Providing the PrEP Ring to Pregnant and Breastfeeding People

TRAINING COURSE POWERPOINT

FEBRUARY 2023

PEPFAR

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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 the dapivirine vaginal ring (PrEP ring) for pregnant and breastfeeding people (PBFP) using a facility-based and/or hybrid approach to training, capacity-building, and mentorship of health care workers.

Module	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 use of the PrEP ring for PBFP	1 hour 25 min.
Module 4: Laboratory testing, documentation, and scheduling follow-up	1 hour 5 min.
Module 5: Supporting continued use of the PrEP ring	1 hour 25 min.
Module 6: Additional health services and intimate partner violence	1 hour 10 min.
Module 7: Active safety surveillance	30 min.
Module 8: Key messages	55 min.

At the end of this session…

Learners will be able to state the following:

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

1 MODULE 1: USE OF 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 ring screening, delivery, and management.

The World Health Organization (WHO) recommends the PrEP ring

WHO supports provision of the PrEP ring to women who are at continuing risk of acquiring HIV.

"The PrEP ring may be offered as an additional prevention choice 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

An overview of the 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 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.
- The PrEP ring is available in one size and is inserted into the vagina and 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 appears safe for PBFP

- The PrEP ring could be particularly useful for clients who are unable or do not want to take oral pre-exposure prophylaxis (PrEP) or when oral PrEP is not available.
- To date, no worsening of pregnancy or perinatal outcomes has been shown to be associated with use of the PrEP ring across a range of different countries and populations.
- The PrEP ring is safe and well tolerated for breastfeeding people and their infants. The amount of dapivirine that passes into milk has been shown to be very low.
- Silicone elastomer has been shown to be safe when used to make many medical devices, such as contact lenses, catheters, and other types of vaginal rings (e.g., contraceptive rings).
- Side effects of PrEP ring use, if any, are typically mild and often resolve without the need to remove the ring.

PrEP ring side effects are generally mild

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

Not everyone experiences side effects. Most side effects are mild and often resolve on their own.

Side effects may include:

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

**Side effects listed were observed in previous studies.*

The PrEP ring is compatible with other medicines

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

Examples

- COVID-19 vaccines
- Tetanus toxoid or pertussis vaccination
- Iron and folic acid tablets
- Multiple micronutrient supplements or other prenatal vitamins
- Penicillin or other antibiotics
- Sulfadoxine-pyrimethamine
- Single-dose albendazole or mebendazole
- Stool softeners
- Vaginally administered miconazole nitrate
- 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
- Medications used for fever or pain
- Malaria treatment

