Providing Oral PrEP to Pregnant and Breastfeeding People

TRAINING COURSE PRESENTATION

FEBRUARY 2023

PEPFAR

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MOSAIC
Maximizing Options to Advance Informed Choice for HIV Prevention

Introduction and Purpose

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

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

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

At the end of this session…

- Learners will be able to state:

1. The rationale for prescribing oral PrEP to PBFP
2. Key actions to take before prescribing oral PrEP
3. Counseling messages and techniques for PBFP
4. How to address common oral PrEP side effects and monitor continued safety of oral PrEP
5. Important additional services for PBFP using oral PrEP

MODULE

USE OF ORAL PrEP FOR PBFP

The World Health Organization (WHO) recommends oral PrEP!

- **WHO supports** provision of oral PrEP to PBFP who are at continuing substantial risk of acquiring HIV.
- “Oral pre-exposure prophylaxis (PrEP) containing tenofovir disoproxil fumarate (TDF) should be offered as an additional prevention choice for pregnant women at substantial risk of HIV infection as part of combination prevention approaches.”

World Health Organization

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

Background

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

Due to:

- Biological factors
- Social factors
- Behavioral factors

- It is harder 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 oral PrEP screening, delivery, and management.

Oral PrEP appears safe for PFBP

- The most common oral PrEP regimen is a tablet containing emtricitabine and tenofovir (FTC/TDF).
  - Some countries use TDF + lamivudine (3TC) for oral PrEP.
- Exposure to TDF, FTC, and 3TC during pregnancy among women with HIV is safe and well-tolerated.
- No worsening of pregnancy or perinatal outcomes is associated with oral PrEP exposure.
- Oral PrEP is well tolerated by breastfeeding people and infants.
- Oral PrEP is also effective for HIV prevention, even if the PBFP client may also be using injection drugs.
- Side effects are typically mild and resolve for both users and infants in 2 to 3 days.
- The amount of the oral PrEP drug that passes into milk has been shown to be very low.

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

- **Lamivudine (3TC)** is a medication (nucleoside analog) used for HIV treatment, in combination with other antiretroviral drugs.
- Studies have not shown adverse effects in infants exposed in utero:
  - 3TC exposure during pregnancy was not associated with adverse outcomes in **growth, hearing, language, neurodevelopment, metabolic, hematologic/clinical chemistry,** or **blood lactate.**
  - Fewer spontaneous abortions and preterm births are associated with 3TC-containing regimens in the context of HIV treatment.
  - Hepatitis B virus (HBV) flare may occur if 3TC is stopped in a person who has acquired HBV; similar risk of flare exists for those stopping TDF.
  - 3TC and TDF use is not a contraindication for those with hepatitis B, but hepatitis B treatment needs (and prevention of perinatal transmission) should be addressed for those using 3TC- or TDF-containing oral PrEP.

Oral PrEP side effects are generally mild

- 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.

For most users, gastrointestinal symptoms typically resolve within the first few weeks of use. People with Hepatitis B (HBV) who stop taking oral PrEP that contains TDF and/or 3TC may have a worsening of HBV.

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

Oral PrEP is compatible with other medicines

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

Medications listed on the next slide.

Medications commonly prescribed during pregnancy and the postnatal period include:

- Iron and folic acid tablets
- Multiple micronutrient supplements or other prenatal vitamins
- Penicillin
- 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
- 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.*

MODULE 2

BEFORE PRESCRIBING ORAL PrEP

Who is a good candidate for oral PrEP?

- In settings of high HIV incidence, **all HIV-negative PBFP** should be considered candidates for oral PrEP, unless individual clinical contraindications exist.
  - Further guidance available in WHO Implementation tool for pre-exposure prophylaxis (Oral PrEP) of HIV Infection Module 1.

Consider oral PrEP for a wide range of clients

This may include:

- Routine ANC and postnatal (PNC) clients;
- Clients taking oral PrEP who subsequently become pregnant.
- Clients who may access oral PrEP through facility or community-based oral PrEP delivery programs.
- 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 6 months, not virally suppressed, or viral suppression status unknown

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.

