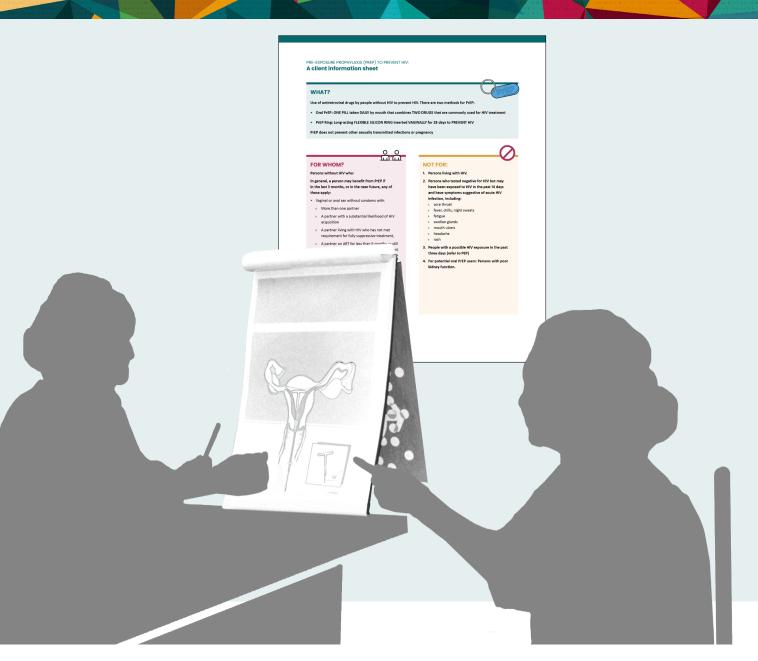
Resources for Providing PrEP in Family Planning Settings



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BACKGROUND

Why integrate pre-exposure prophylaxis (PrEP) into family planning services (FP)

Integration of PrEP services into voluntary FP programming may help to better meet the sexual and reproductive health (SRH) needs of FP clients and increase client satisfaction. Family planning services are well established and well utilized by sexually active clients and their partners who rely on FP providers to help them make voluntary and informed decisions about their SRH, plan if and when to have children, and decide how to prevent sexually transmitted infections (STIs), including HIV. Well established FP services with trusted providers offer a natural synergy for integrating PrEP services for clients who may need to prevent HIV in addition to pregnancy. While many FP clients may be women and girls of reproductive age, clients may also include other people who can become pregnant such as transgender or nonbinary individuals of reproductive age, as well as men. In this publication, references to FP clients include all these populations. This package covers daily oral PrEP and the dapivirine vaginal ring (PrEP ring). A future version will include injectable cabotegravir for PrEP (CAB PrEP).

When offering PrEP in FP settings, health providers/ managers should consider the following to provide safe, effective, timely, efficient, accessible, and equitable services:

- Provide all clients with appropriate and efficient integrated care based on their needs and, if any component of the full package of care is not available onsite, make a referral to a site that can accommodate their needs.
- Assess the flow of services and address any potential bottlenecks to efficient service delivery such as provider availability and competencies, record keeping, data collection and reporting, follow-up requirements, referral processes, and drug dispensing.
- Identify opportunities to synergize services:
 - » Integrate community- and facility-based demand creation efforts to raise awareness and pre-position clients to be ready to make informed decisions about the care they need.
 - » Expand client education and counseling to include HIV prevention counseling and testing and PrEP screening.
 - » Integrate sharing information about PrEP into FP community-based delivery and outreach activities.
 - » Support policies for multi-month drug dispensing of PrEP and contraceptive methods, when applicable, and coordinate resupply visits when appropriate and feasible; for example, allow clients to pick up a

multi-month resupply of short-acting contraceptive methods (subcutaneous injectables, oral contraceptives, emergency contraceptive pills) and PrEP from the same provider or pharmacy or pick-up PrEP refills during return visits for contraceptive reinjection.

