# Providing Oral PrEP or the PrEP Ring to Pregnant and Breastfeeding People

TRAINING COURSE POWERPOINT

FEBRUARY 2023

PEPFAR

USAID
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MOSAIC
Maximizing Options to Advance Informed Choice for HIV Prevention

# Introduction

**Purpose**: The purpose of this course is to help Ministries of Health, program managers, and trainers expand access to high-quality oral pre-exposure prophylaxis (PrEP) or the dapivirine vaginal ring (the PrEP ring or ring) for pregnant and breastfeeding people (PBFP) using a facility-based and/or hybrid approach to training, capacity-building, and mentorship.

| Module | Duration |
|---|---|
| Module 1: Use of oral PrEP or the PrEP ring for PBFP | 45 min. |
| Module 2: Before prescribing oral PrEP or the PrEP ring | 45 min. |
| Module 3: Counseling on use of oral PrEP or the PrEP ring for PBFP | 1 hour |
| Module 4: Laboratory testing, documentation, and scheduling follow-up | 45 min. |
| Module 5: Supporting continued use of oral PrEP or the PrEP ring | 1 hour 30 min. |
| Module 6: Oral PrEP use in special situations | 1 hour |
| Module 7: Additional health services and intimate partner violence | 45 min. |
| Module 8: Active safety surveillance | 10 min. |
| Module 9: Key messages | 5 min. |

# At the end of this session…

**Learners will be able to state:**

1. The rationale for offering oral PrEP or the PrEP ring to PBFP
2. Considerations before prescribing oral PrEP or the PrEP ring
3. Counseling messages and techniques for PBFP
4. Common side effects and monitor safety of oral PrEP and the PrEP ring
5. Important additional services for PBFP using oral PrEP or the PrEP ring

# 1

# MODULE 1: USE OF ORAL PrEP OR THE PrEP RING FOR PBFP

# Background

Evidence has shown that the **chances of HIV acquisition are higher during pregnancy and the postnatal period**.

**Due to:**

- Biologic factors
- Social factors
- Behavioral factors

It is more difficult to prevent vertical transmission (also referred to as mother-to-child transmission) when a person acquires HIV during pregnancy or the postnatal period, compared to people who acquire HIV outside of those periods.

*It is important to include these populations in PrEP screening, delivery, and management.*

# The World Health Organization (WHO) recommends oral PrEP and the PrEP ring

**WHO supports** provision of oral PrEP or the dapivirine ring (PrEP ring) to women who are at continuing substantial risk of acquiring HIV.

"Oral pre-exposure prophylaxis or the dapivirine ring (PrEP ring) may be offered as additional prevention choices for women at substantial risk of HIV infection as part of combination prevention approaches."

World Health Organization

SOURCE: WHO recommendations on antenatal care (ANC) for a positive pregnancy experience

# Oral PrEP appears safe for PBFP

## Oral PrEP

- The most common oral PrEP regimen is a tablet containing emtricitabine and tenofovir (FTC/TDF).
- Some countries use TDF + lamivudine (3TC) for oral PrEP regimens. 3TC has a good safety record and is a medication (nucleoside analog) also used for HIV treatment, in combination with other antiretroviral drugs.

- Studies have not shown adverse effects in infants exposed to these medications 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 are associated with use of lamivudine-containing regimens in the context of HIV treatment.
- It is important to note that Hepatitis B virus (HBV) flare may occur if 3TC is stopped in a person who has acquired HBV.
- Oral PrEP is also effective for HIV prevention, if the PBFP client may also be using injection drugs.
- Oral PrEP does not prevent other sexually transmitted infections or pregnancy.

# PrEP ring appears safe for PBFP

**PrEP ring**

- The PrEP ring is made of a flexible silicone material containing 25 mg of an antiretroviral (ARV) drug used only for HIV prevention called dapivirine.
- Dapivirine belongs to a class of ARVs called non-nucleoside reverse transcriptase inhibitors (NNRTI) that reduce the ability of HIV to make more copies of itself inside a healthy cell.
- The PrEP ring is available in one size and is inserted into the vagina. It should remain in place for one month to ensure maximum effectiveness during periods of possible exposure to HIV.
- Clients can insert, remove, and replace the PrEP ring themselves each month, or with the assistance of a health care provider if desired

- The PrEP ring has been studied for prevention of HIV only among those assigned female sex at birth (AFAB) during receptive vaginal sex and does not prevent HIV acquisition through any other mode of transmission.
- The PrEP ring only prevents HIV for the user, not their sexual partner.
- The PrEP ring does not prevent other sexually transmitted infections or pregnancy.
- Studies have not shown adverse effects to infants exposed to the ring in utero.

# Both oral PrEP and the PrEP ring side effects are generally mild

## Oral PrEP Side Effects

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

**1** in **10** oral PrEP users may have mild side effects.

Most oral PrEP clients do not experience significant side effects and most side effects usually resolve within one month.

**Side effects** may include:

- Gastrointestinal symptoms (diarrhea and nausea, decreased appetite, abdominal cramping, and flatulence)
- Dizziness
- Headaches
- Decreased kidney function, though rare, is another potential side effect

*For most users, gastrointestinal symptoms typically resolve within the first few weeks of use. People with hepatitis B who suddenly stop taking oral PrEP may have a worsening of hepatitis symptoms.*

## PrEP Ring Side Effects

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

**Side effects** may include:

- Urinary tract infections
- Vaginal discharge
- Vulvar itching
- Pelvic and lower abdominal pain

**Not everyone experiences side effects. Side effects observed in previous studies usually resolve without the need to remove the ring.*

**Oral PrEP is systemic while the PrEP ring is locally acting, which may be an important point during counseling and explaining the differences to clients

# Oral PrEP and PrEP ring are compatible with other medicines

- The medications used in oral PrEP and PrEP ring have **no known drug interactions** with the medications most commonly prescribed during pregnancy or the postnatal period. These medications may include:
  - Iron and folic acid tablets
  - Multiple micronutrient supplements or other prenatal vitamins
  - Penicillin or other antibiotics
  - Tetanus toxoid or pertussis vaccination
  - Sulfadoxine-pyrimethamine
  - Single-dose albendazole or mebendazole
  - Stool softeners
  - Medications recommended in WHO's 2016 ANC Guidelines for treatment of common physiologic symptoms of pregnancy
  - Family planning (FP) methods such as oral contraceptive pills, injectable progestin methods, sub-dermal implants, intrauterine devices, and barrier methods
  - Vaginally administered miconazole nitrate.
  - Medications used for fever or pain
  - Malaria treatment
  - Anti-diarrheal medication
  - Rubella vaccine (postnatal period only)

** This list is just a sampling and does not include all possible medications.*

# PrEP ring research brief overview

**Studies looking at safe use of the PrEP ring during pregnancy and breastfeeding are ongoing, as such, regulatory status of the PrEP ring varies by country.**

- Studies have been conducted in the United States, South Africa, Zimbabwe, Uganda, and Malawi.
- Pregnancy research to date has shown no increase in negative side effects or negative impact on pregnancy or infants.
  - Results of more pregnancy research with the PrEP ring is expected in 2023.
- Breastfeeding research has shown no increase in negative side effects or negative impact on pregnancy or infants.
  - The level of dapivirine that passes into milk is so low that it is difficult to measure it.
  - Using the PrEP ring during breastfeeding does not cause problems with quantity or quality of breast milk.