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

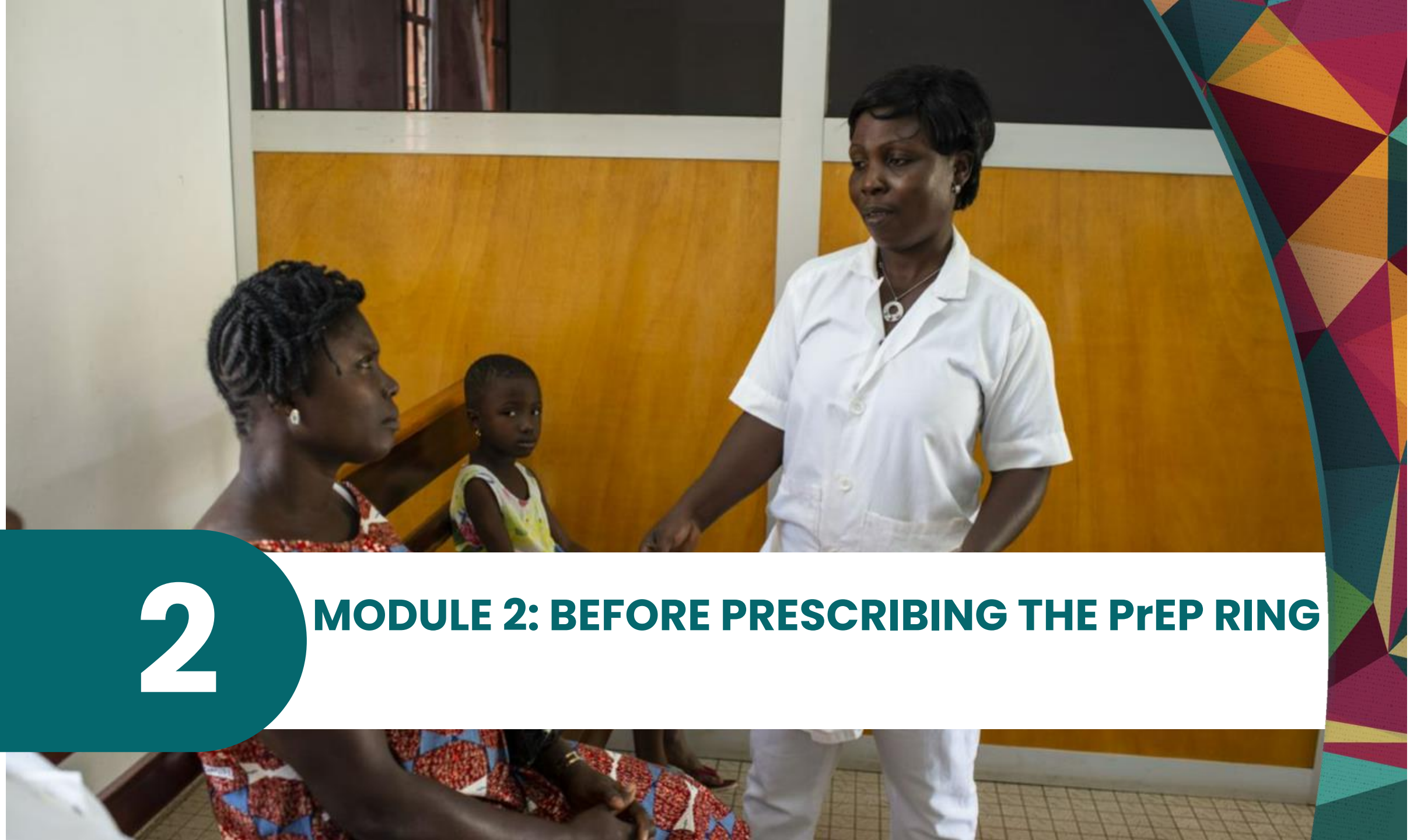
How did we learn about safe use of the PrEP ring during pregnancy and breastfeeding?

- 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 varies by country

- Health care providers should follow local policies regarding use of the PrEP ring by pregnant and breastfeeding populations 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 THE PrEP RING

Who is a good candidate for the PrEP ring?

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

Who is a good candidate for the PrEP ring?

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

- Routine antenatal care (ANC) and PNC (postnatal care) clients.
- Clients who are using the PrEP ring and then subsequently become pregnant may continue to use 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 the PrEP ring through facility or community-based service delivery programs, including adolescent girls and young women.

**Local policy permitting*

Know the contraindications to starting the PrEP ring

Contraindications for PrEP ring 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
- Known exposure to HIV in the past 72 hours (because such clients may derive more benefit from post-exposure prophylaxis (PEP) if the potential for HIV exposure was high)
- Signs of acute HIV infection AND potential exposure within the past 14 days
- Inability to commit to effectively using the ring and attending scheduled follow-up visits
- Allergy or hypersensitivity to active substance or other substances listed in the product information sheet

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

Know the contraindications to starting the PrEP ring

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

Know the contraindications to starting 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. This is due to potential discomfort inserting the PrEP ring, and potential challenges differentiating and managing side effects.
  - However, it should be noted that the presence of sexually transmitted infection(s) may increase the possibility of acquiring HIV. These individuals may be especially critical candidates for prompt start of an effective HIV prevention method.

3 MODULE 3: COUNSELING ON USE OF 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 patient 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 the PrEP ring for PBFP is more likely to be successful when person-centered services are provided.

IOM, 2001; Afulani et al., 2017.

Discussing the PrEP ring with PBFP

The PrEP ring may be introduced in a variety of different facility-based and community contexts. While PrEP ring can be introduced and included in counseling opportunities in many community-based settings, it 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
(beyond standard PrEP ring 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 the PrEP ring during pregnancy and the postnatal period outweigh potential risks. Using the PrEP ring is generally safer for the client and 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 during pregnancy and while breastfeeding.

Continue key counseling messages on the next slide.

Key counseling messages for PBFP
(beyond standard PrEP ring counseling messages)

5. The amount of 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. PrEP ring use during pregnancy and breastfeeding has not been shown to cause babies to be too big or too small.

7. The PrEP ring has not been shown to have any impact on the 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 without the need to remove the ring.

