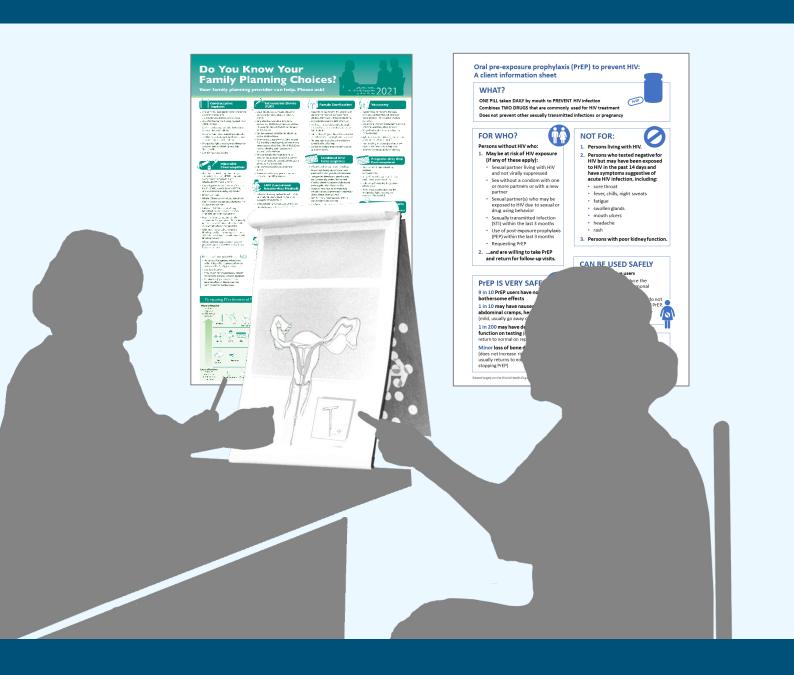
Resources for Providing Oral PrEP in Family Planning Settings









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

Integration of oral 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 acquisition in addition to pregnancy. While the majority of FP clients are cisgender women and girls, people of all genders, including cisgender men and boys and trans and gender diverse people, may access and benefit from these services.

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

- Ensure that all clients receive 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 the client's 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 and coordinate resupply visits when appropriate and feasible; for example, allow clients to pick up a multi-month resupply of short-acting contraceptive methods such as oral 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 ensure that clients for both services receive a high quality of care:

- Implement adolescent-responsive services to ensure that young people's
 preferences are integrated in the programming so that their needs for FP and PrEP
 can be appropriately addressed.
- Provide training, mentoring, and supportive supervision to FP providers offering integrated FP/PrEP 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 first-line support and referral when necessary
 - 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 FP/PrEP 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. These job aids can be branded and adapted as needed by countries and programs. The original source files for the job aids are available for download.

Other resources:

WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection. Geneva: World Health Organization; 2017-22.

<u>Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Technical Brief</u>. Geneva: World Health Organization; 2022

<u>Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach</u>. Geneva: World Health Organization; 2021.

PrEPWatch https://www.prepwatch.org/

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.

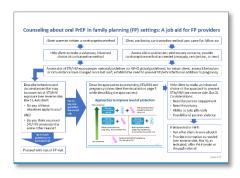
<u>Family Planning for Adolescents and Women at High Risk of HIV</u> (new chapter, 2021 from *Family Planning: A Global Handbook for Providers* <u>www.fphandbook.org</u>).

<u>Integration of HIV testing and linkage in family planning and contraception services:</u> <u>implementation brief.</u> World Health Organization, 2021

<u>Caring for women subjected to violence: A WHO curriculum for training health-care providers.</u>
Geneva: World Health Organization; 2021.

Overview of Resources for Providing Oral PrEP in Family Planning Settings

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



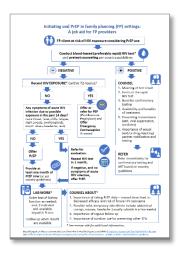
This four-page job aid can be used in all FP settings offering PrEP, including those where clients are counseled about PrEP, but PrEP initiation is offered through referral only.