# Regulatory status of the PrEP ring varies by country

- Health care providers should follow local policies regarding use of the PrEP ring by pregnant and breastfeeding p opulations as approval by population may be different and evolving.
- Different scenarios for regulatory approval are possible. In some places, PrEP ring may not be approved for PBFP at all. In others, it may be approved for use only during pregnancy and/or breastfeeding. See table for some possible scenarios.

| Some possible country regulatory status scenarios for approval of PrEP ring | | |
|---|---|---|
| Not pregnant and not breastfeeding | Pregnancy | Breastfeeding |
| NO | NO | NO |
| YES | NO | NO |
| YES | NO | YES |
| YES | YES | YES |

# 2

# MODULE 2: BEFORE PRESCRIBING ORAL PrEP OR THE PrEP RING

# Who is a good candidate for oral PrEP or the PrEP ring?

In settings of high HIV incidence, **all HIV-negative PBFP** should be considered candidates for PrEP (oral PrEP and the PrEP ring), unless individual clinical contraindications exist, or local policies prohibit this.

# Who is a good candidate for oral PrEP or PrEP ring?

## Consider oral PrEP or the PrEP ring for a wide range of clients*:

- Routine antenatal (ANC) and postnatal (PNC) clients
- Clients taking oral PrEP and the PrEP ring and then subsequently become pregnant may continue to use oral PrEP and the PrEP ring
- Clients seeking pregnancy, currently pregnant, or currently breastfeeding with partner(s) who may:
  - Have unknown HIV status
  - Be living with HIV, but not on HIV treatment
  - Be living with HIV, but on treatment less than six months, not virally suppressed, or viral suppression status unknown
- Clients who may access oral PrEP and the PrEP ring through facility or community-based delivery programs

**Local policy permitting*

# Know the contraindications to prescribing oral PrEP

**Contraindications for oral PrEP** use in pregnancy and breastfeeding are mostly the same for non-pregnant, non-breastfeeding clients. These include:

- A positive HIV test result according to the national HIV testing algorithm
- Signs of acute HIV infection AND potential exposure within the past 14 days
- Inability to commit to using oral PrEP effectively and attending scheduled follow up visits
- Probable recent exposure to HIV (past 3 to 14 days)
- Creatinine clearance of less than 60 ml/min
- Allergy or hypersensitivity to active substance or other substances listed in the product information sheet

*In such circumstances, consider deferring PrEP start for four weeks and having the person tested for HIV again, which will allow time for possible HIV seroconversion to be detected.*

**For PBFP, avoid prescribing oral PrEP for those with a current suspected or confirmed diagnosis of a condition that can negatively impact liver or kidneys, such as pre-eclampsia.**

*Once pregnant, clients can continue to use oral PrEP, provided they do not have any contraindications.*

# Contraindications to prescribing the PrEP ring

## Generally

- A positive HIV test result according to the national HIV testing algorithm
- Signs of acute HIV infection AND potential exposure within the past 14 days
- Inability to commit to using the PrEP ring effectively and attending scheduled follow up visits
- Probable recent exposure to HIV (past 3 to 14 days)
- Allergy or hypersensitivity to active substance or other substances listed in the product information sheet

## During pregnancy

- Active labor at any gestational age
- Vaginal bleeding
- Suspected or confirmed rupture of the amniotic membranes (bag of waters)
- Cervical cerclage (treatment for increased risk of preterm birth in those with history of cervical weakness)
- Suspected or confirmed intrauterine infection, i.e., chorioamnionitis

## During the postnatal period

- Unresolved postnatal vaginal bleeding (intermittent spotting during the postnatal period can be normal)
- Unresolved vaginal bleeding may be due to infection or retained products of pregnancy/placenta
- Uterus not yet returned to near pre-pregnancy size through normal involution

# Contraindications to prescribing the PrEP ring

**Following spontaneous or therapeutic abortion**

- Suspected or confirmed intrauterine infection
  - In addition, it may be prudent to defer the PrEP ring for some participants who have not yet completed treatment for **symptomatic** sexually transmitted or urinary tract infections, vaginitis, or pelvic inflammatory disease, due to potential discomfort and challenges understanding and managing side effects from different causes.
  - However, it should be noted that presence of sexually transmitted infection may increase the risk for getting HIV, and these individuals may be especially critical candidates for prompt start of an effective HIV prevention method.

# 3

# MODULE 3: COUNSELING ON USE OF ORAL PrEP OR THE PrEP RING FOR PBFP

# Counseling and communication: Important components of person-centered maternity care

- Person-centered maternity care is maternity care that is respectful of and responsive to client preferences, needs, and values.
- Such care includes system and provider responsiveness, patient-provider communication, interpersonal treatment, and patient engagement.
- Person-centered care influences health-seeking behavior.
- Provision of oral PrEP and the PrEP ring for PBFP is more likely to be successful when person-centered services are provided.

IOM, 2001; Afulani et al., 2017.

# Discussing oral PrEP and the PrEP ring with PBFP

Oral PrEP and the PrEP ring may be ***introduced*** in a variety of different community and facility-based contexts. While Oral PrEP and the PrEP ring can be introduced and included in counseling opportunities in many community-based settings, they should only be offered in settings where trained nurses are available, and where appropriate supplies, re- testing for HIV, and psychosocial support can be guaranteed.