Continue key counseling messages on the next slide.

Key counseling messages for PBFP
(beyond standard PrEP ring counseling messages)

9. 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.

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

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

12. The PrEP ring has not been shown to affect milk production or the taste or quality of breast milk.

Key counseling messages for PBFP
(beyond standard PrEP ring counseling messages)

13 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.

14 If the client is experiencing violence in their life, encourage them to talk about it with a health care provider who can help them to keep themselves and their baby safe. *(More information on intimate partner violence (IPV) can be found in Module 6, later in this training.)*

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, and sexually transmitted infection (STI) testing and treatment.

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 PrEP ring.
- Clear visual instructions should be offered with the PrEP ring.

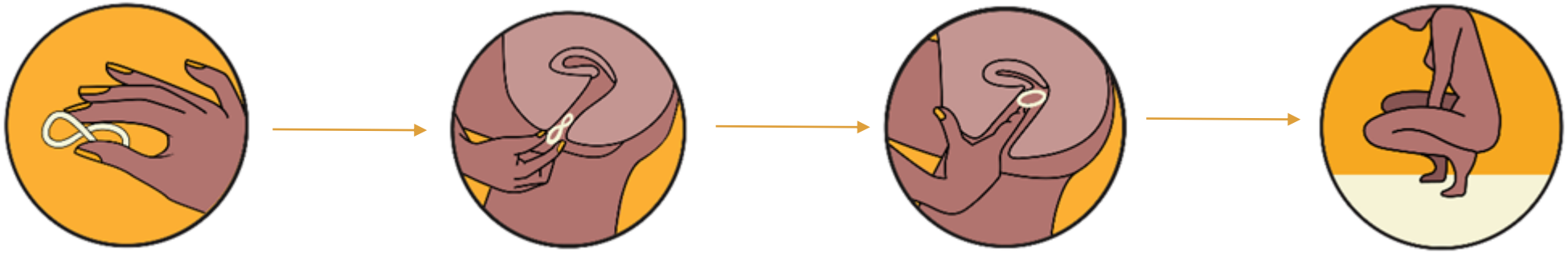
Staff should be sensitive to the fact that those later in pregnancy may not feel comfortable inserting the PrEP ring themselves. In these cases, the health care provider should offer to assist. After correct placement is confirmed, the clinician may ask the client if they would like to feel the position 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 the PrEP ring placement is not typically required.
- If the client expresses discomfort after inserting the PrEP ring and wants reassurance that it has been placed correctly, the provider can offer to check the PrEP ring placement.
- After the 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.



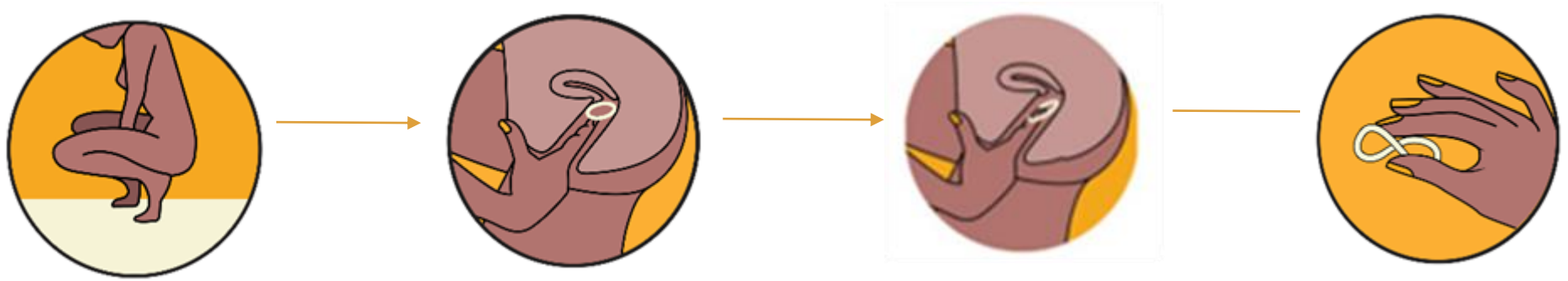
The PrEP ring insertion should be painless. If client experiences any bleeding or discomfort upon insertion, client should contact health care provider.

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

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.



PrEP ring removal should be painless. If client experiences any bleeding or discomfort upon removal, client should contact health care provider.

4

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

Rule out HIV before prescribing the PrEP ring!

