your group.	Handout 5-6

Handout 5-1: Ways to Identify and Manage Side Effects

PrEP use is generally well-tolerated outside of and during pregnancy and the postnatal periods. However, some side effects are possible.

PrEP providers should address client concerns with a thoughtful and systematic approach that includes:

- History-taking
- Targeted physical examination
- Diagnosis
- Suggested measures to alleviate side effects
- Appropriate counseling
- Plan for future evaluation

Discussion Questions

- What additional questions would you ask someone exhibiting your assigned signs/symptoms?
- How could you determine if they are side effects or something else?

Handout 5-2: Deciding to Pause or Stop PrEP Use

Any provider decision to discontinue PrEP based on side effects should be discussed with the client, including consideration of potential risks, benefits, and alternatives.

Where capacity allows, **serum creatinine** is recommended to monitor kidney function for PrEP users who are pregnant, with a repeat test performed every three months.

Before deciding to pause or stop PrEP use, it is important to consider whether or not there is reasonable suspicion that a complaint was caused by PrEP use.

Clinicians can consider the following **guiding questions**:

- What is the sign or symptom noted by the client?
- Did the problem begin soon after the start of PrEP use?
- If the client has already stopped PrEP use, has there been any improvement after stopping?
- Did the issue come back if the participant stopped and restarted PrEP?
- Is the problem something that has been seen before in other people using PrEP?
- Is it plausible (does it make sense) that PrEP could have caused the problem?
- Is there any other explanation?

Discussion Questions

- What are some questions you can ask to determine if a sign/symptom is caused by PrEP use?
- What are some reasons you might ask someone to stop PrEP use for PBFW?

Handout 5-3: Reference Table - Evaluation of possible PrEP side effects during pregnancy and breastfeeding

Sign or symptom	Possible expected finding in pregnancy	Possible expected finding in postnatal period	Expected with some (not all) family planning methods	May be related to PrEP	May be related to another condition
Back pain	X	X			Yes, like back injury
Constipation	X				Yes, like iron pills
Nausea or vomiting	X		X	X	Yes, like foodborne illness
Diarrhea				X	Yes, like foodborne illness
Mild abdominal pain or cramping	X (especially round ligament pain or heartburn)	X (uterine involution or post-cesarean pain)	X	X	Yes, like preterm contractions, foodborne illness
Vaginal discharge	X	X (if consistent with normal lochia)	X		Yes, like vaginitis or sexually transmitted infection
Frequent urination	X				Yes, like urinary tract infection
Dizziness	X		X	X	Yes, like anemia, dehydration
Headache	X		X	X	Yes, like pre-eclampsia (serious complication of blood pressure)
Fatigue	X	X	X	X	Yes, like anemia or depression, other possibilities
Sleep issues	X	X		X	Yes, like anxiety or depression
Abnormal kidney function tests (e.g., serum creatinine)				X	Yes, like pre-eclampsia
Abnormal liver function tests (e.g., AST, ALT)				X	Yes, like HELLP syndrome (serious complication of pre-eclampsia) or hepatitis (liver infection)

Handout 5-4: Determining the Best Location for Clients

There is no single best place to manage PrEP use for PBFW that are transitioning from one care setting to another, or who may be eligible to receive services from multiple settings at once.

Consider:

- Client needs and preferences
- Capacity of service delivery of each setting

Discussion Questions

- What are some things you currently consider when determining the best location for treatment for clients with any health issue?
- What additional things might you need to consider for managing PrEP in pregnant women?
- What additional services might these women need?

Handout 5-5: Helping Clients Change PrEP Delivery Settings

Clients should be **supported to continue PrEP** as they transition between different clinical contexts and service delivery settings.

Examples of transitions may include:

- Safer conception or FP to ANC
- KP or AGYW to ANC
- ANC to PNC
- ANC to FP
- PNC to FP
- PNC to another facility or provider

Individual Activity

Make a list of things you can do specific to your location and partner organizations to help clients transition between clinical contexts.

Handout 5-6: Case Study

Case Study

Jamila is breastfeeding her 2-month old daughter and comes to your clinic for her postnatal care. She has been taking PrEP since the beginning of her pregnancy and has continued while breastfeeding. She comes to see you and complains of some back and stomach pain. She has had these symptoms for a couple of weeks, but it is difficult to travel to the clinic given that she has an infant as well as other children at home and unreliable transportation.

You know of a small clinic closer to her home that could help manage her PrEP administration while you continue to see her through her for postnatal care. You'd like to transfer her routine PrEP care to this other clinic and ensure that she receives ongoing family planning counseling and care.

Discussion Questions

- During your exam, what questions should you ask Jamila?
- If you decide to transfer her PrEP care to another clinic, what information should you share and capabilities should you confirm before making the transfer?
- How can you ensure communication between both clinics?
- How will you address her family planning needs today and ensure that also remains part of her ongoing care plan?
- What will be the biggest challenges in transferring care? How will you overcome those challenges?