**In group counseling sessions for ANC or PNC clients and/or their partners**

**During individual ANC contacts at community or facility level**

**During individual PNC and FP contacts at community or facility level**

**In other community-based settings**

# Key counseling messages for PBFP on oral PrEP or PrEP ring use

## *(beyond standard PrEP counseling messages)*

1. In general, the chances of HIV acquisition are higher during pregnancy and the postnatal period.

2. For most clients who live in areas where HIV is common, the potential benefits of oral PrEP or the PrEP ring during pregnancy and the postnatal period outweigh potential risks. Using oral PrEP or the PrEP ring is generally safer for the client and baby, compared to acquiring HIV.

3. There is no evidence that oral PrEP and/or the PrEP ring increases the chance of birth defects, miscarriage, or other complications during pregnancy, birth, or after birth.

4. Oral PrEP and the PrEP ring do not have any known negative interactions with the medications and supplements most commonly prescribed for during pregnancy and while breastfeeding.

*Continue key counseling messages on the next slide.*

# Key counseling messages for PBFP on oral PrEP or PrEP ring use (continued)

5. The amount of oral PrEP or dapivirine that may pass to a baby during pregnancy and breastfeeding is very small and has not been shown to cause any serious health problems for babies.
6. Oral PrEP or PrEP ring use during pregnancy and breastfeeding has not been shown to cause babies to be too big or too small.
7. Oral PrEP and the PrEP ring have not been shown to have any impact on the ability to become pregnant in the future.
8. Oral PrEP and PrEP ring supplies should be kept in a safe place where children cannot reach them.
9. Some people using oral PrEP or PrEP ring experience side effects, but they are generally mild, not dangerous, and resolve without having to stop product use.
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 two years or beyond.

*If a client declines both the PrEP ring and oral PrEP, the provider should counsel on other safe and effective approaches for HIV prevention such as condoms, the availability of post-exposure prophylaxis (PEP), and the option to start either (or a different) prevention method in the future. Clients who decline any type of PrEP still need to know about their HIV prevention options for testing of partner(s), treatment of partner(s) living with HIV as prevention, condom use, use of safer sexual practices, use of safer drug injection practices, and sexually transmitted infection (STI) testing and treatment.*

# Additional key counseling messages for PBFP on PrEP ring use only

11. The PrEP ring (and oral PrEP) have not been shown to affect milk production or the taste or quality of breast milk.

12. The PrEP ring rests at the top of the vagina, right below the opening of the cervix, and in this position, it does not enter the uterus or touch the baby. Sexual partners will more than likely not notice or feel the PrEP ring.

13. The PrEP ring should be removed before delivering the baby, ideally when contractions start or when arriving to the hospital for delivery of the baby.

14. The PrEP ring can be restarted after delivering your baby, ideally after the uterus has returned to its pre-pregnancy size and bleeding has diminished.

*Counseling messages on routine use and care of the PrEP ring can be found on page 17 of the* Clinical Practice Guidelines for Dapivirine Ring Use in Pregnant and Breastfeeding Populations September 2022.

# Inserting and removing the PrEP ring: key considerations and counseling

- Clients may need initial guidance and support to learn how to use the PrEP ring.
- Once confident, clients can continue to use the PrEP ring on their own.
- Some clients may be comfortable inserting and using the PrEP ring on their own with minimal support from their first use.
- However, for clients who prefer support, a health care provider can help insert the PrEP ring or confirm placement.
- The PrEP ring is inserted with fingers; there is no need to use a speculum or other tools to insert the ring. Clear visual instructions should be offered with the PrEP ring.

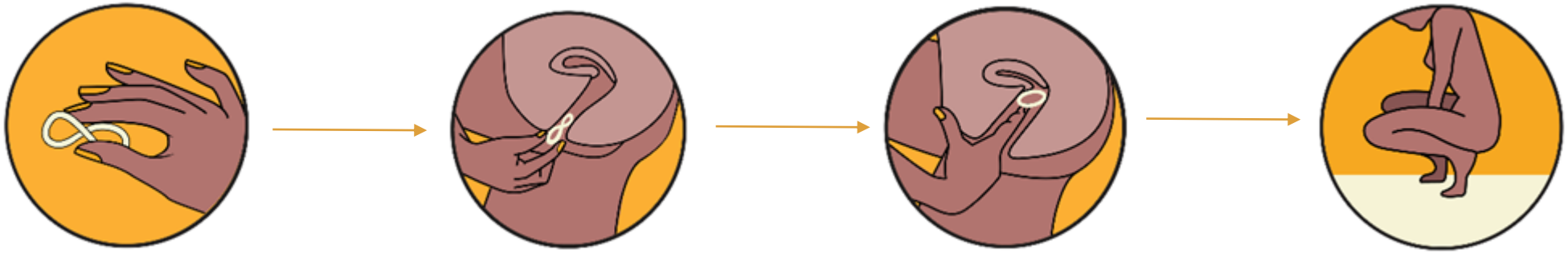
*Staff should be sensitive to the fact that those later in pregnancy may not feel comfortable inserting the ring themselves. In these cases, the health care provider should offer to assist. After correct placement is confirmed, the clinician may ask the client if they would like to feel the position of the ring. This will help ensure an understanding of what correct placement feels like, should the client need to check this at any time.*

# Checking the PrEP ring placement: key considerations and counseling

- Checking for PrEP ring placement is not typically required.
- If the client expresses discomfort after inserting the PrEP ring and wants reassurance that is has been placed correctly, the provider can offer to check the PrEP ring placement.
- After PrEP ring placement, the participant should walk around prior to verification of correct ring placement.
- The client should then lie comfortably on the examination couch in supine position (on her back).
- Upon genital inspection, the PrEP ring must not be visible on the external genitalia.
- If the PrEP ring is visible, the placement is not correct.
- The PrEP ring should not press on the urethra.
- On digital examination, the PrEP ring must be placed at least 2 cm above the introitus beyond the levator ani muscle.
- If, on inspection, the PrEP ring is found to be inserted incorrectly, the PrEP ring should be removed and reinserted correctly by the client or the clinician.
- Should the PrEP ring spontaneously dislodge, client should insert a new ring immediately or contact a health care provider for assistance.

# Inserting the PrEP ring: key considerations and counseling

- Get into a position that is comfortable for inserting the PrEP ring, such as squatting, one leg lifted, or lying down. If a health care provider is assisting, client should be in a reclining position.
- With clean hands, squeeze the PrEP ring between the thumb and forefinger, pressing both sides of the PrEP ring together so that the ring forms a “figure 8” shape.
- Use the other hand to open the folds of skin around the vagina.
- Place the tip of the PrEP ring into the vaginal opening and use fingers to push the folded PrEP ring gently up into the vagina.
- Push the PrEP ring as far toward the lower back as possible. If the PrEP ring feels uncomfortable, it is probably not inserted far enough into the vagina. Use a finger to push it as far up into the vagina as is comfortable.