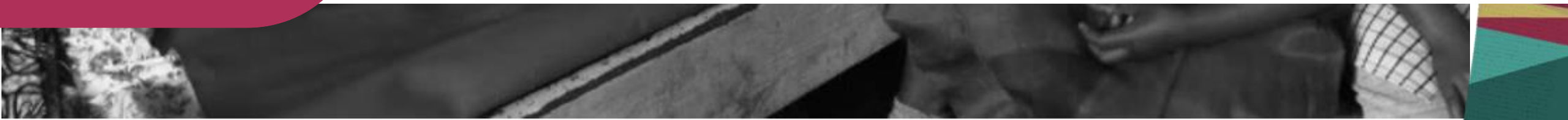
- A positive HIV test result according to the national HIV testing algorithm
- Known exposure to HIV in the past 72 hours (because such clients may derive more benefit from post-exposure prophylaxis (PEP) if the potential for HIV exposure was high)
- Signs of acute HIV infection AND potential exposure within the past 14 days (covered in Module 4)
- Creatinine clearance of less than 60 ml/min
- Allergy to any medicine in the oral PrEP regimen
- Unable to commit to attend scheduled visits and take oral PrEP as directed

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.

MODULE 3

COUNSELING ON USE OF ORAL PrEP FOR PBFP



Counseling and communication: Important parts 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 to PBFP is more likely to be successful when person-centered services are provided.**

IOM, 2001; Afulani et al., 2017.

Discussing oral PrEP with PBFP

- Oral PrEP may be introduced in a variety of different community and facility-based contexts.

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

***Oral PrEP can be introduced in many community-based settings, but 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.**

13 Key counseling messages for PBFP *(beyond standard oral 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 use during pregnancy and the postnatal period outweigh potential risks. Taking oral PrEP is generally safer for the client and baby, compared to acquiring HIV.

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

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

Continue key counseling messages on the next slide.

13 Key counseling messages for PBFP *(beyond standard oral PrEP counseling messages)*

5 The amount of oral PrEP drug that may pass to the baby during pregnancy and breastfeeding is very small and has not been shown to cause any serious health problems for babies.

6 Oral PrEP use during pregnancy and breastfeeding has not been shown to cause babies to be too big or too small.

7 Oral PrEP has not been shown to have any impact on the ability to become pregnant in the future.

8 Oral PrEP does not prevent pregnancy or sexually transmitted infections.

9 Some people taking oral PrEP experience side effects, but they are generally mild, not dangerous, and resolve quickly.

13 Key counseling messages for PBFP *(beyond standard oral PrEP counseling messages)*

10 Oral PrEP supplies should be kept in a safe place where children cannot reach it.

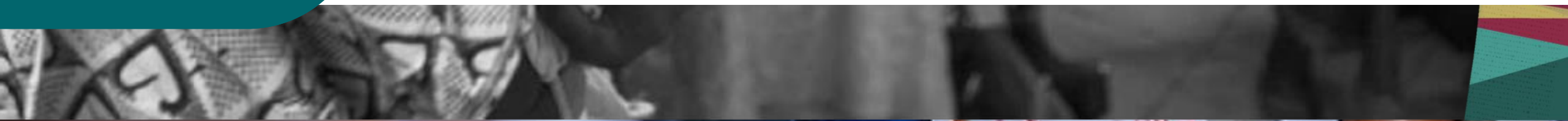
11 Exclusive breastfeeding for the first six months of life is the recommended way of feeding infants, for both clients not using PrEP and for those using PrEP, followed by continued breastfeeding with appropriate complementary foods for two years or beyond.

