

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

LEARNER GUIDE

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Introduction

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

Course description and format

The course is designed as a series of modules and includes a variety of activities for course delivery. See **Table 1 below** for a summary of the modules and the estimated completion times for each module. For maximum flexibility, this course may be offered in a single two-day training or multiple sessions spread across a series of days. Suggested times are approximate and can be modified as needed.

The teaching/learning methods included in this course include didactic instruction, small group work, discussions, and case studies. Lecture should be used as minimally as possible. If this course is delivered using a hybrid approach¹, 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.

The activities listed throughout the guide are suggested activities only. The context, experience level of participants, and identified needs should be considered in adapting activities to best fit the situation.

Facilitators will need to make sure Learner Guides are available/printed for all participants prior to the beginning of the training. Case studies and learning questions for discussions are included in the Learner Guide.

Table 1. Course Overview & Duration

Day 1:

Module Title	Duration
Module 1: Use of oral PrEP for PBFP	1 hour 15 min.
Module 2: Before prescribing oral PrEP	30 min.
Module 3: Counseling on use of oral PrEP for PBFP	1 hour
Module 4: Laboratory testing, documentation, and scheduling follow-up	1 hour 5 min.

Day 2:

Module Title	Duration
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¹ Hybrid training refers to combined in-person and virtual or online delivery of the training. Some facilitators may opt for a fully in-person training while others may prefer a hybrid approach. The implementation guide included in the training package expands on delivering the course using a hybrid approach.

Module 5: Supporting continued use of oral PrEP	1 hour 35 min.
Module 6: Oral PrEP use in special situations	50 min.
Module 7: Additional health services and intimate partner violence (IPV)	1 hour 5 min.
Module 8: Active safety surveillance	30 min.
Module 9: Key messages	55 min.

Learning Objectives

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

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

Module 1: Use of oral PrEP for PBFP

Module Objective

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

- The rationale for offering oral PrEP to PBFP

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 oral PrEP	The WHO recommends the provision of oral PrEP to PBFP who are at continuing substantial risk of HIV infection.		<u>WHO recommendations on antenatal care</u>
Background	Reflection questions	Individual Reflection	Section 1-1
Oral PrEP safety	Oral PrEP appears safe for PBFP.	Group Discussion: Why might PBFP be reluctant to begin oral PrEP?	

Oral PrEP medications	Lamivudine (3TC) is part of some oral PrEP regimens and also has a good safety record.	Small Group Activity	Section 1-2
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Section 1-1: WHO recommends oral PrEP

WHO supports the provision of oral PrEP to pregnant and breastfeeding people 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 people 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?

Section 1-2: Oral PrEP regimens

Lamivudine (3TC) is part of some oral 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 (ARVs).

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. Most people do not get hepatitis flares. If flares occur, they are mostly asymptomatic and resolve spontaneously.

Oral 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 oral PrEP have no known drug interactions with the medications most commonly prescribed during pregnancy or the postnatal period.

Discussion Questions

- Identify common medications that PBFP may be taking.
- Brainstorm how to respond to concerns about prescribing oral PrEP in addition to taking those medications.

Module 2: Before prescribing oral PrEP

Module Objective

By the end of the module, learners will be able to identify good candidates for oral 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
Who is a good candidate for oral PrEP?	In settings of high HIV incidence, all HIV-negative pregnant and breastfeeding people should be considered candidates for oral 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 oral PrEP.	<u>WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection</u>
Contraindications	Review the PPT for the contraindications.		PPT Review

Module 3: Counseling on use of oral PrEP for PBFP

Module Objective

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

- Counseling messages and techniques for PBFP

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	Oral PrEP may be introduced in a variety of different community and facility-based contexts.		
Additional counseling messages	Counseling messages in addition to standard oral PrEP counseling messages for PBFP are important.	Role Play	Section 3-1
Case Study 1	Case Study 1 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.	Section 3-2

Section 3-1: Key additional counseling messages

1. In general, PBFP are at higher risk for acquiring HIV when they are pregnant or breastfeeding compared to times when they are not.
2. For most PBFP who live in areas where HIV is common, the potential benefits of oral PrEP for mothers outweigh potential risks. Taking oral PrEP is generally safer for you and your baby, compared to acquiring HIV.
3. There is no evidence that oral PrEP increases the chance of birth defects, miscarriage, or other complications during pregnancy, birth, or after the birth.
4. Oral PrEP does not have any known negative interactions with the medications and supplements most commonly prescribed for PBFP in pregnancy and during breastfeeding.
5. The amount of oral 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. Oral PrEP use during pregnancy and breastfeeding has not been shown to cause your baby to be too big or too small.
7. Oral PrEP has not been shown to have any impact on your ability to become pregnant in the future.
8. Some people taking oral PrEP experience side effects, but they are generally mild, not dangerous, and resolve quickly.
9. Please keep your oral 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. Oral 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 clients.
- One partner plays the role of the provider and one the client.
- The “provider” should provide counseling messages and the “client” should identify concerns to be addressed through counseling messages.
- Then, switch roles.

Section 3–2: Case Study 1

Case Study 1: Rose

Rose 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. Rose is concerned about her personal risk and is unsure about her partner’s HIV status and ongoing risk. Rose tested negative for HIV and you recommend that she start oral PrEP and continue throughout her pregnancy and while breastfeeding.