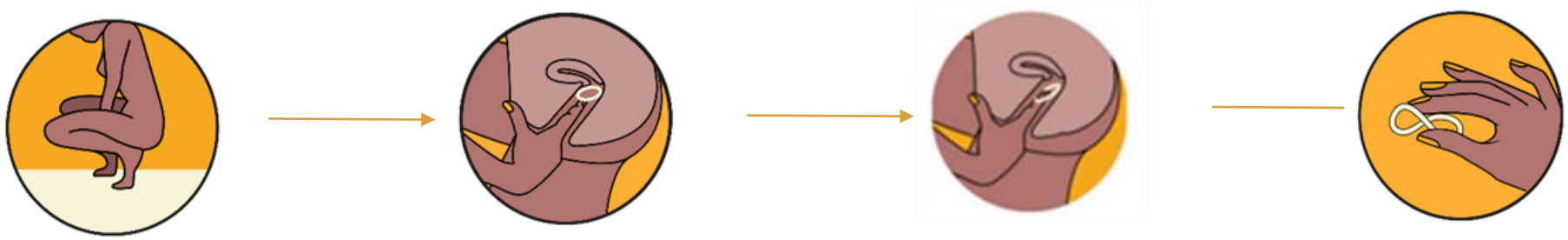
*Ring insertion should be painless. If you client experiences any bleeding or discomfort upon insertion, client should contact your health care provider.*

# Removing the PrEP ring: key considerations and counseling

- Clients can remove the PrEP ring without the help of a health care provider. However, for clients who prefer support, a health care provider can help remove the PrEP ring. The PrEP ring is removed with fingers; there is no need to use a speculum or other tools to remove the PrEP ring . If a client is being assisted by a health care provider, they should be in a reclining position during removal.
- The ring should be removed before delivering the baby, ideally when contractions start or when arriving to the hospital for delivery of the baby (see next slide for more information).

PrEP ring removal steps

- Get into a position that is comfortable for removal, such as squatting, one leg lifted, or lying down.
- With clean hands, insert one finger into the vagina and hook it around the edge of the PrEP ring.
- Gently pull the PrEP ring out of the vagina.



*Ring removal should be painless. If client experience any bleeding or discomfort upon removal, client should contact your health care provider.*

# Starting or restarting the PrEP ring after childbirth: key considerations and counseling

**Following delivery,** PrEP ring use should continue to pause while the uterus returns to its pre-pregnant size (uterine involution).

Clients may experience pain from uterine contractions, called afterpains, and notice a discharge called lochia in the weeks following delivery. Both are normal signs of uterine involution, which may take up to approximately six weeks.

If the client wishes to restart PrEP ring use following delivery, it is prudent to wait until vaginal bleeding has diminished.

Refer to eligibility guidelines when restarting the PrEP ring in the postnatal period and provide information on where to access the appropriate services.

***Note***: These precautions apply to PrEP ring use only, not oral PrEP use.

# 4

# MODULE 4: LABORATORY TESTING, DOCUMENTATION, AND SCHEDULING FOLLOW-UP

# Rule out HIV before prescribing oral PrEP or the PrEP ring!

! **HIV should be ruled out** by testing before prescribing oral PrEP or the PrEP ring.

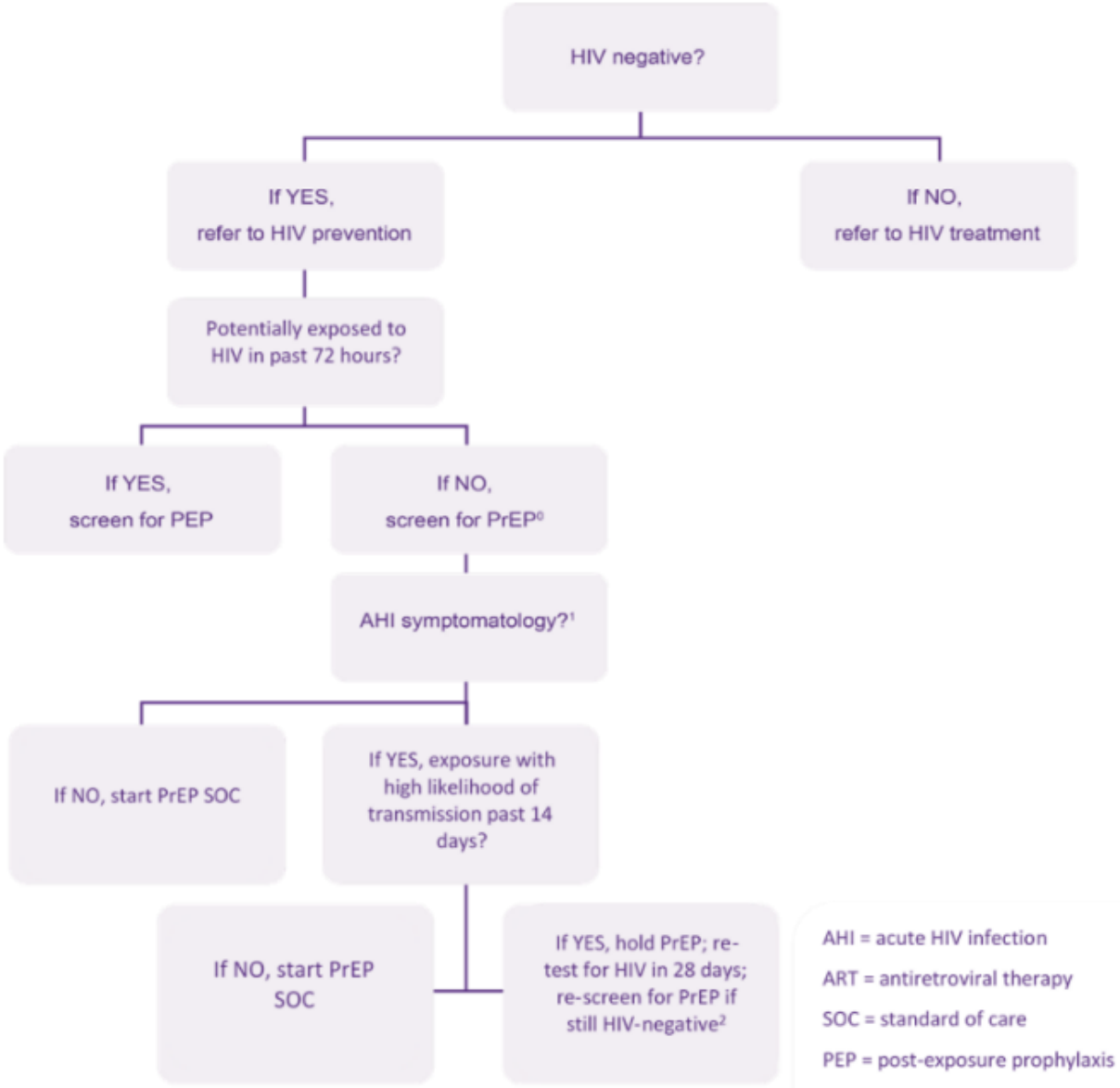
**Three steps to ruling out HIV infection:**