12 Oral PrEP has not been shown to affect a mother's milk production or the taste or quality of breast milk.

13 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 7, later in this training.)*

MODULE 4

LABORATORY TESTING, DOCUMENTATION, AND SCHEDULING FOLLOW-UP



Testing before prescribing oral PrEP

- HIV test*
- Serum creatinine* where capacity allows, to monitor kidney function
- Hepatitis B surface antigen where capacity allows
- Sexually transmitted infections, such as syphilis, gonorrhea, and chlamydia

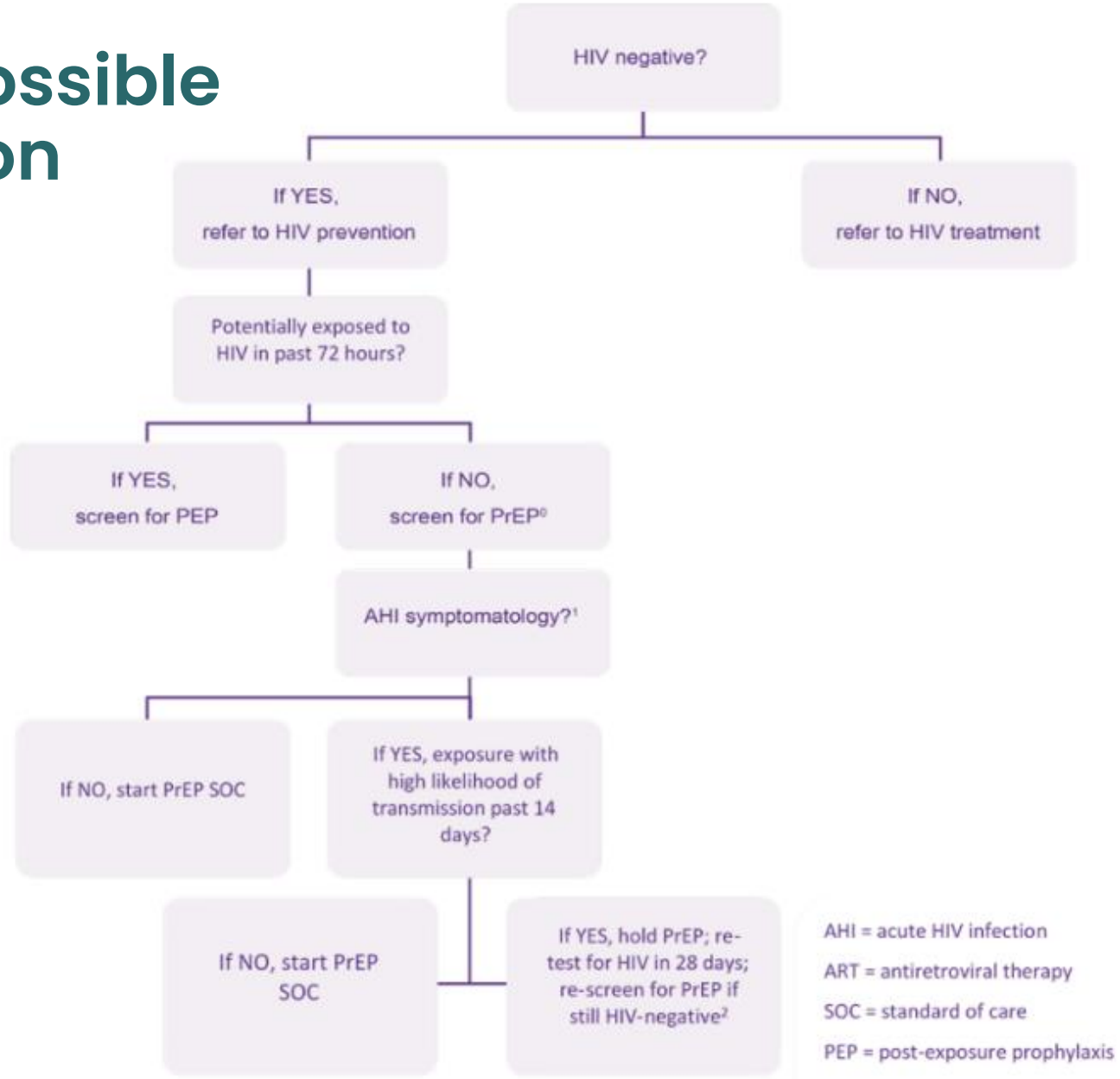
**Testing frequency should follow national guidelines. Testing for kidney function and STIs, including HBV, is covered more extensively in Modules 6 and 7.*

Rule out HIV before prescribing oral PrEP!

