

# Providing the PrEP Ring to Pregnant and Breastfeeding People: A Training Manual for Health Care Workers

## LEARNER GUIDE

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# Table of Contents

Introduction.....	3
Module 1: Use of the PrEP ring for PBFP.....	5
Module 2: Before prescribing the PrEP ring.....	7
Module 3: Counseling on use of the PrEP ring for PBFP.....	8
Module 4: Laboratory testing, documentation, and scheduling follow-up.....	11
Module 5: Supporting continued use of the PrEP ring.....	12
Module 6: Additional health services and intimate partner violence.....	17
Module 7: Active safety surveillance.....	20
Module 8: Key messages.....	21

# Providing the PrEP Ring to Pregnant and Breastfeeding People: Training Syllabus

## Introduction

The purpose of this course is to help ministries of health, program managers, and providers expand access to the dapivirine vaginal ring (PrEP ring) for Pregnant and Breastfeeding People (PBFP) using a facility-based or hybrid approach for training, capacity building, and mentorship of healthcare workers.

## Course description and format

The course is designed as a series of modules and includes various 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 approach<sup>1</sup>, 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 facilitator’s 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 must ensure Learner Guides are available/printed for all participants before training begins. 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 the PrEP ring for PBFP	1 hour 25 min.
Module 2: Before prescribing the PrEP ring	1 hour
Module 3: Counseling on the use of the PrEP ring for PBFP	1 hour 25 min.
Module 4: Laboratory testing, documentation, and scheduling follow-up	1 hour 5 min.

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<sup>1</sup> 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.

## Day 2:

Module Title	Duration
Module 5: Supporting continued use of the PrEP ring	1 hour 25 min.
Module 6: Additional health services and intimate partner violence (IPV)	1 hour 10 min.
Module 7: Active safety surveillance	30 min.
Module 8: Key messages	55 min.

## Learning Objectives

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

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

# Module 1: Use of the PrEP ring for PBFP

## Module Objective

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

- The rationale for prescribing the dapivirine ring (PrEP ring) 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 the PrEP ring	The WHO recommends the provision of the PrEP ring to PBFP who are at continuing substantial risk of HIV infection.		<a href="#">WHO recommendations on antenatal care</a>
Background	Reflection questions	Individual reflection	Section 1-1
PrEP ring safety	The PrEP ring appears safe for PBFP.	Group Discussion: Why might PBFP be reluctant to use the PrEP ring?	
PrEP ring medications	Dapivirine is part of the PrEP ring regimen and has a good safety record.	Small Group Activity	Section 1-2

## Section 1-1: WHO Recommends the PrEP ring!

**WHO supports** provision of the PrEP ring to pregnant and breastfeeding people who are at continuing substantial risk of acquiring HIV.

“The dapivirine ring (DVR) containing 25 mg of an antiretroviral drug 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 PBFP 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: The PrEP ring regimens

The flexible silicone material containing 25 mg of an antiretroviral (AVR) drug is part of the PrEP ring regimen and has good safety record.

**Dapivirine** 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:

- Dapivirine 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 dapivirine-containing regimens in the context of HIV treatment.

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

The medications used in the PrEP ring 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 starting the PrEP ring in addition to taking those medications.

# Module 2: Before prescribing the PrEP ring

## Module Objective

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

## 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 the PrEP ring?	In settings of high HIV incidence, all HIV-negative pregnant and breastfeeding people should be considered candidates for the PrEP ring.	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 ring.	
Contraindications	Review the PPT for the contraindications.		PPT Review

# Module 3: Counseling on use of the PrEP ring 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
Important components of person-centered maternity care	Counseling and communication are important in maternity care.		
Discussing PrEP ring in different care contexts	The PrEP ring may be introduced in a variety of different community and facility-based contexts.		
Additional counseling messages	Counseling messages beyond standard PrEP ring 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 the PrEP ring outweigh potential risks. Using the PrEP ring is generally safer for you and your baby, compared to acquiring HIV.
3. There is no evidence that the PrEP ring increases the chance of birth defects, miscarriage, or other complications during pregnancy, birth, or after the birth.
4. The PrEP ring does not have any known negative interactions with the medications and supplements most commonly prescribed for clients in pregnancy and during breastfeeding.
5. The amount of the PrEP ring 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. The PrEP ring use during pregnancy and breastfeeding has not been shown to cause your baby to be too big or too small.
7. The PrEP ring has not been shown to have any impact on your ability to become pregnant in the future.
8. Some people using the PrEP ring experience side effects, but they are generally mild, not dangerous, and resolve quickly.
9. Please keep your PrEP ring 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. The PrEP ring 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 PBFP.
- 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