When offering PrEP in FP settings, FP policy makers, program managers, and providers should consider the following to provide high quality care to clients for both services:

- Implement adolescent-responsive services to integrate young people's preferences into programming so that their needs for FP and PrEP can be appropriately addressed.
- Provide training, mentoring, and supportive supervision to FP providers offering integrated PrEP/FP services, including:
 - » Interpersonal communication and services free of biases, stigma, or discrimination against clients based on a person's age, gender identity, disability, participation in sex work, or injection use behaviors
 - » Integrated counseling that addresses voluntary informed choices of approaches to prevent pregnancy, HIV and other STIs
 - » Screening for gender-based violence (GBV) and intimate partner violence (IPV) and offering firstline support and, when applicable, referrals for additional services
 - » HIV testing and PrEP screening within a routine FP visit

- » PrEP initiation and follow-up (if available onsite).
- Provide standard operating procedures and job aids for offering integrated PrEP/FP services.

The job aids in this publication were developed to facilitate integration of PrEP into FP services by giving FP providers practical guidance on PrEP eligibility assessment, key informed choice counseling messages about PrEP, and initiation of PrEP for clients who are eligible and want to use it.¹

Other resources:

Actions for improved clinical and prevention services and choices: preventing HIV and other sexually transmitted infections among women and girls using contraceptive services in contexts with high HIV incidence. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Daily oral PrEP, event-driven PrEP, and PrEP ring template guidelines 2022. MOSAIC Project.

<u>Guidelines on long-acting injectable cabotegravir for HIV prevention. Geneva: World Health Organization.</u> 2022. Licence: CC BY-NC-SA 3.0 IGO

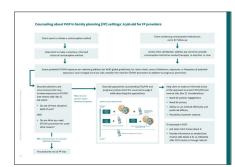
<u>Family Planning for Adolescents and Women at High Risk of HIV</u> (new chapter, 2021 from *Family Planning: A Global Handbook for Providers* <u>www.fphandbook.org</u>).

Integration of HIV testing and linkage in family planning and contraception services: implementation brief. World Health Organization, 2021. License: CC BY-NC-SA 3.0 IGO

¹ The materials in this collection have been adapted from job aids developed under the Envision FP project, initially for specifically oral PrEP and FP.

Overview of Resources for Providing PrEP in Family Planning Settings

1. Counseling about PrEP in family planning (FP) settings: A job aid for FP providers



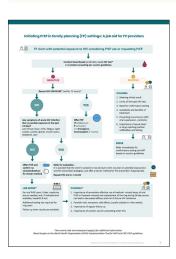
This four-page job aid can be used in all FP settings offering PrEP, including those where clients are counseled about PrEP, but PrEP initiation is offered through referral only.

AUDIENCE: Family planning providers.

PURPOSE: The job aid helps FP providers to incorporate assessment of STI/HIV exposure based on individual circumstances while integrating discussion of preventive approaches into the natural flow of an FP visit. It guides providers to assist new and returning FP clients to assess their potential exposure to HIV and

other STIs and make an informed decision about which combination of options—contraceptive method, condoms, PrEP—best suits their needs. It also includes key counseling messages on PrEP to share with clients who are considering PrEP use. After establishing the need/interest in PrEP, PrEP should be offered either through referral or on site (using the job aid for initiating oral PrEP below).

2. Initiating PrEP in family planning (FP) settings: A job aid for FP providers



This two-page job aid is intended for FP settings where providers offer a full range of PrEP services, including PrEP initiation by method. In these settings, providers should use the job aid above first and continue with this one.

AUDIENCE: Family planning providers who can initiate PrEP within an FP setting.

PURPOSE: A decision tree to guide providers through the step-by-step process of establishing PrEP eligibility and initiating PrEP for interested clients. Includes recommendations on HIV testing and other lab work to support safe use of PrEP. It contains key counseling messages for clients who decide to use PrEP.