1. **HIV testing** should be performed the same day that Oral PrEP or the PrEP ring is started using a point-of-care rapid HIV test, following national HIV testing algorithms.

2. **Screening for PEP eligibility, for clients reporting possible HIV exposure in past 72 hours**: Clients with possible HIV exposure (last 72 hours) should **not** be offered oral PrEP or the PrEP ring, but instead be offered post-exposure prophylaxis (PEP). The client should then be re-tested for HIV after 28 days. Oral PrEP or the PrEP ring may be offered to clients who test negative at this point.

3. **Screening for signs/symptoms** (see next slide) or **acute HIV infection and HIV exposure** in past 14 days.

# Ruling out PEP indication and possible acute HIV infection




AHI = acute HIV infection

ART = antiretroviral therapy

SOC = standard of care

PEP = post-exposure prophylaxis

# Signs and symptoms of acute HIV infection

- Signs and symptoms of fever
- Sore throat, aches, and pains
- Lymphadenopathy (swollen glands)
- Mouth sores, headache, or rash

If the client has any of these signs or symptoms and reports a possible HIV exposure in the past 14 days, consider the possibility they may have acute HIV infection. In such circumstances, consider deferring further PrEP screening and having the person test again for HIV in four weeks, which will allow time for possible HIV seroconversion to be detected. If the client is HIV-negative at the time of re-testing, resume screening for PrEP eligibility.

# Testing before prescribing oral PrEP or the PrEP ring

- HIV test
- Serum creatinine, where capacity allows, to monitor kidney function (for oral PrEP)
- Hepatitis B surface antigen (for oral PrEP)
- Sexually transmitted infections (STIs), such as syphilis, gonorrhea, and chlamydia. Note that STIs can be diagnosed and treated without the need to remove the PrEP ring

*All testing should follow national guidelines. Testing for kidney function and STIs, including HBV, is covered more extensively in Modules 6 and 7.*

# Document care in clinical records

Normally, **all clinical care associated with oral PrEP or PrEP ring use should be documented** on the client's handheld ANC record as well as any relevant ANC, PNC, FP, or PrEP-specific facility-based records and registers.

- All PrEP use clinical care should be documented in facility-based records.
- Important data points to record include dates of insertion/removal, reasons for removal, side effects reported, number of PrEP ring given to client, etc.
- Consult with client before documenting PrEP use on handheld records.

*Avoid unintentional disclosure to partners, family, or other household members.*

# Determining the best service delivery settings for clients

There is no single best place to manage 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 the following:**

**Client's needs and preferences**

**Capacity of each service delivery setting**

# PrEP delivery settings

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

**Examples of transitions** may include:

Safer conception or FP → ANC

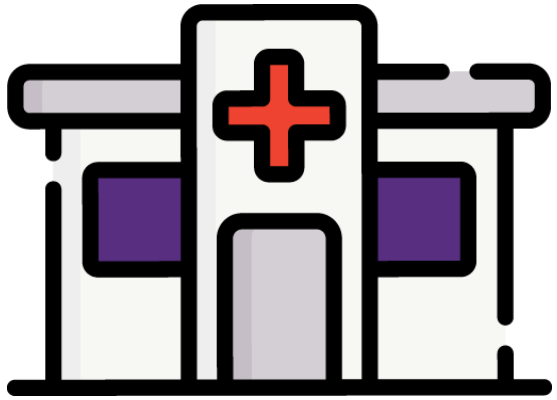
KP or AGYW* → ANC

ANC → PNC

ANC → FP

PNC → FP

PNC → Other facility or provider



*KP: Key Population; AGYW: Adolescent Girls and Young Women

# Scheduling follow-up and promoting oral PrEP and the PrEP ring continuation

If the client is receiving oral PrEP or PrEP ring services through an ANC, PNC, or FP service delivery sites, try to align the clients visits to minimize trips to the clinic, as frequent visits discourage some clients from continuing oral PrEP or PrEP ring.

# Optimize chances for continuation of PrEP

- Understand the client's motivations for choosing oral PrEP or the PrEP ring.
- Talk to the client about potential barriers in returning to the clinic and continuing oral PrEP or PrEP ring use as well as ways the client may overcome these barriers.
- Ask about the potential for return one month after initiation for assessment and confirmation of HIV-negative test status, assessment for early side effects and discussion of any difficulties with effective use or any other client concerns.
- Consider providing a supply of oral PrEP or PrEP ring that will last beyond the time of the next recommended visit, particularly if the client is not sure they will make it back.
- After the one-month visit, follow up visits are important and should follow national guidelines.
- Ask about partner reactions and strategies to communicate PrEP use with partners who are not supportive.
- Provide anticipatory counseling to help the client manage side effects.
- Assist the client to set up a reminder on their phone, if the client has one, with a message the client finds personally motivating (e.g., My baby is healthy and so am I!).


# 5

# MODULE 5: SUPPORTING CONTINUED USE OF ORAL PrEP OR THE PrEP RING

# Integration of PrEP services into care for pregnant and breastfeeding clients

After the pregnant or breastfeeding client starts oral PrEP or the PrEP ring, the health care provider has several important roles:

- Continue providing high-quality ANC or PNC (including FP services) to the client to address her needs and integrate PrEP care into the client's routine ANC, PNC, or FP services.
- Monitor how the client is doing with oral PrEP or PrEP ring use.
- Help the client to be an active partner in their care.

**At each follow-up visit,** the health care provider needs to integrate information from history-taking, targeted physical examination, and any laboratory data to help the client reach their goals.