Module 6: PrEP Use in Special Situations

Module Objective

By the end of the module, learners will be able to state:

- How to manage PrEP among women with hypertensive disorders of pregnancy or with Hepatitis B infection during pregnancy

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
PrEP Use in Women with Hypertensive Disorders	Strategies for avoiding starting PrEP in clients with evidence of renal function or conditions that may impair renal function. WHO's Classification Framework for Hypertensive Disorders and the categories, diagnostic criteria, and suggested management.	Group Discussion: What types of clinical tests or assessments can you perform to assess hypertensive disorders?	Managing Complications in Pregnancy and Childbirth
Hepatitis B Infection During Pregnancy	It is important to test for HBV infection before prescribing PrEP.		

Module 7: Additional Health Services

Module Objective

By the end of the module, learners will be able to state:

- Important additional services for PBFW taking PrEP

Information for Facilitators

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
Additional HIV Prevention and Family Planning Services	Several services should be advised in addition to PrEP		
Treatment of STIs in Pregnancy	It is important to test for and identify possible problems caused by STIs in pregnancy.	Group Discussion	Handout 7-1

Handout 7-1: Determining the Best Location for Clients

STIs during pregnancy can cause different kinds of problems:

- Premature labor (labor before 37 weeks or pregnancy)
Early birth is the number one cause of infant death and can lead to long-term developmental and health problems in children
- Infection in the fetus, leading to blindness, deafness, severe anemia, or death
- Infection in the newborn and in the uterus after birth

Discussion Questions

- Identify ways you provide or refer clients for additional services.
- Identify ways you can overcome resistance to discussing STIs and related testing/services.

Module 8: Intimate Partner Violence (IPV)

Module Objective

By the end of the module, learners will be able to state:

- Important additional services related to IPV for PBFW taking PrEP

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
Screening for Intimate Partner Violence	It is important to screen for IPV.		
Clinical and Routine Enquiry for IPV	Differences between clinical and routine enquiry for violence. Minimum requirements for conducting routine enquiry.	Pair Activity	WHO LIVES approach Handout 8-1
First-Line Support	Review the first-line support goals.	Group Discussion	Handout 8-2

Handout 8-1: Clinical and Routine Enquiry for IPV

All PrEP sites should conduct routine enquiry for IPV with all clients.

- **Clinical Enquiry for IPV:** When a clinician asks only clients she/he suspects are experiencing IPV or fears IPV
- **Routine Enquiry for IPV:** When a clinician asks all clients who present for specific services about experiencing IPV or fears IPV

Discussion Questions

- Does your location provide clinical or routine enquiry for violence?
- What are the benefits of providing one or the other?
- What are some common challenges you face in providing clinical and routine enquiry?
 - How do you overcome these challenges?

Handout 8-2: Providing First-Line Support

All community-based programs delivery HIV or GBV prevention activities must ensure that **facilitators are trained** so they can respond appropriately to someone who discloses violence.

First-line support goals include:

- **Listen** closely with empathy, not judging
- **Inquire** about the client's needs and concerns – assess and respond to the survivor's needs and concerns
- **Validate** – show that you believe and understand the survivor
- **Enhance safety** – conduct a safety assessment and safety planning to reduce the risk of further harm
- **Support** – help the survivor connect to services, social support

Discussion Questions

- Discuss examples of ways your location provides first-line support.

Module 9: Active Safety Surveillance

Module Objective

By the end of the module, learners will be able to state:

- Importance of active surveillance of maternal, newborn, and child outcomes
- Available tools for tracking health outcomes of women, newborns, and infants and young children exposed to antiretroviral (ARV) drugs

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
Surveillance for adverse outcomes	WHO recommendation for ongoing and active safety surveillance		
Surveillance Tools	Sample Data Collection / Case Report Form Sample register page		Handouts provided by facilitator: Case Report Form Sample Register

Module 10: Key Messages

Instructions

The table below outlines the content area, questions, and activities you will complete during the module. Your packet contains the materials you will need for the activities and discussions.

Content	Topic Overview	Questions or Activity	Materials
Key Messages	Key messages from the training.		Handout 10-1

Handout 10-1: Key Messages

Global guidance and evidence support PrEP use by PBFW

- PBFW are at higher risk for getting HIV
- PrEP use for PBFW is generally safe and well tolerated

PrEP providers should feel comfortable

- Providing key counseling messages
- Monitoring continued safety of PrEP use
- Managing common PrEP side effects
- Ensuring that clients receive other key services, e.g., family planning and IPV

Reflection Questions

- Did you identify additional key messages or take-aways?
- What action items they have taken from the training?