3. Pre-exposure prophylaxis (PrEP) to prevent HIV: A client information sheet

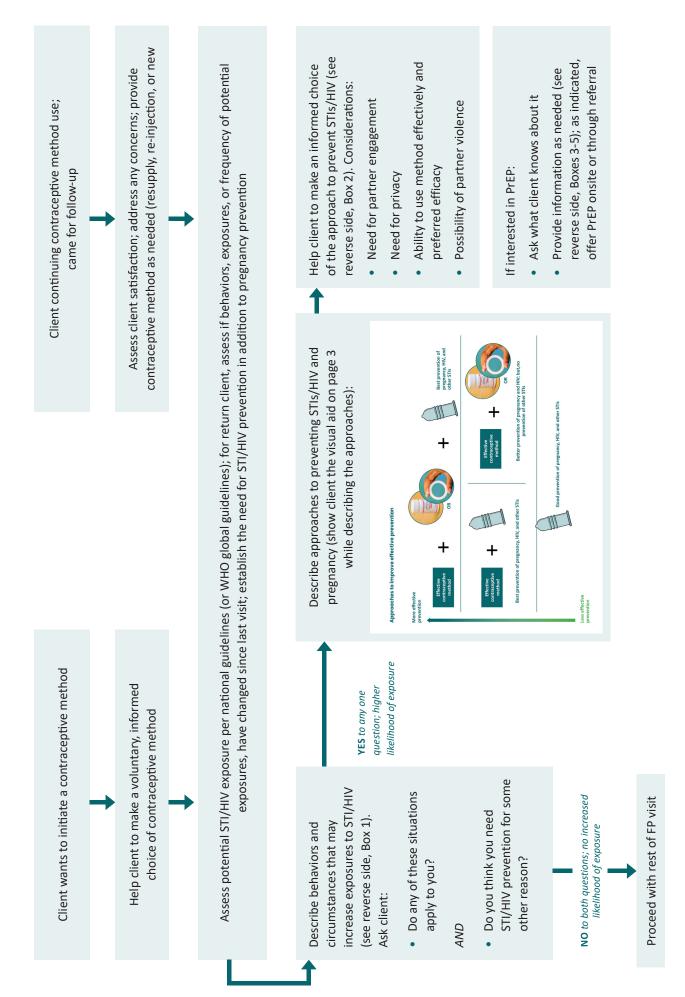


This poster or one-page flyer can be made available to clients in the waiting area or during counseling sessions.

AUDIENCE: Family planning clients interested in learning more about available PrEP methods.

PURPOSE: A resource for clients interested in learning more about PrEP. It includes basic information about what PrEP is; what different PrEP methods are; who can and should not use these PrEP methods; a summary of possible effects associated with PrEP methods; a reminder of PrEP safety, as well as for contraceptive users and pregnant and breastfeeding clients; and the tests that are required and recommended before PrEP can be initiated.

Counseling about PrEP in family planning (FP) settings: A job aid for FP providers



Box 1: Use national guidelines (where available) to assess likelihood of STI/HIV exposure

In general, a person may benefit from PrEP if in the last 3 months, or in the near future, any of these apply:

- Vaginal or anal sex without condoms with:
 - » More than one partner
 - » A partner with a higher likelihood of HIV exposure
 - » A partner living with HIV who has not met requirement for fully suppressive treatment A partner on ART for less than 6 months or still has a high viral load (or viral load is not known)
- Having an STI (based on lab test, syndromic STI treatment, or self-report)
- Post-exposure prophylaxis (PEP) use
- Sharing of injection material and/or equipment
- Emergency contraceptive use (implying vaginal sex without a condom)

Box 2: Facilitate informed choice of STI/HIV prevention approaches

Questions to ask client when making an informed choice:

- If you do not know your partner(s') HIV status, would you be able to discuss it with them?
- How do you feel about talking to your partner(s) about PrEP?
- How do you feel about talking to your partner(s) about condom use?
- Do you think you and your partner(s) will have access to and be willing to use condoms every time you have sex?
- How do you think your partner(s) may feel about you using PrEP? Would they support you?
- Do you have reasons to fear a violent reaction from your partner(s)?*
- If you must hide your PrEP use from your partner(s), will you be able to use it effectively without their knowledge?
- Do you think you can and will follow dosing requirements?
 - » For oral PrEP: remember to take a PrEP pill every day?
 - » For PrEP ring: replace 28 days after insertion?