HIV should be ruled out by testing before prescribing oral PrEP. This is because oral PrEP is meant for people who are HIV-negative.

- Three steps to ruling out HIV infection:
  1. HIV testing should be performed the same day that oral PrEP is started using a point-of-care rapid HIV test, following national HIV testing algorithm.
  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, but instead be offered post-exposure prophylaxis (PEP). The client should then be re-tested for HIV after 28 days. Oral PrEP may be offered to clients who test negative at this point.
  3. Screening for signs/symptoms (see next slides) 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 oral 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 oral PrEP eligibility.

Document care in clinical records

- Normally, **all prescriptions would be documented** on the client's handheld ANC record as well as any relevant ANC, PNC, FP, or oral PrEP-specific facility-based records and registers.

All oral PrEP use clinical care should be documented in facility-based records.

Consult with client before documenting oral PrEP use on handheld records.

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

Scheduling follow-up and promoting oral PrEP continuation

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

Determining the best location for clients

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

Client needs and preferences

Capacity of each service delivery setting

How can clients be supported to continue to receive oral PrEP in various delivery settings?

- Clients should be **supported to continue oral PrEP** as they transition between different clinical contexts and service delivery settings.
- **Examples of transitions** may include:

Safer conception or FP	→	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*

Optimize chances for oral PrEP continuation

- Understand the client's motivations for taking oral PrEP.
- Provide client with a supply of oral PrEP that will last beyond the time of their next recommended visit or community-based contact.
- Talk to the client about potential barriers in returning to the clinic and continuing oral PrEP, as well as ways they might overcome these barriers.
- Ask about partner reactions and strategies to communicate about oral PrEP with partners who are not supportive.
- Address intimate partner violence, if present (see Module 7).
- Provide anticipatory counseling to help the client manage side effects.
- Help the client identify an existing habit with which to “couple” taking oral PrEP.
- Help the identify a trigger to remind them to take their oral PrEP (e.g., a specific radio show, children leaving for school, etc.).
- Assist the client to set up a reminder on their phone, if they have one, with a message they find personally motivating (e.g., My baby is healthy and so am I!).

MODULE 5

SUPPORTING CONTINUED USE OF ORAL PrEP

Integration of oral PrEP into care for pregnant and breastfeeding clients

- After the pregnant or breastfeeding client starts oral PrEP, 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 oral PrEP care into the client's routine ANC, PNC, or FP services.
  - Monitor how the client is doing on oral PrEP.
  - Help the client to be an active partner in their own care.

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

Family planning settings providing oral PrEP for breastfeeding clients

- In general, clinical guidance is the same for breastfeeding clients receiving oral PrEP services in PNC and FP settings.
- 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.

Oral PrEP drugs have no known adverse interaction with family planning methods.

Managing oral PrEP side effects

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

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

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

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

Continue to evaluation of possible Oral PrEP side effects on the next slide.

Possible oral PrEP 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 oral 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
Mild abdominal pain or cramping	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		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

Testing kidney function during pregnancy

- Where capacity allows, **serum creatinine testing** is recommended to monitor kidney function for oral PrEP users who are pregnant, with a repeat test per national guidelines. 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

- 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 pregnant clients**, kidney function rapidly returns to pre-pregnant levels soon after delivery.
- **For breastfeeding oral PrEP clients**, monitor serum creatinine after the start of oral PrEP per national guidelines.

More frequent monitoring may be warranted if there are comorbid conditions that can affect renal function, such as diabetes mellitus and hypertension.