Audience: Family planning providers.

Purpose: The job aid helps FP providers to incorporate assessment of STI/HIV risk based on individual behaviors and 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 risk of 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 oral 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. 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 ensure safe use of PrEP. It contains key counseling messages for clients who decide to use PrEP.

3. Oral 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.

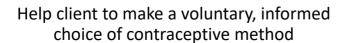
Audience: Family planning clients interested in learning more about oral PrEP.

Purpose: A resource for clients interested in learning more about PrEP. It includes basic information about what PrEP is; who can and should not use it; a summary of possible effects associated with PrEP; a reminder that PrEP is safe in general, 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 oral PrEP in family planning (FP) settings: A job aid for FP providers

Client wants to initiate a contraceptive method

Client continuing contraceptive method use; came for follow-up



Assess client satisfaction; address any concerns; provide contraceptive method as needed (resupply, re-injection, or new)



Assess risk of STI/HIV exposure per national guidelines (or WHO global guidelines); for return client, assess if behaviors or circumstance have changed since last visit; establish the need to prevent STI/HIV infection in addition to pregnancy

Describe behaviors and circumstances that may increase risk of STI/HIV exposure (see reverse side, Box 1). Ask client:

 Do any of these situations apply to you?

AND

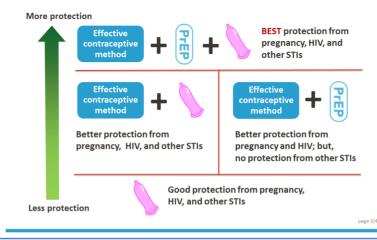
 Do you think you need STI/HIV prevention for some other reason?

No to both questions; no increased risk

Proceed with rest of FP visit

Yes to any one question; increased risk Describe approaches to preventing STIs/HIV and pregnancy (show client the visual aid on page 3 while describing the approaches):

Approaches to improve level of protection



Help client to make an informed choice of the approach to prevent STIs/HIV (see reverse side, Box 2). Considerations:

- Need for partner engagement
- Need for privacy
- Ability to take pills daily
- Possibility of partner violence



If interested in PrEP:

- Ask what client knows about it
- Provide information as needed (see reverse side, Box 3); as indicated, offer PrEP onsite or through referral

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

In general, a person who experienced any of these in the last 3 months may be at increased risk of STI/HIV exposure:

- Had sex without a condom with one or more partners:
 - whose HIV status is not known.
 - who may have been exposed to HIV due to sexual or injection drug using behavior.
- Has been diagnosed or treated for an STI or has had symptoms to indicate a possible STI.
- Has used emergency contraception (which implies sex without a condom).
- Used or wanted to use PrEP or postexposure prophylaxis (PEP) due to possible HIV exposure.
- Has shared injection drug material and/or equipment.
- Had sex without a condom with partner who has HIV and:
 - is not on antiretroviral therapy (ART).
 - is on ART but not taking medications daily.
 - has been on ART for less than six months.
 - still has a high viral load (or viral load is not known).

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 partners' HIV status, would you be able to discuss it with them?
- How do you feel about talking to your partner(s) about oral 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 taking oral 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 store and take your pills without their knowledge?
- Do you think you can remember to take a PrEP pill every day?
- * If client is at risk of, or reports partner violence, 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.

Box 3: Provide information about oral PrEP

Key messages:

- PrEP stands for **Pre-E**xposure **P**rophylaxis; prophylaxis means prevention of disease.
- PrEP allows individuals who may be exposed to HIV to remain HIV-free
- PrEP combines two different antiretroviral drugs in one pill. These are two of the same drugs that are commonly used as part of ART to treat HIV.
- To prevent HIV infection, one pill should be taken every day, even on days when the person does not have sex.
- PrEP is highly effective if taken correctly. However, 7 days of continuous use are needed for it to become effective.
- A client must test negative for HIV before PrEP is started.
- PrEP users must come for follow-up visits with a provider one month after starting PrEP and every three months thereafter. An HIV test is done during every visit.
- PrEP is safe to use during pregnancy and breastfeeding, and with contraception. PrEP does <u>not</u> make hormonal contraceptives less effective.
- For the first few weeks, PrEP may cause mild side effects such as nausea, abdominal cramps, and headaches.
- PrEP is not for people living with HIV, people with symptoms suggestive of acute HIV infection, or people with poor kidney function.
- PrEP does not prevent other STIs. Consider using condoms in addition to PrEP.
- PrEP users can stop PrEP anytime they feel there is no more risk of HIV exposure. To stop safely, continue taking PrEP for 7 days after your last possible exposure to HIV.

October 2022 page 2/4

Approaches to improve level of protection

More protection



Effective contraceptive method







BEST protection from pregnancy, HIV, and other STIs

Effective contraceptive method





Better protection from pregnancy, HIV, and other STIs

Effective contraceptive method





Better protection from pregnancy and HIV; but, no protection from other STIs



Good protection from pregnancy, HIV, and other STIs

Less protection

Instructions for using the visual aid: Approaches to improve level of protection

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 provide good protection from pregnancy as well as from HIV and other STIs, but only if used consistently and correctly every time you have sex. This requires access to condoms. It also requires that a partner be willing to use a condom. Unless you can negotiate condom use with every partner, this approach may not provide the desired protection. 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 protection from pregnancy. However, while a condom offers protection from HIV/STIs, it depends on a partner's willingness to use it and you may or may not have control over it (even if you use a female condom, partner engagement is still required).

- Using an effective contraceptive method (other than a condom) and taking a PrEP pill provides better protection from pregnancy and HIV. The advantage is that you can control how consistently you take PrEP to ensure reliable HIV protection; however, it doesn't protect from other STIs.
- Finally, using an effective contraceptive method in combination with a condom and oral PrEP provides the best protection from pregnancy, HIV, and other STIs even though reliable STI protection 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 oral PrEP in family planning (FP) settings: A job aid for FP providers



FP client at risk of HIV exposure considering PrEP use

Conduct blood-based (preferably rapid) HIV test* and pretest counseling per country guidelines







POSITIVE

Recent HIV EXPOSURE* (within 72 hours)?

YES



Any symptoms of acute HIV infection due to possible exposure in the past 14 days?

(sore throat, fever, chills, fatigue, night sweats, swollen glands, mouth ulcers, headache, rash)

NO

Offer

PrEP

_

Provide at least one month of PrEP now (or per country guidelines) YES

PEP

Offer or refer for PEP

(Post Exposure Prophylaxis) and Offer

Emergency Contraception

if needed



- 1. Meaning of test result
- 2. Limits of the rapid HIV test
- 3. Need for confirmatory testing
- 4. Availability and benefits of treatment
- 5. Preventing transmission (ART, viral suppression, condoms)
- Importance of sexual (and/or drug-injecting) partner notification and testing



Repeat HIV test in 1 month;

if negative, and no symptoms of acute HIV infection, offer PrEP.



REFER

Refer immediately for confirmatory testing and ART based on country guidelines



LAB WORK*

Order test of kidney function as needed; and, if indicated and available, hepatitis B test.

Follow up when results are available.

COUNSEL ABOUT*

- 1. Importance of taking PrEP daily missed doses lead to decreased efficacy and risk of future HIV resistance
- 2. Possible mild, temporary side effects include abdominal cramps, nausea, headache (usually subside in a few weeks)
- 3. Importance of regular follow up
- 4. Importance of condom use for preventing other STIs



^{*} See reverse side for additional information.

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 the past 14 days, 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.