**Counsel the client** on the need to remove the PrEP ring in case of the following:

- Suspected or confirmed rapture of amniotic membranes
- Vaginal bleeding
- Uterine infection
- Cervical cerclage
- Labor at any gestation

# Family planning settings providing PrEP services for breastfeeding clients

In general, clinical guidance is the same for breastfeeding clients receiving PrEP services in PNC and family planning settings.

FP provider should:

- Provide counseling that assists clients to meet their personal family planning and HIV prevention goals.
- Provide comprehensive clinical assessment to support safe continuation of family planning and HIV prevention methods.

Oral PrEP and the PrEP ring have no known adverse interactions with FP methods. *

*PrEP ring is not recommended for use with the contraceptive ring or diaphragm.

# Managing oral PrEP or PrEP ring side effects

As noted earlier, **oral PrEP and the PrEP ring are generally well-tolerated** outside of and during pregnancy. 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

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

*Continue to evaluation of possible oral PrEP or PrEP ring side effects on the next slide.*

# Evaluating potential side effects

Ask the client to tell you more about the sign or symptom.

Do a targeted physical exam.

Consult with an experienced provider and/or specialist if needed.

Consider other possible reasons for side effects.

Document your care in the client's record.

Evaluate how the client is doing by phone or at a follow-up visit, depending on your clinical judgement.

*Consider other possible reasons for side effects (see next slides)

# Evaluating reasons for potential side effects

| Sign or symptom | Possible expected finding in pregnancy | Possible expected finding in postnatal period | Expected with some (not all) FP methods | May be related to PrEP | May be related to another condition such as: |
|---|---|---|---|---|---|
| Back pain | X | X | | | Back injury |
| Constipation | X | | | | Iron pills |
| Nausea or vomiting | X | | X | X | Foodborne illness |
| Diarrhea | | | | X | Foodborne illness |
| Pelvic and lower abdominal pain | X (especially round ligament pain or heartburn) | X (uterine involution or post-cesarean pain) | X | X | Preterm contractions, foodborne illness |
| Vaginal discharge | X | X (if consistent with normal lochia) | X | X | Vaginitis or sexually transmitted infection |
| Frequent urination | X | | | | Urinary tract infection |
| Dizziness | X | | X | X | Anemia, dehydration |
| Headache | X | | X | X | Pre-eclampsia (serious complication of blood pressure) |
| Fatigue | X | X | X | X | Anemia or depression, other possibilities |
| Sleep issues | X | X | | X | Anxiety or depression |
| Abnormal kidney function tests (e.g., serum creatinine) | | | | X | Pre-eclampsia |
| Vulvar itching | | | | X | Candidiasis |
| Urinary tract infection | X | X | X | X | Urinary frequency and pain |

# Vaginal discharge in pregnant PrEP ring users

Increased vaginal discharge is a normal occurrence in pregnancy. Physiologic discharge of pregnancy is typically clear to white and homogenous and increases in amount with advancing gestational age.

! When a participant reports increased vaginal discharge, it is incumbent on the clinician to ascertain through history whether the discharge might be amniotic fluid in a client whose amniotic sac spontaneously ruptured.

Signs and symptoms which raise the possibility of ruptured membranes rather than physiologic discharge include the following:

- Colorless to slightly yellow thin watery discharge (the consistency of urine)
- An associated gushing or “pop” sensation
- Significant volume to saturate undergarments and clothes

# Deciding whether to pause or stop oral PrEP or PrEP ring use for PBFP

Before deciding to pause or stop oral PrEP or PrEP ring use, it is important to consider whether there is reasonable suspicion that a complaint was caused by oral PrEP or 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 oral PrEP or PrEP ring use?
- If the client has already stopped oral PrEP or PrEP ring use, has there been any improvement after stopping?
- Did the issue come back if the client stopped and restarted oral PrEP or the PrEP ring?
- Is the problem something that has been seen before in other people using oral PrEP and the PrEP ring?
- Is it plausible (does it make sense) that oral PrEP or the PrEP ring could have caused the problem?
- Is there any other explanation?

# Stopping PrEP use due to HIV seroconversion

It is possible that a pregnant or breastfeeding client who has been prescribed oral PrEP and the PrEP ring will experience HIV seroconversion.

If this occurs, it's important for the health care provider to take several actions:

**Counsel the client on key post-test counseling topics:**

- ✓ Coping with the diagnosis
- ✓ Learning the actions to take to keep the client and baby healthier and prevent transmission to the baby
- ✓ Deciding whether to share the clients results with others, especially their partner, so they can also get tested

**Start client on recommended antiretroviral therapy as soon as possible after a confirmed positive HIV test result. *Confirm the client's reactive rapid test result.**

*Additional information can be found in national guidelines for prevention of vertical transmission (also referred to as mother-to-child transmission) of HIV infection.*

# Evaluating potential problems in breastfeeding infants

**Oral PrEP and PrEP ring use** have not been associated with safety concerns among client's breastfeeding infants.

When assessing whether a finding might be related to the client's oral PrEP or PrEP ring use, providers can consider the guiding questions previously noted in the section, ***Deciding whether to pause or stop oral PrEP or PrEP ring use for PBFP.***

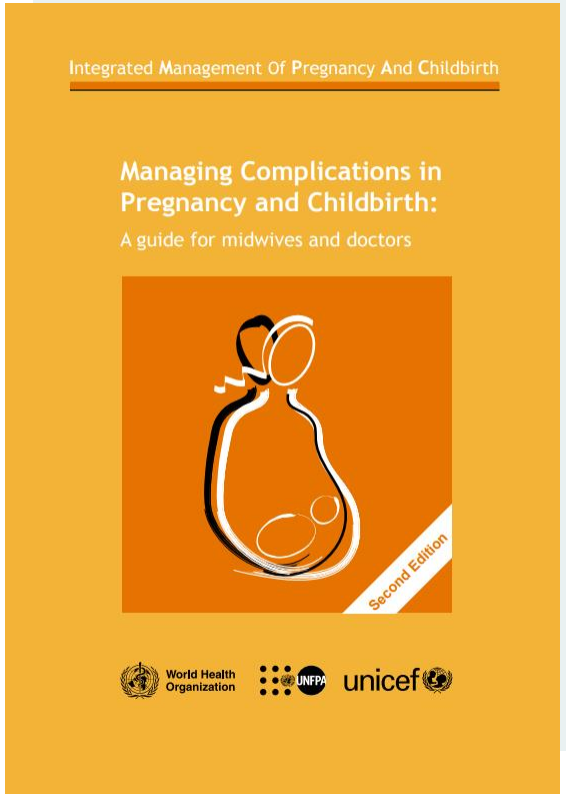

**Severe abnormal signs or symptoms in an infant** are unlikely to be related to maternal oral PrEP or PrEP ring use but should be evaluated promptly according to the WHO *Paediatric emergency triage, assessment and treatment: care of critically-ill children* or other national guidance as appropriate.