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

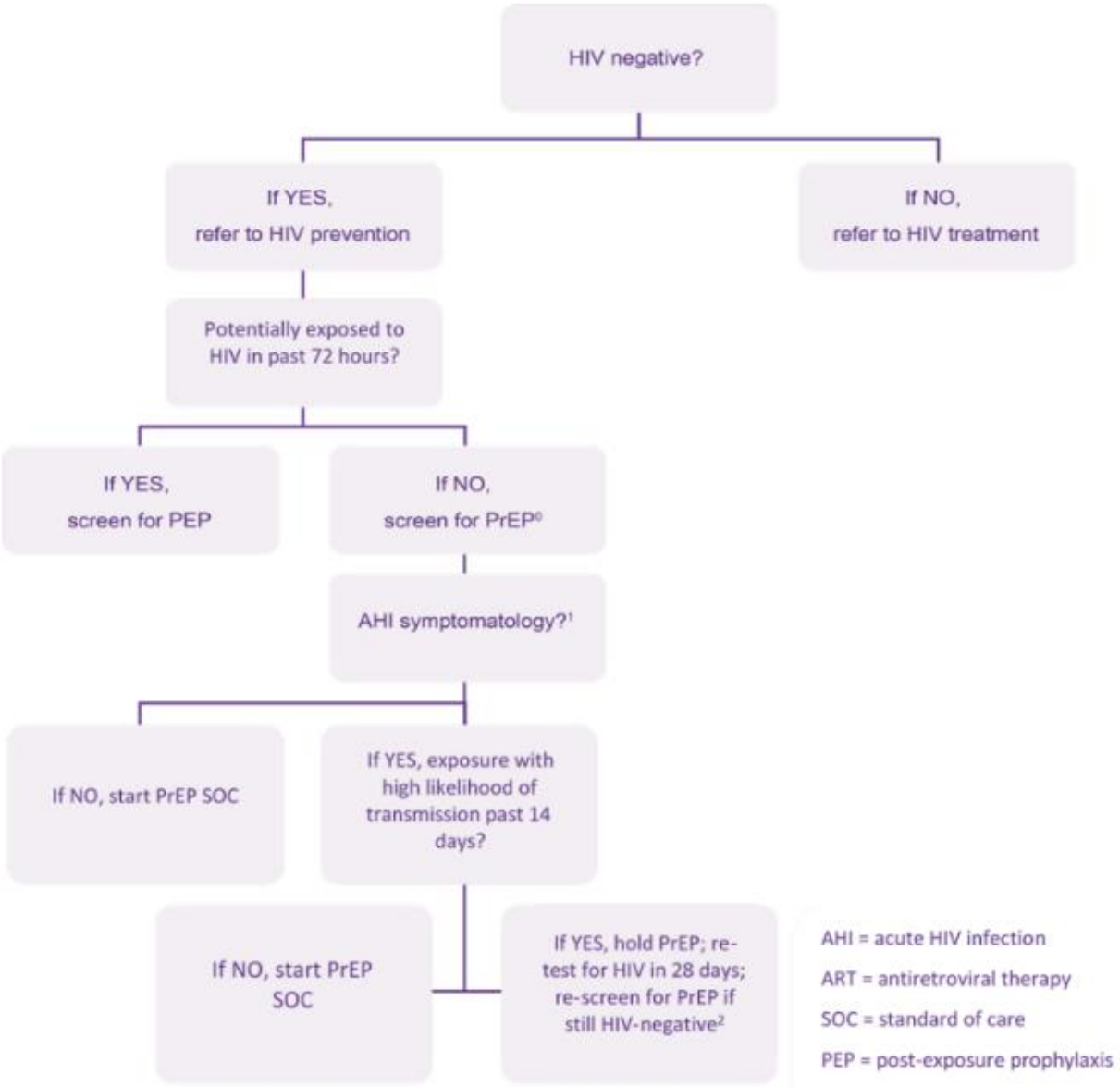
Three steps to ruling out HIV infection:

1. **HIV testing** should be performed the same day that 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 the PrEP ring, but instead be offered post-exposure prophylaxis (PEP). The client should then be re-tested for HIV after 28 days. 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



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 4 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.

Also test for other STIs before using the PrEP ring

- In addition to HIV testing, it is recommended to test* clients for other sexually transmitted infections (STIs), such as syphilis, gonorrhea, and chlamydia prior to starting the PrEP ring. STIs can be diagnosed and treated without the need to remove the PrEP ring.