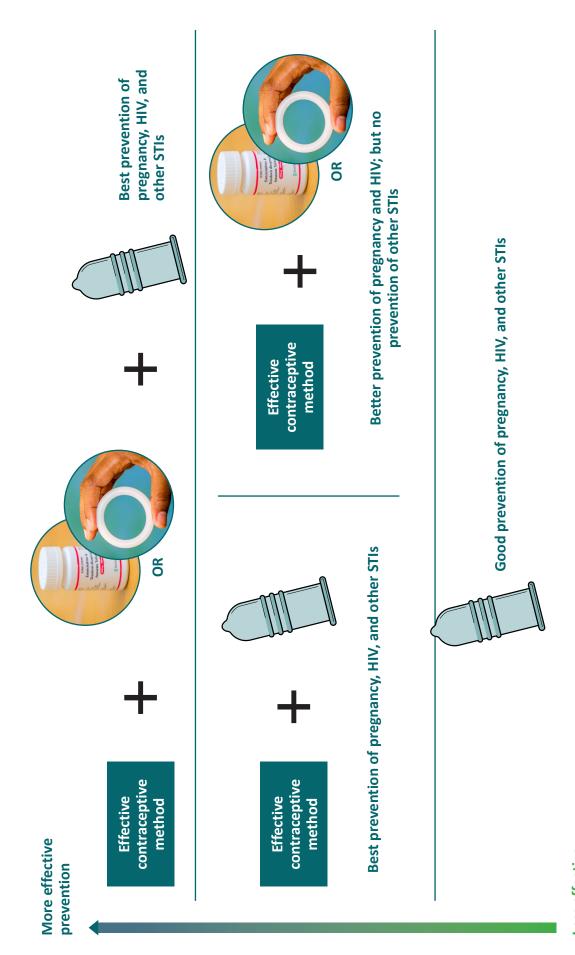
Box 3: Provide information about PrEP

Key messages:

- PrEP stands for Pre-Exposure Prophylaxis; 'pre' means before, 'exposure' means any activity or situation that can lead to HIV acquisition, and 'prophylaxis' means prevention of disease.
- Currently available PrEP methods include daily and event-driven oral PrEP and the dapivirine vaginal ring (PrEP ring or the ring). PrEP ring prevents HIV exposure during vaginal sex only, while oral PrEP prevents HIV in all potential exposure scenarios. For more information, please reference study product factsheets.
- PrEP supports individuals who may be exposed to HIV to remain HIV negative.
- A client should test negative for HIV before PrEP is started; same day testing is ideal but not always feasible or required.
- Oral PrEP can be used with all modern contraceptive methods. The PrEP ring can be used with all modern contraceptive methods except contraceptive vaginal rings.
- Oral PrEP is safe to use during pregnancy and breastfeeding. Although research is limited on PrEP ring use during pregnancy, the potential benefits of ring use during pregnancy and breastfeeding outweigh potential risks for pregnant and breastfeeding clients who cannot or do not want to use oral PrEP.
- PrEP does not make hormonal contraceptives less effective or impact fertility.
- PrEP is not for people living HIV, people with symptoms suggestive of acute HIV infection AND recent exposure. Oral PeEP is not for people with poor kidney function.
- PrEP does not prevent other STIs. Consider using condoms in addition to PrEP.

^{*}If client is at risk of or reports partner violence, provide first-line support and refer for care as needed. Clients who experience partner violence should not be prohibited from using PrEP. Providers should help them consider how to use it safely. Guidance on screening and support for PrEP clients who have experienced violence can be found at: https://www.prepwatch.org/resources/guidance-standard-operating-procedures-for-addressing-partner-relationships-and-gender-based-violence-in-pre-exposure-prophylaxis-prep-services/

Approaches to improve effective prevention



Less effective prevention

INSTRUCTIONS FOR USING THE VISUAL AID:

Approaches to improve effective prevention

An important responsibility of FP providers is helping clients decide how they can prevent pregnancy, HIV, and other STIs and what approach will work best for them. This visual aid can help explain the available options. Show the visual aid to the client when describing how various approaches provide less or more protection.

- Condoms alone effectively prevent pregnancy as well as HIV and most other STIs, but only if used consistently and correctly every time you have sex. This requires access to condoms. It also requires that your partner(s) be willing to use a condom. Unless you can negotiate condom use with every partner, every time, this approach may not provide the desired prevention. In addition, it is not as effective for pregnancy prevention as some other contraceptive methods. [Use the method effectiveness chart to discuss which methods are more effective at preventing pregnancy.]
- Using an effective contraceptive method and a condom provides better, more reliable pregnancy prevention. However, while a condom can prevent HIV/ STIs, it depends on a partner's willingness to use it and you may or may not have control over it