# 6 MODULE 6: ORAL PrEP USE IN SPECIAL SITUATIONS

# Oral PrEP use in clients with hypertensive disorders during pregnancy

It is prudent to **avoid prescribing oral PrEP** to clients with evidence of impaired renal function or conditions that may impair renal function.

- ✓ Conduct an assessment
- ✓ Manage these conditions to avoid life-threatening complications




*The WHO Managing Complications in Pregnancy and Childbirth (MCPC): A Guide for Midwives and Doctors (2nd Edition) provides guidance on symptoms, clinical criteria for diagnosis, and management of hypertensive disorders of pregnancy.*

# WHO's classification framework for hypertensive disorders during pregnancy

1. Chronic hypertension (elevation of blood pressure noted before 20 weeks of gestation or persisting more than 12 weeks postpartum)
2. Gestational hypertension
3. Mild pre-eclampsia
4. Severe pre-eclampsia
5. Eclampsia
6. Chronic hypertension with superimposed pre-eclampsia

| Category | WHO Diagnostic Criteria | Suggested Management |
|---|---|---|
| Chronic hypertension | Elevation of blood pressure noted before 20 weeks of gestation or persisting more than 12 weeks postpartum | Initiate oral PrEP only after laboratory assessment of kidney function, in consultation with an experienced obstetrician or high-risk pregnancy specialist, and follow an individualized, comprehensive plan for monitoring of blood pressure, medication use, and kidney function. |
| Mild pre-eclampsia | New onset hypertension and proteinuria after 20 weeks of gestation:<br>• Systolic blood pressure (SBP) >140 and/or diastolic blood pressure (DBP) >90 after 20 weeks of gestation<br>• Proteinuria 2+ on dipstick<br>• No severe features of pre-eclampsia/eclampsia present | Do not initiate or continue oral PrEP use in clients with suspected or confirmed diagnosis of mild pre-eclampsia. These clients should have management consistent with recommendations in the WHO MCPC manual. For clients initially suspected to have pre-eclampsia, but are subsequently ruled out, consider starting or restarting oral PrEP use, with careful monitoring for recurrence of signs or symptoms of pre-eclampsia. Clients with pre-eclampsia may begin oral PrEP after birth if kidney function remains normal, or when kidney impairment resolves. |
| Severe pre-eclampsia | New onset hypertension and proteinuria after 20 weeks of gestation:<br>• SBP > 160 and/or DBP >110 after 20 weeks of gestation<br>• Proteinuria 2+ on dipstick<br>Pre-eclampsia with any of the following present is severe pre-eclampsia:<br>• Neurologic: headache, vision changes, hyperreflexia or clonus<br>• Pulmonary: difficulty breathing (rales on auscultation due to fluid in lungs)<br>• Hepatic: upper abdominal pain, nausea/vomiting or liver enzymes elevated (>2 times the baseline)<br>• Renal: serum creatinine >1.1mg/dL or doubling of baseline, oliguria (<40 cc urine in 24 hours)<br>• Hematologic: platelets <100,000 cells/mcL | Do not initiate or continue oral PrEP use in clients with suspected or confirmed diagnosis of severe pre-eclampsia. These clients should have management consistent with recommendations in the WHO MCPC manual.<br><br>For clients who are initially suspected to have pre-eclampsia, but are subsequently ruled out for this diagnosis, consider starting or restarting oral PrEP use, with careful monitoring for recurrence of signs or symptoms of pre-eclampsia.<br><br>Clients with pre-eclampsia may begin oral PrEPafter birth if kidney function remains normal, or when kidney impairment resolves. |

# Testing kidney function during pregnancy in oral PrEP clients

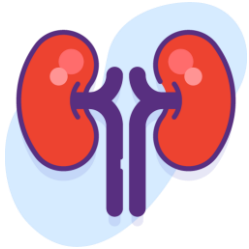
Where capacity allows, **serum creatinine testing** is recommended to monitor kidney function for oral PrEP users who are pregnant, with a repeat test performed every three months. Note: Waiting for kidney function test results should not delay initiation or continuation for oral PrEP

!

**For pregnant clients with serum creatinine > 0.9 mg/dl**
Health care provider should evaluate the client for possible acute kidney injury or undiagnosed prior chronic kidney disease. Consult with specialist.

*Pregnant clients who had normal serum creatinine levels before oral PrEP use, but then developed elevated levels outside the reference range for normal after starting oral PrEP should prompt the provider to pause oral PrEP provision due to the possibility of abnormal kidney function and consult with an obstetrician and/or kidney specialist, if available.*

*More information on screening for renal impairment is available in Differentiated and simplified pre-exposure prophylaxis for HIV prevention: Update to WHO implementation guidance TECHNICAL BRIEF, including testing methods, recommended testing frequency, and calculation options.*



# Proteinuria on urine dipstick and oral PrEP use

- Increased protein in urine is one potential sign of impaired kidney function.
- Urine dipstick is a method of point-of-care semi-quantitative testing for proteinuria.
- Clients with 2+ proteinuria on urine dipstick should be referred for serum creatinine testing.
- It is important to rule out pre-eclampsia before assigning another etiology for the presence of proteinuria in a pregnant client with elevated blood pressure. **Oral PrEP** should not be started or continued while the etiology is being determined.