*Testing requirements and frequency should follow national guidelines.

Document care in clinical records

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

- ✓ All PrEP ring use clinical care should be documented in facility-based records.
- ? Important data points to record include dates of insertion/removal, any reported side effects, reasons for removal, number of PrEP rings given to client.
-  Consult with client before documenting the PrEP ring use on handheld records to avoid unintentional disclosure to partners, family, or other household members.

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 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 the following:

Client's needs and preferences

Capacity of each service delivery setting

PrEP ring delivery settings

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

Examples of transitions may include:

Safer conception or FP → ANC

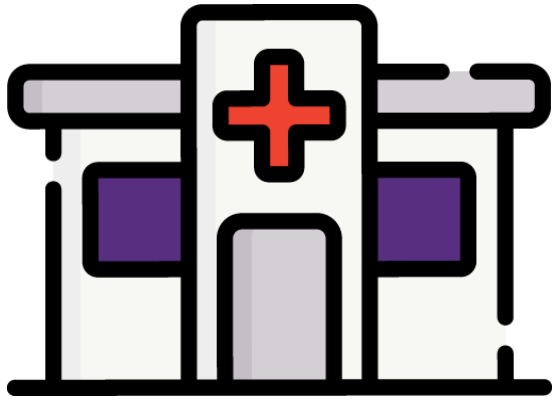
KP or AGYW* → ANC

ANC → PNC

ANC → FP

PNC → FP

PNC → Other facility or provider



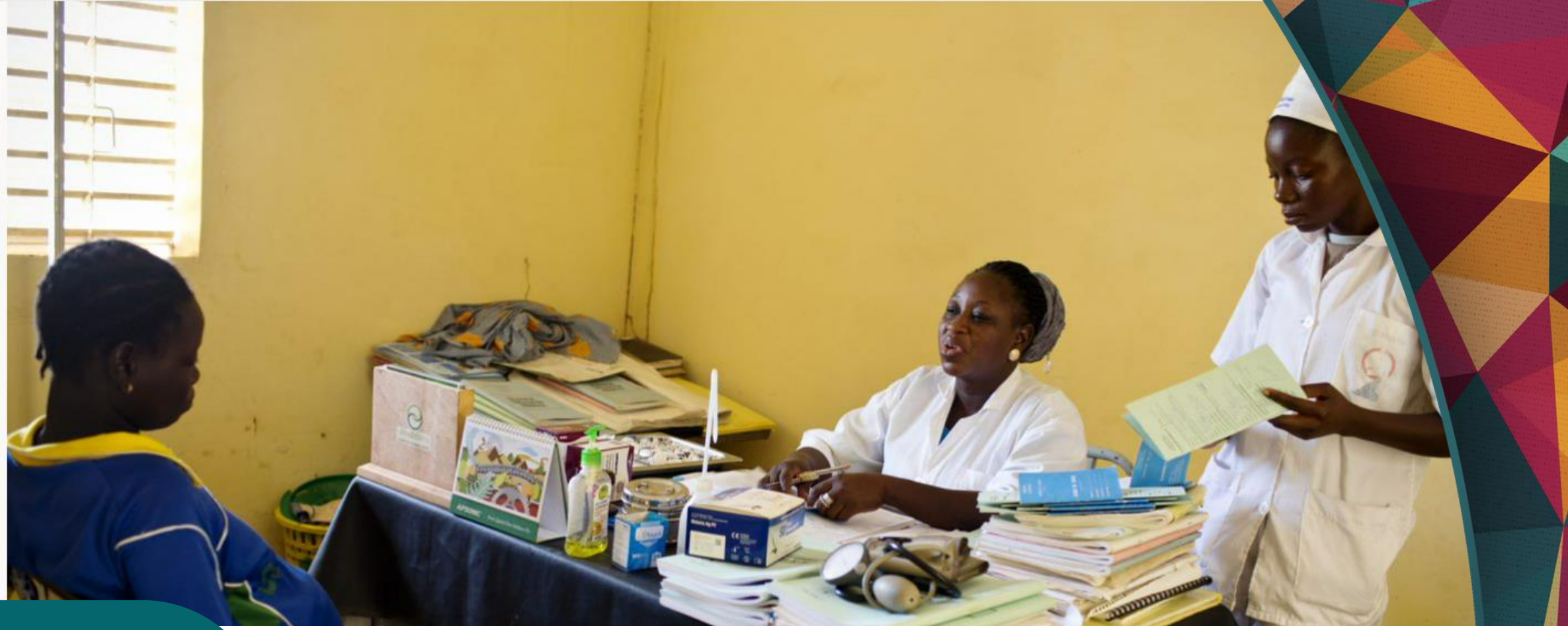
*KP: Key Population; AGYW: Adolescent Girls and Young Women