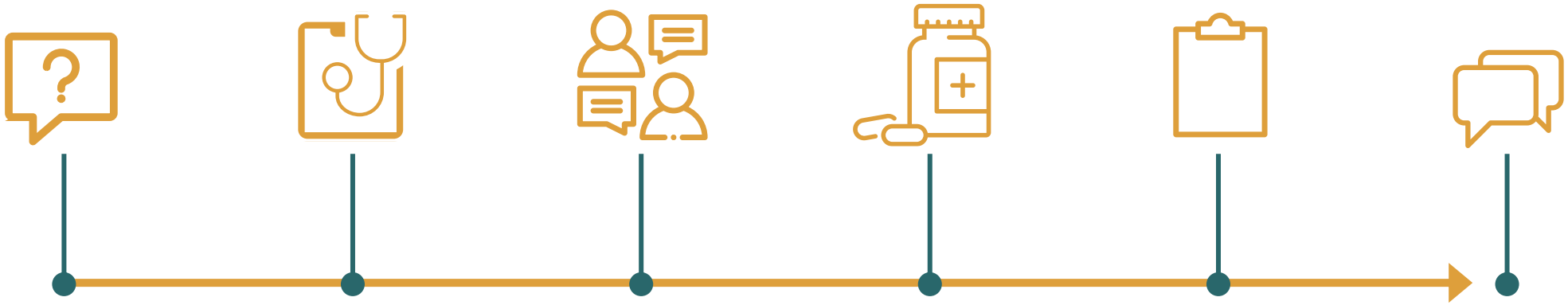
*WHO and Jhpiego have developed an app to access the WHO Implementation Tool for Oral PrEP of HIV infection, and a free creatinine clearance calculator is available within **this app**.*

Deciding whether to pause or stop oral PrEP use for PBFP

- Before deciding to pause or stop oral PrEP use, it is important to consider whether or not there is reasonable suspicion that a complaint was caused by oral PrEP use.
- Clinicians can consider the following guiding questions:

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

Evaluating potential side effects of oral PrEP



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

Do a targeted physical exam.