Rose 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 oral 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 Rose about taking oral PrEP with other medications?
- What should you tell Rose about the safety of oral 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 Rose 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 oral 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
Testing before starting oral PrEP	Testing must be performed prior to starting oral PrEP.		None
Rule out HIV infection	It is important to rule out HIV infection before starting treatment.	Group Discussion: How should you discuss/approach this with a client who is reluctant to get tested?	None
Documenting clinical care	Requirements for documenting care in clinical records.		None
Scheduling follow-up	Requirements 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 oral PrEP continuation.	Section 4-1
Determining the best location for clients	There is no single best place to manage oral PrEP use for PBFP that are transitioning from one care setting to another, or who may be eligible to receive services from multiple settings at once.	Group Discussion	Section 4-2
Helping clients change oral PrEP delivery settings	Clients should be supported to continue oral PrEP as they transition between different clinical contexts and service delivery settings.	Individual Activity	Section 4-3

Section 4-1: Pair Activity

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

Section 4-2: Determining the best location for clients

There is no single best place to manage oral PrEP use for PBFP 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 oral PrEP in PBFP?
- What additional services might these clients need?

Section 4-3: Helping clients change oral PrEP delivery settings

Clients should be supported to continue oral 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.

Module 5: Supporting continued use of oral PrEP

Module Objective

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

- How to address common oral PrEP side effects and monitor continued safety of oral 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 oral 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?	None
Managing oral PrEP side effects	Ways to identify and manage side effects.	Small Group Activity	Section 5-1
Kidney Function	Where capacity allows, serum creatinine is recommended to monitor kidney function for oral PrEP users who are pregnant, with a repeat test performed every three months.		None
Deciding whether to pause or stop oral PrEP for PBFP	Before deciding to pause or stop oral PrEP use, it is important to consider whether or not there is reasonable suspicion that a complaint was caused by oral PrEP use.	Group Discussion	Section 5-2
		Reference Table	Section 5-3
Stopping oral PrEP due to HIV seroconversion	It is possible that a pregnant or breastfeeding client who has been prescribed oral PrEP will experience HIV seroconversion. In the event that this occurs, it's important for the health provider to take several actions.		None
Evaluating potential problems in breastfeeding infants	Oral PrEP use in mothers has not been associated with significant safety concerns among their breastfeeding infants.		None
Case Study 2		Case Study: Read the case study. Discuss the	Section 5-4

		case study questions with your group.	
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Section 5-1: Ways to identify and manage side effects

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

Oral 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?

Section 5–2: Deciding to pause or stop oral PrEP use

Any provider decision to discontinue oral 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 oral PrEP users who are pregnant, with a repeat test performed every three months. Before deciding to pause or stop oral PrEP use, it is important to consider whether or not there is reasonable suspicion that a complaint was caused by oral 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 oral PrEP use?
- If the client has already stopped oral PrEP use, has there been any improvement after stopping?
- Did the issue come back if the participant stopped and restarted oral PrEP?
- Is the problem something that has been seen before in other people using oral PrEP?
- Is it plausible (does it make sense) that oral 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 oral PrEP use?
- What are some reasons you might ask someone to stop oral PrEP use for PBFP?

Section 5–3: Reference Table – Evaluation of possible oral 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)

Section 5–4: Case Study 2

Case Study 2: Jamila

Jamila is breastfeeding her two-month-old daughter and comes to your clinic for her postnatal care. She has been taking oral 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 oral PrEP administration while you continue to see her through for postnatal care. You'd like to transfer her routine oral 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 oral 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: Oral PrEP use in special situations

Module Objective

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

- How to manage oral 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
Oral PrEP use in clients with hypertensive disorders	Strategies for avoiding starting oral 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 virus (HBV) infection during pregnancy	It is important to test for HBV infection before prescribing oral PrEP.		

Module 7: Additional health services and intimate partner violence (IPV)

Module Objective

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

- Important additional services for PBFP taking oral 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
Additional HIV prevention and family planning services	Several services should be advised in addition to oral PrEP		
Treatment of Sexually Transmitted Infections (STIs) in pregnancy	It is important to test for and identify possible problems caused by STIs in pregnancy.	Group Discussion	Section 7-1
Screening for Intimate Partner Violence (IPV)	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 Guidance: Standard Operating Procedures for Addressing Partner Relationships and Gender-Based Violence in Pre-Exposure Prophylaxis (PrEP) Services – PrEPWatch * Section 7-2
First-line support	Review the first-line support goals.	Group Discussion	Section 7-3

**Additional guidance is available from a Standard Operating Procedure developed by the CHARISMA project. This guidance is intended to be utilized by programs providing PrEP so that support staff can identify clients who are experiencing IPV and provide appropriate violence response services. It also provides procedures and counseling messages to help clients decide whether to talk to their partner(s) about their PrEP use and strategies for using PrEP with or without their partner's knowledge. The PrEP Job Aid for Discussing Partner Relationships was developed to support the implementation of this SOP guidance. It can be found at <https://www.prepwatch.org/>.*

Section 7-1: Treatment of STIs in pregnancy

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

Section 7-2: Clinical and Routine Enquiry for IPV

All PrEP service delivery 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 fearing IPV
- **Routine Enquiry for IPV:** When a clinician asks all clients who present for specific services about experiencing IPV or fearing 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?

Section 7-3: Providing First-Line Support

All community-based programs delivering 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 8: Active safety surveillance

Module Objectives

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 clients, newborns, 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 9: Key messages

Module Objectives

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

- Importance of HIV prevention during pregnancy and the post-natal period
- General competencies for providers who work with PBFP clients

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.		Section 9-1

Section 9–1: Key messages

Global guidance and evidence support oral PrEP use by PBFP.

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

Oral PrEP providers should feel comfortable.

- Providing key counseling messages
- Monitoring continued safety of oral PrEP use
- Managing common oral 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 takeaways?
- What action items they have taken from the training?