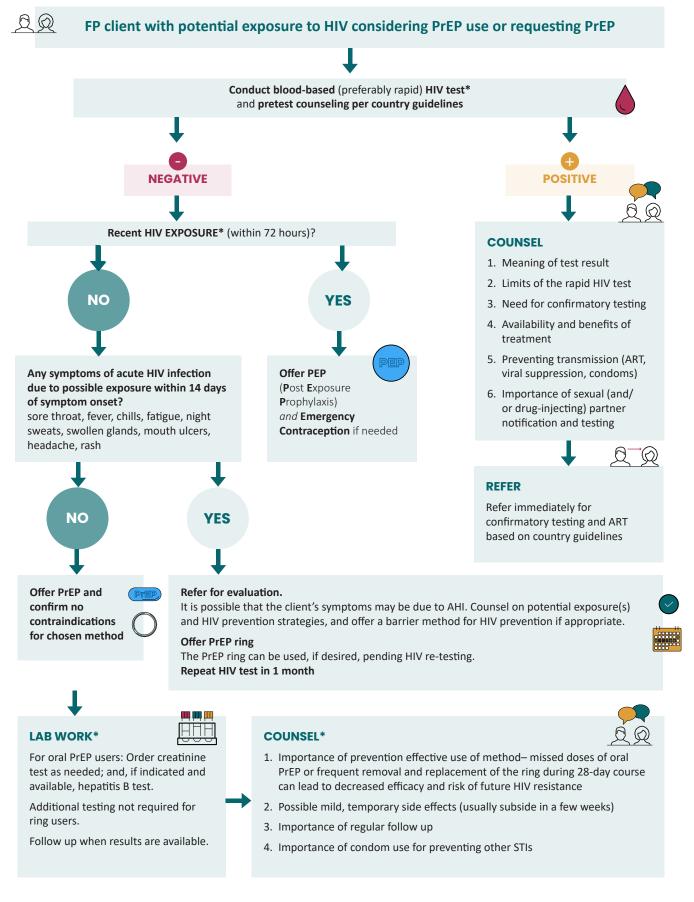
- Using an effective contraceptive method (other than a condom) and using PrEP provides better pregnancy and HIV prevention. The advantage is that you can control PrEP use for reliable HIV prevention; however, it doesn't prevent other STIs.
- Finally, using an effective contraceptive method in combination with a condom and PrEP is the most effective at preventing pregnancy, HIV, and other STIs even though reliable STI prevention still depends on your access to and partner's willingness to use a condom.

Clients who come for FP services rely on providers to create a supportive environment where they can openly discuss their concerns.

When counseling clients, focus on helping them consider what is possible for them to control given their individual circumstances and decide which approach best suits them. The questions in Box 2 on page 2 are designed to help clients consider what is possible in their individual situation. If counseling partners together, adapt the questions as needed.

Support from partners improves contraceptive continuation and may also improve correct and consistent use of PrEP—encourage partner engagement if it's possible and safe for the client.

Initiating PrEP in family planning (FP) settings: A job aid for FP providers



*See reverse side and subsequent page(s) for additional information.

Based largely on the World Health Organization (WHO) Implementation Tool for PrEP and CDC PrEP guidelines.

ADDITIONAL GUIDANCE and KEY MESSAGES

Testing for HIV

Negative blood-based HIV test result should (ideally) be obtained on the day that PrEP is started.

- If test result is inconclusive, defer PrEP, refer for confirmatory test following the national guidelines, and provide risk-reduction counseling.
- If the client has symptoms suspicious for acute HIV infection due to possible HIV exposure within 14 days of symptom onset, defer PrEP, refer for evaluation if needed, and repeat rapid HIV test in one month.

Recent HIV Exposure

Counsel that post-exposure prophylaxis (PEP) can prevent HIV if taken within 72 hours of possible exposure. Explain that:

- PEP is a regimen of anti-retroviral (ARV) medications taken for a period of 28 days.
- Blood-based HIV test will be repeated after PEP regimen is completed and if negative, PrEP can be started immediately.

If needed, offer emergency contraception (EC). Reassure that EC remains safe and effective if taken with PEP.

In cases where clients have screened positive for GBV during FP counseling prior to PrEP counseling, provide LIVES where indicated.