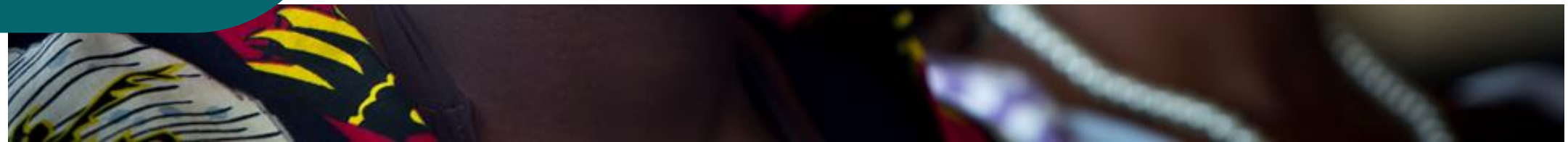
# Kidney function during the postnatal period

- **For most clients,** kidney function rapidly returns to pre-pregnant levels soon after delivery.
- **For breastfeeding oral PrEP clients,** monitor serum creatinine per national guidelines after the start of oral PrEP.
- *More frequent monitoring may be warranted if there are comorbid conditions that can affect renal function, such as diabetes mellitus and hypertension.*


*WHO and Jhpiego have developed an app to access the WHO Implementation Tool for Oral PrEP of HIV infection, and a free creatinine clearance calculator is available within* ***this app****.*

# 7

# MODULE 7: ADDITIONAL HEALTH SERVICES AND INTIMATE PARTNER VIOLENCE



# Additional HIV prevention and family planning services

Recommended services to be made available, in addition to oral PrEP or the PrEP ring:

- HIV testing services to identify those who can benefit from HIV prevention services *(repeat testing per national guidelines).*
- HIV testing services for the client's sexual partner(s) and drug injecting partner(s), refer those partners testing positive for immediate antiretroviral therapy services.
- Refer male sexual partner(s) to voluntary medical male circumcision.
- Screen for and treat STIs according to local guidance and offer the same to sexual partners.
- Offer male and female condoms and counsel on correct and consistent use.
- Offer HIV risk reduction counseling.

FP counseling should be offered to all pregnant and breastfeeding clients with appropriate method provision.

# Treatment of STIs in pregnancy is important!

STIs during pregnancy can cause different kinds of problems:

- Premature labor (labor before 37 weeks or pregnancy)
- Infection in the fetus, leading to blindness, deafness, severe anemia, or death
- Infection in the newborn and in the uterus after birth

Early birth is the number one cause of infant death and can lead to long-term developmental and health problems in children.

# Hepatitis B during pregnancy

- In HBV-endemic areas, PrEP services provide an opportunity to screen for HBV and provide linkage to care. Lack of HBV testing should not be a barrier to PrEP initiation and PrEP can be initiated before test results are available. HBV testing is not a requirement for PrEP use.
- Pregnant people who test positive for HBV surface antigen (HBsAg) should be referred to specialist care and be tested for HBV DNA, which can help to guide the use of antiviral medication to prevent perinatal transmission. People who test positive for HBsAg also need a repeat test per national guidelines to help understand if they have chronic, active HBV.
- To prevent vertical transmission of HBV, WHO recommends that all newborns receive a timely birth-dose of HBV vaccination, and that those who tested HBsAg-positive during pregnancy and are at high risk of transmitting the virus to their infants receive TDF prophylaxis from the 28th week of pregnancy until at least delivery

**PrEP services are an important opportunity for HBV screening, though PrEP initiation should not be delayed if screening or results are not immediately available.**

Source: Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance, 27 July 2022

# Screening for intimate partner violence (IPV)

Clients may experience new, continued, or increased IPV during pregnancy and the postnatal period.

**IPV is associated with higher likelihood of HIV acquisition, plus:**

- Lower PrEP uptake
- Increased PrEP interruption
- Lower adherence to PrEP
- Stress
- Forgetting to use PrEP
- Leaving home without PrEP
- Partners throwing away PrEP

*Note: Remember that IPV is driven by gender norms, power, and control. No HIV prevention method causes HIV. Rather, a violent individual may seek power in the relationship by controlling the sexual and reproductive health choices of their partner.*

# Clinical and routine enquiry for IPV

All oral PrEP and PrEP ring sites should conduct routine enquiry for IPV with all clients. Disclosure of violence is not a contraindication for PrEP use.

**Clinical enquiry for IPV**

*When a clinician asks only clients they suspect are experiencing IPV or fears of IPV*

**Routine enquiry for IPV**

*When a clinician asks all clients who present for specific services about experiencing IPV or fears of IPV*

*Routine enquiry should only be completed by trained providers. After conducting routine enquiry for IPV, sites must offer appropriate first-line support (the WHO LIVES approach or similar) and referrals to IPV response services. Routine enquiry for IPV can also be used in non-PEPFAR-funded programs.*

# Six minimum requirements for conducting routine enquiry

1. A protocol or standard operating procedure exists for conducting routine enquiry.
2. A questionnaire, with standard questions where providers can document responses, exists.
3. Providers offer first-line support (WHO LIVES approach or similar, see details on next slide).
4. Providers have received training on how to ask about IPV or sexual violence.
5. A private setting is available, and confidentiality is ensured.
6. A system for referrals or linkages to other services is in place.

# 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** include:

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

**The WHO Clinical Handbook for providing healthcare for women subjected to intimate partner violence or sexual violence, including more details on the LIVES approach, can be found at this link.*

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# MODULE 8: ACTIVE SAFETY SURVEILLANCE

# Active safety surveillance

While available data indicate that use of oral PrEP and the PrEP ring among PBFP is safe, some countries may opt to undertake surveillance:

- Adverse **maternal** outcomes: treatment-limiting toxicities associated with antiretroviral therapy in pregnant clients, particularly mortality;
- Adverse **birth** outcomes: including stillbirths, preterm births, low birthweight, major congenital anomalies or early infant deaths. Adverse birth outcomes may be routinely monitored by integrating an additional indicator into the national monitoring and evaluation system; and
- Adverse **infant and child** outcomes: health outcomes in infants and young children exposed to antiretroviral drugs in utero or via breast milk, particularly any impact on growth and development.

# Tools for safety surveillance

- **Data Collection/Case Report Form -** Facilitates a standardized approach to collection of relevant data for active surveillance of oral PrEP and PrEP ring use during pregnancy and breastfeeding.
- **Register -** Includes a shorter list of key indicators than the data collection form, formatted for printing as a clinic register for aggregating data within a facility.

Sample surveillance tools are available on PrEPwatch.org and can be accessed using the following links: Case Report Form and Surveillance Register

9

# MODULE 9: KEY MESSAGES

# Key messages

- Global guidance and evidence supports oral PrEP and PrEP ring use by pregnant and breastfeeding persons.
  - The chances of getting HIV are higher during pregnancy and the postnatal period.
  - Oral PrEP and PrEP ring use for PBFP is generally safe and well tolerated for pregnant people and their babies.

- PrEP providers should feel comfortable:
  - Providing key counseling messages.
  - Monitoring continued safety of oral PrEP and the PrEP ring.
  - Managing common oral PrEP and PrEP ring side effects.
  - Ensuring that clients receive other key services and screening.

*You have completed this course. Thank you!*

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