### 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 pills with her iron and folic acid tablets, and she worries about her partner finding the oral PrEP pills in their home. You suggest the option of PrEP ring, however, she is hesitant. She is afraid to insert the ring as she does not 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 using the PrEP ring with other medications?
- What should you tell Rose about the safety of the PrEP ring 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 prescribing the PrEP ring

## 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 HIV infection	It is important to rule out HIV infection before prescribing the PrEP ring.	<b>Group Discussion:</b> How should you discuss/approach this with a client who is reluctant to get tested?	
Testing before prescribing the PrEP ring	Testing must be performed prior to prescribing the PrEP ring		
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 ring continuation.	Section 4-1

## Section 4-1: Pair Activity

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

# Module 5: Supporting continued use of the PrEP ring

## Module Objective

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

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

## 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 the PrEP ring into ANC (Antenatal Care) and PNC (Postnatal Care)	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 ring side effects	Ways to identify and manage side effects.	Small Group Activity	Section 5-1
Deciding Whether to Pause or Stop the PrEP ring for PBFP	Before deciding to pause or stop the PrEP ring use, it is important to consider whether there is reasonable suspicion that a complaint was caused by PrEP ring use.	Group Discussion	Section 5-2
		Reference Table	Section 5-3
Stopping the PrEP ring due to HIV seroconversion	It is possible that a pregnant or breastfeeding client who has been prescribed the PrEP ring will experience HIV seroconversion.  If this occurs, it is important for the health provider to take several actions.		
Evaluating potential problems in breastfeeding infants	PrEP ring use in mothers has not been associated with significant safety concerns among their breastfeeding infants.		
Determining the best location for clients	There is no single best place to manage PrEP ring 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 5-4
Helping clients change PrEP ring delivery settings	Clients should be supported to continue the PrEP ring as they transition between different clinical contexts and service delivery settings.	Individual Activity	Section 5-5
Case Study 2		Case Study 2: Read the case study. Discuss the case study questions with your group.	Section 5-6

## Section 5-1: Ways to identify and manage side effects

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

PrEP ring 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 PrEP ring use

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

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

## Section 5-3: Reference Table – Evaluation of possible PrEP ring 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 ring use	May be related to another condition
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	X	X	X	Yes, like urinary tract infection
Vulvar itching				X	Candidiasis
Pelvic and lower abdominal pain	X			X	Preterm contractions, foodborne illness
Sleep issues	X	X		X	Yes, like anxiety or depression
Abnormal kidney function tests (e.g., serum creatinine)				X	Yes, like pre-eclampsia

## Section 5-4: Determining the best location for clients

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

## Section 5-5: Helping clients change PrEP ring delivery settings

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

Examples of transitions may include:

- Safer conception or FP (Family Planning) to ANC
- KP (Key Populations) or AGYW (Adolescent Girls and Young Women) 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.

## Section 5–6: Case Study

### Case Study 2: Jamila

Jamila is breastfeeding her two-month-old daughter and comes to your clinic for her postnatal care. She has been using the PrEP ring 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 ring administration while you continue to see her through her for postnatal care. You would 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 ring 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 it 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: Additional health services and intimate partner violence

## Module Objective

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

- Important additional services for PBFP prescribing the PrEP ring.

## 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 the PrEP ring		PPT
Treatment of STIs (Sexually Transmitted Infections) in pregnancy	It is important to test for and identify potential problems caused by STIs in pregnancy.	Group Discussion	Section 6-1
Hepatitis B Virus (HBV) infection during pregnancy	PrEP services are an important opportunity for HBV screening.		
Screening for intimate partner violence (IPV)	It is important to screen for IPV as IP vis associated with higher likelihood of HIV acquisition.		
Clinical and routine enquiry for IPV screening	Differences between clinical and routine enquiry for violence Minimum requirements for conducting routine enquiry	Pair activity	Section 6-2  WHO LIVES (Listen, Inquire, Validate, Enhance Safety) approach  Guidance: Standard Operating Procedures for Addressing Partner Relationships and Gender-Based Violence in Pre-Exposure Prophylaxis (PrEP) Services – PrEPWatch*

First-line support	Ensuring program facilitators are trained on the WHO LIVES approach.	Review the first-line support goals Group Discussion	Section 6-3 <a href="#">WHO LIVES approach</a>

*\*The CHARISMA project has developed guidance that 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 6-1: Treatment of STIs in pregnancy

STIs during pregnancy can cause a range 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 6-2: 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 6-3: Providing first-line support

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

First-line support goals, which make up the 'WHO LIVES approach,' 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 7: 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 and sample register page		Handouts provided by facilitator: Case Report Form Sample Register

# Module 8: Key Messages

## Module Objective

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 8-1

## Section 8-1: Key Messages

Global guidance and evidence support PrEP ring use by PBFP

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

PrEP ring providers should feel comfortable

- Providing key counseling messages
- Monitoring continued safety of the PrEP ring use
- Managing common PrEP ring 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 have they taken from the training?