Supportive tools for routine enquiry can be found here.

Lab Work for PrEP Users

Monitoring Kidney Function

For PrEP ring users: Kidney function measurement is not necessary for use of the PrEP ring.

For oral PrEP users: Counsel that a very small number of people may not be able to use PrEP because they have problems with their kidneys.

- If available test for kidney function (creatinine clearance). It is not required on the day of oral PrEP initiation but should ideally be done within 1-3 months of taking PrEP in clients 30 years and older, and those younger than 30 but with health conditions that may affect kidney function (e.g., diabetes, hypertension).
- When referring/sending blood for testing, provide a
 record of the client's age, weight, and sex assigned
 at birth or gender identify if taking hormones over
 a specific threshold (for transgender persons, use
 sex assigned at birth unless more than 3 months on
 hormone therapy) so creatinine clearance can
 be calculated.
- Those with a creatinine clearance <60ml/min should undergo a repeat test on a different day and stop oral PrEP if creatinine clearance confirmed to be <60ml/ min. If creatinine clearance normalizes within 1-3 months, PrEP can be restarted.

Assessing for Chronic Hepatitis B and C Viruses (HBV, HCV)

Ask if the client was ever diagnosed with chronic HBV or HCV.

- If yes, explain that it is safe for people with chronic HBV or HCV to use PrEP, but they may experience flare-ups of the infection after PrEP is stopped if they are taking oral PrEP.
 - » If HBV or HCV status is unknown and testing is available, consider HBV or HCV testing:
 - » If tested negative for HBV surface antigen (HBsAg), offer HBV vaccination.
 - » If HBsAg or HCV positive, chronic infection is likely. Refer for clinical assessment/HBV/HCV management.
- Offer PrEP regardless of HBV or HCV status or if HBV or HCV status is unknown and testing is unavailable.

Key Counseling Messages for PrEP Initiation

- PrEP is the use of antiretroviral drugs by people without HIV to prevent HIV. There are currently two PrEP methods available: oral pills and a vaginally inserted ring.
- PrEP is not immediately effective. Use additional preventive approaches (e.g., condoms, abstain from vaginal or anal sex) for the first 7 days of taking oral PrEP and the first 24 hours after ring insertion. You can engage in safe oral sex and/or mutual masturbation.
- You should take PrEP for as long as you feel you may be exposed to HIV. Some people need to take PrEP only during certain times in their lives, while others have an ongoing need to use PrEP.
- Taking PrEP while you are using alcohol or other recreational drugs will not hurt you, but they might make it challenging to use PrEP (and potential contraceptive method of choice) correctly, so plan to continue using PrEP effectively if you use alcohol or other substances.
- PrEP does not prevent pregnancy or any STIs other than HIV.
- It is okay to start one PrEP method now and decide later that you want to use another PrEP method or another HIV prevention strategy. Many people switch between methods as their needs change
- You can stop PrEP anytime you feel there are no more
 potential exposures to HIV. To stop oral PrEP safely, you
 should continue taking PrEP for 7 days after your last
 possible exposure to HIV. To stop the PrEP ring, remove
 and discard.
- Regardless of potential exposure, clients should be screened for GBV and IPV.

Oral PrEP

- If you forget to take a PrEP pill, take it as soon as you remember. Missing pills may decrease PrEP efficacy and increase the risk of HIV becoming resistant to some HIV treatment regimens (if treatment is needed in the future).
- When used as prescribed, oral PrEP is more than 90% effective at preventing HIV. The PrEP ring is about 50% effective, and may be more effective with continuous use
- Daily oral PrEP prevents HIV during all types of exposures, while ED-PrEP prevents HIV during sexual exposures. The PrEP ring only prevents HIV during receptive vaginal sex. When choosing a PrEP method, it

- is important to consider which method(s) will work best for you to prevent HIV acquisition during the types of exposures you anticipate, among other factors
- Taking oral PrEP with food or before going to sleep may prevent nausea. Over-the-counter pain killers can help with headaches.
- Oral PrEP can be taken with hormonal contraceptives.
- One out of 10 oral PrEP users may experience side effects including nausea, abdominal cramps, and headache These effects are mild and usually diminish within a few weeks.
- Less than 1% of oral PrEP users (1 in 200) may experience a decrease in their kidney function which requires stopping PrEP for a set period of time or indefinitely.
- Return for follow up in 1 month and every 3 months afterwards. Oral PrEP refills will be provided during these visits if you remain HIV negative, based on national guidelines.