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

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

Document your care in the client's record.

Evaluate how she is doing by phone or at a follow-up visit, depending on your clinical judgment.

Stopping oral PrEP due to HIV seroconversion

- It is possible that a pregnant or breastfeeding client who has been prescribed oral PrEP will experience HIV seroconversion.
- 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 results with others, especially a partner, so they can also get tested

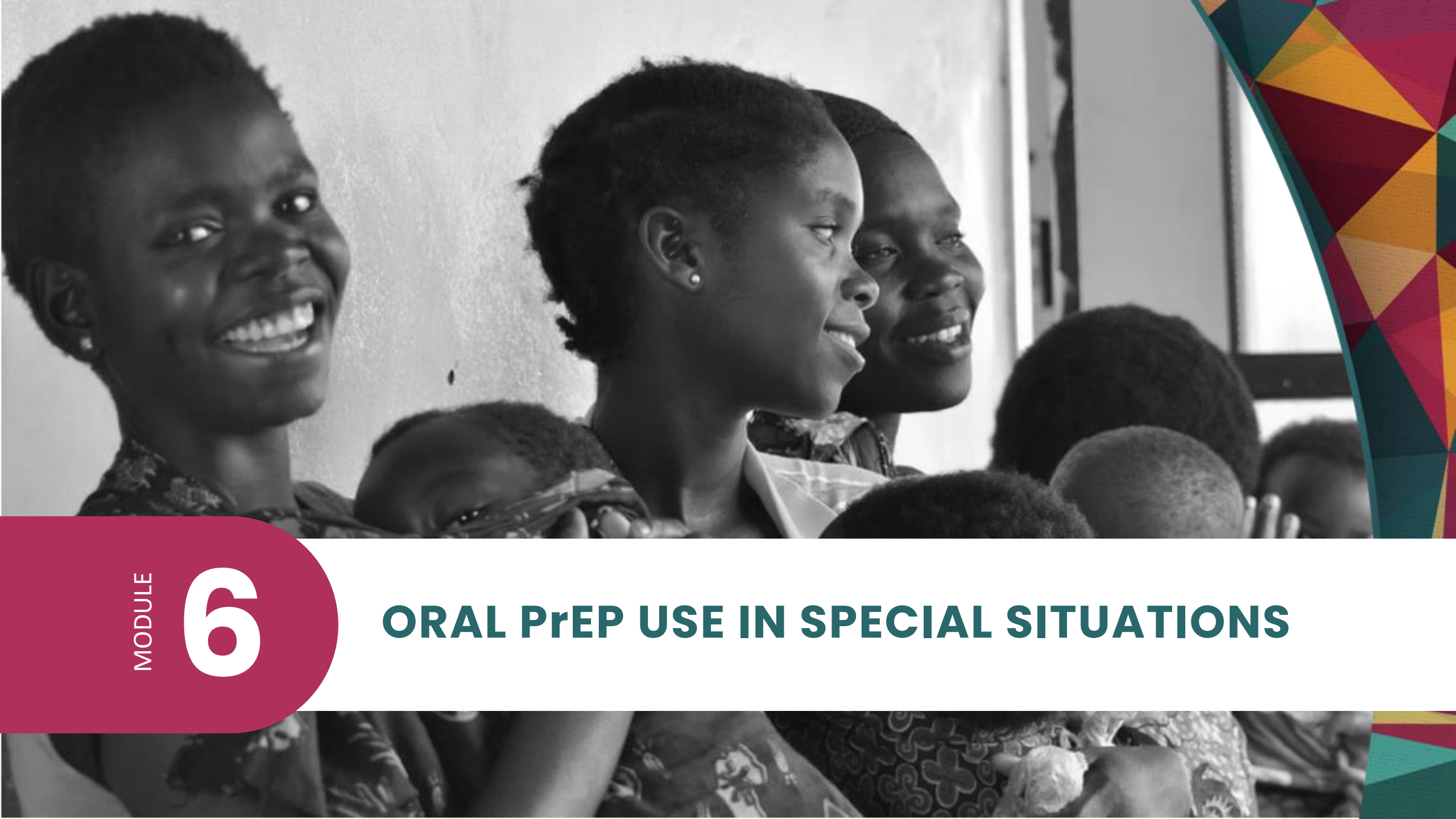
Start client on recommended antiretroviral therapy as soon as possible after a confirmed positive HIV test result. *Confirm the client's reactive rapid test result.