Lab Work

Monitoring Kidney Function

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

- Test for kidney function (either creatinine clearance or estimated glomerular filtration rate [eGFR]) is not required on the day of PrEP initiation but should be done within 1-3 months of taking PrEP in clients of any age with health conditions that may affect kidney function (e.g., diabetes, hypertension) or those aged 50+ years. For clients with no kidney-related health conditions, test is optional if they are younger than 30, and optional but recommended within 1-3 months of PrEP initiation if they are aged 30-49 years.
- When referring for testing (or sending blood), provide a record of the client's age, weight, and sex (for transgender persons, use sex assigned at birth unless more than 3 months on hormone therapy) so creatinine clearance (or eGFR) can be calculated.
- Those with a creatinine clearance <60ml/min or eGFR <60mm/min per 1.73 m² should undergo a repeat test on a different day and stop PrEP if creatinine clearance is confirmed to be <60ml/min or eGFR <60mm/min per 1.73 m². If creatinine clearance (or eGFR) normalizes within 1-3 months, PrEP can be restarted.

Assessing for Chronic Hepatitis B Virus (HBV)*

Ask if the client was ever diagnosed with chronic HBV.

- If yes, explain that it is safe for people with chronic HBV to use daily PrEP, but they may experience flare-ups of the infection after PrEP is stopped.
- If HBV status is unknown and testing is available, consider HBV testing now or within 1-3 months:
 - If tested negative for HBV surface antigen (HBsAg), offer HBV vaccination.
 - If tested HBsAg positive, chronic infection is likely. Refer for assessment for HBV treatment eligibility.
- Offer PrEP regardless of HBV status or if HBV status is unknown and testing is unavailable.
- * Additionally, if a client may be at high risk of infection with the hepatitis C virus (HCV) and HCV testing is available, offer it now or within 1-3 months of PrEP initiation. Lack of HCV testing should not be a barrier to PrEP initiation or use. Oral PrEP can be safely provided to clients with HCV infection; PrEP services provide an opportunity to screen for HCV infection and provide linkages to care.

Key Counseling Messages for Oral PrEP Initiation

- PrEP is a very effective way to prevent HIV infection.
- 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 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 such treatment is needed in the future).
- One out of 10 PrEP users may experience side effects including nausea, abdominal cramps, and headache.
 These effects are mild and usually diminish within a few weeks.

- Taking PrEP with food or before going to sleep may prevent nausea. Over-the-counter pain killers can help with headaches.
- Minor loss of bone density may occur. It does not increase the risk of fractures and usually returns to normal after stopping PrEP.
- Less than 1% of 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.
 PrEP refills will be provided during these visits if you remain HIV-negative.
- You can stop PrEP anytime you feel there are no more potential exposures to HIV. To stop PrEP safely, you should continue taking PrEP for 7 days after your last possible exposure to HIV.

Oral pre-exposure prophylaxis (PrEP) to prevent HIV: A client information sheet

WHAT?

ONE PILL taken DAILY by mouth to PREVENT HIV infection
Combines TWO DRUGS that are commonly used for HIV treatment
Does not prevent other sexually transmitted infections or pregnancy



FOR WHO?

Persons without HIV who:

- May be at risk of HIV exposure (if any of these apply):
 - Sexual partner living with HIV and not virally suppressed
 - Sex without a condom with one or more partners or with a new partner
 - Sexual partner(s) who may be exposed to HIV due to sexual or drug using behavior
 - Sexually transmitted infection (STI) within the last 3 months
 - Use of post-exposure prophylaxis (PEP) within the last 3 months
 - Requesting PrEP
- ...and are willing to take PrEP and return for follow-up visits.

Prep IS VERY SAFE



- 9 in 10 PrEP users have no bothersome effects
- 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)

NOT FOR:



- 1. Persons living with HIV.
- 2. 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. Persons with poor kidney function.

CAN BE USED SAFELY

- By contraceptive users
 - PrEP does not reduce the effectiveness of hormonal contraceptives.
 - Hormonal contraceptives do not reduce the effectiveness of PrEP.
- By clients who are pregnant or breastfeeding

TESTING

Blood-based HIV test (required)

Test for kidney function (if indicated) and screen for hepatitis B (if available)