PrEP Ring

- The PrEP ring can be used with most hormonal contraceptives and barrier methods, though using the ring with a diaphragm or contraceptive vaginal ring is not recommended.
- If PrEP ring users experience side effects, they are mild and can include urinary tract infections, vaginal discharge, vulvar itching, and/or pelvic and lower abdominal pain. Side effects can usually be treated without need to remove the ring. PrEP ring users should contact their health care provider if they have any reproductive tract changes to ensure no treatment is needed.
- The PrEP ring is designed to be in place for a full month without being removed. It should remain in place during menses and sex. However, if you decide to remove the ring, it is important to clean it and insert it again as soon as possible.
- Although it is unlikely, it is possible that the ring may
 fall out. If this happens in a clean location, the PrEP ring
 should be rinsed in clean water and reinserted. If the
 PrEP ring falls out in a dirty location, the ring should be
 replaced with a new ring as soon as possible. Although
 it is unlikely, it is possible that a sexual partner may feel
 the PrEP ring during sex. If this happens, use your finger
 to push the ring further into the vagina, as it may not
 be fully in place.

A client information sheet

WHAT?



Use of antiretroviral drugs by people without HIV to prevent HIV. There are two methods for PrEP:

- . Oral PrEP: ONE PILL taken DAILY by mouth that combines TWO DRUGS that are commonly used for HIV treatment
- Prep Ring: Long-acting FLEXIBLE SILICON RING inserted VAGINALLY for 28 days to PREVENT HIV

PrEP does not prevent other sexually transmitted infections or pregnancy



FOR WHOM?

Persons without HIV who:

In general, a person may benefit from PrEP if in the last 3 months, or in the near future, any of these apply:

- Vaginal or anal sex without condoms with:
 - » More than one partner
 - » A partner with a substantial likelihood of HIV acquisition
 - » A partner living with HIV who has not met requirement for fully suppressive treatment
 - » A partner on ART for less than 6 months or still has a high viral load (or viral load is not known)
- Having an STI (based on lab test, syndromic STI treatment, or self report)
- Post-exposure prophylaxis (PEP) use
- Sharing of injection material and/or equipment
- Emergency contraceptive use (implying vaginal sex without a condom)

...and are willing to use PrEP and return for follow-up visits.



NOT FOR:

- 1. Persons living with HIV.
- Persons who tested negative for HIV but may have been exposed to HIV in the past 14 days and have symptoms suggestive of acute HIV infection, including:
 - » sore throat
 - » fever, chills, night sweats
 - » fatigue
 - » swollen glands
 - » mouth ulcers
 - » headache
 - » rash
- 3. People with a possible HIV exposure in the past three days (refer to PEP)
- 4. For potential oral PrEP users: Persons with poor kidney function.

Prep

Prep is very safe

Most PrEP users have no bothersome effects **ORAL PrEP**:

- 1 in 10 may have nausea, abdominal cramps, headache (mild, usually go away on their own)
- 1 in 200 may have decreased kidney function on testing (results usually return to normal on repeat test)
- Minor loss of bone density (does not increase risk of fractures; usually returns to normal after stopping PrEP)

Prep RING:

- . Possible side effects are typically mild and usually resolve without the need to remove the ring
- Side effects include urinary tract infections, vulvar itching, pelvic and lower abdominal pain
- Urinary tract infections should be treated per standard of care

CAN BE USED SAFELY

- By hormonal contraceptive users
 - » PrEP does not reduce the effectiveness of hormonal contraceptives.
 - » Hormonal contraceptives do not reduce the effectiveness of PrEP.
 - » PrEP ring should not be used with the contraceptive ring.
- By clients who are pregnant or breastfeeding
 - » Evidence is limited for the PrEP ring but the likely HIV prevention benefits outweigh the potential risks for pregnant or breastfeeding clients who cannot or do not want to use oral PrEP.

Other tests based on availability, indication, and national guidelines:

- Blood-based HIV test (required)
- Test for kidney function (if indicated) and screen for hepatitis B and/or C (if available)