Additional information can be found in national guidelines for prevention of mother-to-child transmission of HIV infection.

Evaluating potential problems in breastfeeding infants

- **Oral PrEP use during breastfeeding** has not been associated with safety concerns among their breastfeeding infants.
- When assessing whether a finding might be related to the client's oral PrEP use, providers can consider the guiding questions previously noted in the section, *Deciding whether to pause or stop oral PrEP use for PBFP*.

Severe abnormal signs or symptoms in an infant are unlikely to be related to maternal oral PrEP 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.



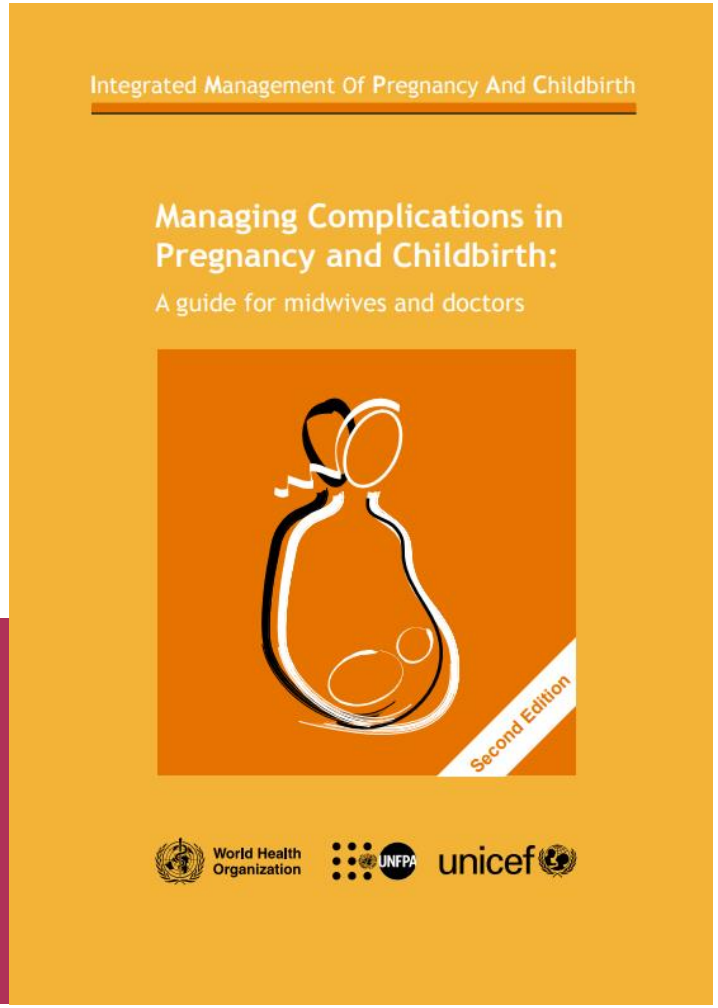
MODULE 6

ORAL PrEP USE IN SPECIAL SITUATIONS

Oral PrEP use in women with hypertensive disorders during pregnancy

- It is prudent to **avoid prescribing oral PrEP** in 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

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

Review managing oral PrEP use on the next slide.

Managing oral PrEP use

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: • Systolic blood pressure (SBP) >140 and/or diastolic blood pressure (DBP) >90 after 20 weeks of gestation • Proteinuria 2+ on dipstick • 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: • SBP > 160 and/or DBP >110 after 20 weeks of gestation • Proteinuria 2+ on dipstick Pre-eclampsia with any of the following present is severe pre-eclampsia: • Neurologic: headache, vision changes, hyperreflexia or clonus • Pulmonary: difficulty breathing (rales on auscultation due to fluid in lungs) • Hepatic: upper abdominal pain, nausea/vomiting or liver enzymes elevated (>2 times the baseline) • Renal: serum creatinine >1.1mg/dL or doubling of baseline, oliguria (<40 cc urine in 24 hours) • 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. 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. Clients with pre-eclampsia may begin oral PrEP after birth if kidney function remains normal, or when kidney impairment resolves.

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 clients 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

MODULE 7

ADDITIONAL HEALTH SERVICES AND INTIMATE PARTNER VIOLENCE (IPV)

Additional HIV prevention and family planning services

- Recommended services to be made available, in addition to oral PrEP:
  - 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/or drug injecting partner(s). Refer partners with positive test results for immediate antiretroviral therapy services.
  - Refer male sexual partners to voluntary medical male circumcision.
  - Screen for and treat STI according to local guidance and offer the same to sexual partners.
  - Offer male and female condoms and counsel on correct and consistent use.
  - Offer clients with 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 which may include:
  - 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.

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 sites should conduct routine enquiry for IPV with all clients. Disclosure of violence is not a contraindication for PrEP use.
  - *Clinical and 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.*

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*

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

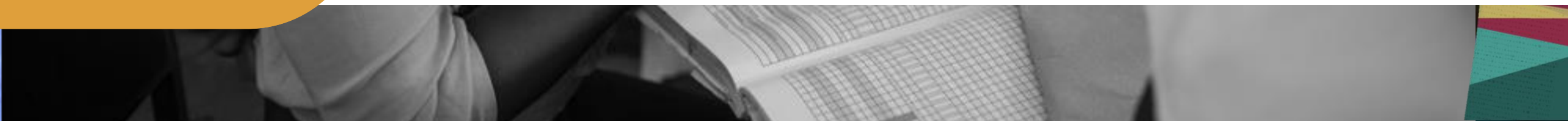
- All community-based programs delivering HIV or IPV prevention activities must ensure that facilitators are trained so they can respond appropriately to someone who discloses violence.
- **First-line support goals**, which make up the *WHO LIVES Approach*, include:

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.*

MODULE 8

ACTIVE SAFETY SURVEILLANCE



Active safety surveillance

- While available data indicate that use of oral PrEP among PBFP is safe, the WHO recommends active surveillance of adverse outcomes including:
  - 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 use during pregnancy and breastfeeding.
- **Register Page** - Includes a shorter list of variables 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
- Surveillance Register

MODULE 9

KEY MESSAGES

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

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

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