Scheduling follow-up and promoting PrEP ring continuation

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

Optimize chances for PrEP ring continuation

- Understand the client's motivations for using the PrEP ring.
- Talk to the client about potential barriers in returning to the clinic and continuing 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 PrEP rings 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 ring 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 THE PrEP RING

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

After the pregnant or breastfeeding client starts 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 their needs and integrate PrEP ring care into the client's routine ANC, PNC, or FP services.
- Monitor how the client is doing with PrEP ring use.
- Help the client to be an active partner in their care.

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

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

Family planning settings providing the PrEP ring for breastfeeding clients

FP provider should:

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

The PrEP ring has no known adverse interactions with FP methods*.

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

Managing PrEP ring side effects

As noted earlier, **PrEP ring use is generally well-tolerated** outside of and during pregnancy. However, some side effects are possible.

PrEP ring providers should address side effect 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 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 PrEP ring side effects on the next slides.

Evaluating potential side effects of the PrEP ring

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

Do a targeted physical exam.

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

Use what you know about the PrEP ring and the client's clinical status to inform your advice.

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 judgment.

*Consider other possible reasons for side effects (refer to 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 ring use	May be related to another condition, such as
Urinary frequency and pain	X	X	X	X	Urinary tract infection
Vaginal discharge	X	X		X	Vaginitis
Vulvar itching				X	Candidiasis
Pelvic and lower abdominal pain	X			X	Preterm contractions, foodborne illness

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

Starting or restarting the PrEP ring after childbirth

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.

Deciding whether to pause or stop PrEP ring use for PBFP

Before deciding to pause or stop PrEP ring use, it is important to consider whether 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 client stopped and restarted using the 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?

Continue to the suggested pathway for evaluating side effects on the next slide.

Stopping PrEP ring use due to HIV seroconversion

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

If this occurs, it is 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 healthy and prevent transmission to the baby
- ✓ Deciding whether to share the client's 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

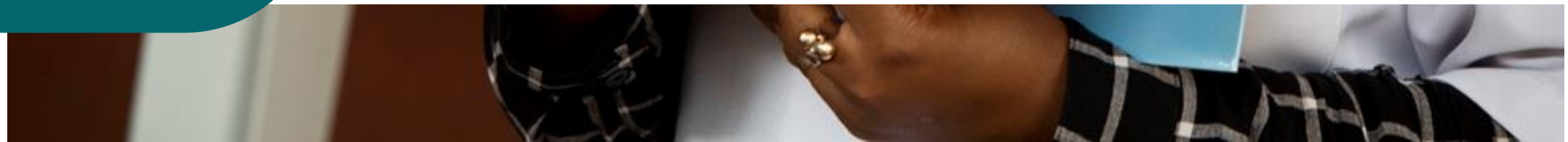
PrEP ring use while breastfeeding has not been associated with safety concerns among client's breastfeeding infants.

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

Severe abnormal signs or symptoms in an infant are unlikely to be related to maternal 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: ADDITIONAL HEALTH SERVICES AND INTIMATE PARTNER VIOLENCE



Additional HIV prevention and family planning services

Recommended services to be made available, in addition to 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 a client's sexual partners and drug injecting partners, 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.
- 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 or if the client tests positive for HBsAg.

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 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 inquiry 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, which make up the 'WHO LIVES approach,' 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 7: ACTIVE SAFETY SURVEILLANCE

Active safety surveillance

While available data indicates that use of PrEP ring among PBFP is safe, it is good practice to routinely record any adverse outcomes observed with treatment in routine data management systems (HMIS). Surveillance for the following outcomes is recommended:

- 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 health management information system (HMIS); 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 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

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MODULE 8: KEY MESSAGES

Key messages

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

- PrEP ring providers should feel comfortable:
  - Providing key counseling messages.
  - Monitoring continued safety of PrEP ring use.
  - Managing common PrEP ring side effects.
  - Ensuring that clients receive other key services (e.g., FP and IPV).

You have completed this course. Thank you!

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