

MODULE 3

# COUNSELLORS



# WHO IMPLEMENTATION TOOL FOR PRE-EXPOSURE PROPHYLAXIS (PrEP) OF HIV INFECTION

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# Introduction

Following the WHO recommendation in September 2015 that “oral pre-exposure prophylaxis (PrEP) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches”, partners in countries expressed the need for practical advice on how to consider the introduction of PrEP and start implementation. In response, WHO has developed this series of modules to support the implementation of PrEP among a range of populations in different settings.

Although there is growing acknowledgement of PrEP’s potential as an additional HIV prevention option and countries are beginning to consider how PrEP might be most effectively implemented, there has been limited experience with providing PrEP outside research and demonstration projects in low- and middle-income countries. Consequently, there is often uncertainty around many implementation issues. The modules in this tool provide initial suggestions for the introduction and implementation of PrEP based on currently available evidence and experience. However, it is recognized that this evidence may evolve following wider PrEP use; therefore, it is likely that this tool will require regular updating.

PrEP should not replace or compete with effective and well-established HIV prevention interventions, such as comprehensive condom programming for sex workers and men who have sex with men and harm reduction for people who inject drugs. Many people who could benefit most from PrEP belong to key population groups that may face legal and social barriers to accessing health services. This needs to be considered when developing PrEP services. Although the public health approach underpins the WHO guidance on PrEP, the decision to use PrEP should always be made by the individual concerned.

## Target audience and scope of tool

This PrEP tool contains modules for a range of stakeholders to support them in the consideration, planning, introduction and implementation of oral PrEP. The modules can be used on their own or in combination. In addition, there is a module for individuals interested in or already taking PrEP. (See Summary of modules below.)

This tool is the product of collaboration between many experts, community organizations and networks, implementers, researchers and partners from all regions. The information presented is aligned with WHO’s 2016 consolidated guidelines on the use of antiretroviral drugs for HIV treatment and prevention.

All modules make reference to the evidence-based 2015 WHO recommendation on PrEP. They do not make any new recommendations on PrEP, focusing instead on suggested implementation approaches.

## Guiding principles

It is important to adopt a public health, human rights and people-centred approach when offering PrEP to those at substantial risk of HIV. Similar to other HIV prevention and treatment interventions, a human rights-based approach gives priority to issues concerning universal health coverage, gender equality and health-related rights including accessibility, availability, acceptability and quality of PrEP services.

## SUMMARY OF MODULES



**Module 1: Clinical.** This module is for clinicians, including physicians, nurses and clinical officers. It gives an overview of how to provide PrEP safely and effectively, including: screening for substantial risk of HIV; testing for HIV before initiating someone on PrEP and how to follow up PrEP users and offer counselling on adherence.



**Module 2: Community educators and advocates.** Community educators and advocates are needed to increase awareness about PrEP in their communities. This module provides information on PrEP that should be considered in community-led activities that aim to increase knowledge about PrEP and generate demand and access.



**Module 3: Counsellors.** This module is for staff who counsel people as they consider PrEP or start taking PrEP and support them in coping with side-effects and adherence strategies. Those who counsel PrEP users may be lay, peer or professional counsellors and healthcare workers, including nurses, clinical officers and doctors.



**Module 4: Leaders.** This module aims to inform and update leaders and decision-makers about PrEP. It provides information on the benefits and limitations of PrEP so that they can consider how PrEP could be effectively implemented in their own settings. It also contains a series of frequently asked questions about PrEP.



**Module 5: Monitoring and evaluation.** This module is for people responsible for monitoring PrEP programmes at the national and site levels. It provides information on how to monitor PrEP for safety and effectiveness, suggesting core and additional indicators for site-level, national and global reporting.



**Module 6: Pharmacists.** This module is for pharmacists and people working in pharmacies. It provides information on the medicines used in PrEP, including on storage conditions. It gives suggestions for how pharmacists and pharmacy staff can monitor PrEP adherence and support PrEP users to take their medication regularly.



**Module 7: Regulatory officials.** This module is for national authorities in charge of authorizing the manufacturing, importation, marketing and/or control of antiretroviral medicines used for HIV prevention. It provides information on the safety and efficacy of PrEP medicines.



**Module 8: Site planning.** This module is for people involved in organizing PrEP services at specific sites. It outlines the steps to be taken in planning a PrEP service and gives suggestions for personnel, infrastructure and commodities that could be considered when implementing PrEP.



**Module 9: Strategic planning.** As WHO recommends offering PrEP to people at substantial HIV risk, this module offers public health guidance for policy-makers on how to prioritize services, in order to reach those who could benefit most from PrEP, and in which settings PrEP services could be most cost-effective.



**Module 10: Testing providers.** This module is for people who provide testing services at PrEP sites and laboratories. It offers guidance in selecting testing services, including screening of individuals before PrEP is initiated and monitoring while they are taking PrEP. Information is provided on HIV testing, creatinine, HBV and HCV, pregnancy and STIs.



**Module 11: PrEP users.** This module provides information for people who are interested in taking PrEP to reduce their risk of acquiring HIV and people who are already taking PrEP – to support them in their choice and use of PrEP. This module gives ideas for countries and organizations implementing PrEP to help them develop their own tools.



**Module 12: Adolescents and young adults.** This module is for people who are interested in providing PrEP services to older adolescents and young adults who are at substantial risk for HIV. It provides information on: factors that influence HIV susceptibility among young people; clinical considerations for safety and continuation on PrEP; ways to improve access and service utilization; and inclusive monitoring approaches to improve the recording and reporting of data on young people.

## ANNEXES

**Review of evidence.** A wide range of evidence including the following two systematic reviews informed the 2015 WHO recommendation on PrEP for people at substantial risk of HIV infection: (i) Fonner VA et al. *Oral tenofovir-based HIV pre-exposure prophylaxis (PrEP) for all populations: a systematic review and meta-analysis of effectiveness, safety, behavioural and reproductive health outcomes*; (ii) Koechlin FM et al. *Values and preferences on the use of oral pre-exposure prophylaxis (PrEP) for HIV prevention among multiple populations: a systematic review of the literature*.

**Annotated Internet resources.** This list highlights some of the web-based resources on PrEP currently available together with the stakeholder groups they are catering to. WHO will continue to provide updates on new resources.

## The counsellors module

This module is for staff in clinical and other settings who counsel PrEP users. Those who counsel PrEP users may be lay, peer or professional counsellors and healthcare workers including nurses, clinical officers and doctors.

This module does not include information about community education; that is the focus of the module for community educators and advocates. Community education can shape awareness of and demand for PrEP, HIV testing and treatment. If people receive accurate information about PrEP in the community, counselling may support plans for effective use, for example promoting adherence in PrEP users.

### WHO Recommendation for PrEP

The World Health Organization recommends that PrEP containing tenofovir disoproxil fumarate (TDF) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches (*strong recommendation; high-quality evidence*).

PrEP as an additional prevention choice should not replace or undermine other effective and well-established HIV prevention interventions, such as condom programming and harm reduction.

### Counselling goals related to PrEP

The goals of counselling depend on whether the client is starting PrEP or is already using PrEP. Counselling may explore current sexual health and drug use protection plans and raise awareness about PrEP and other prevention strategies. Mixing sexual health education with client-centred discussion (see below) can facilitate open communication about sexual health desires, goals and plans. Counsellors can help clients develop broader plans for fertility, pregnancy prevention and sexual health, and the ways to carry out these plans without acquiring sexually transmitted infections (STIs). Counselling also plays a critical role in reducing risks associated with injecting drug use and in adopting harm reduction interventions.

Counselling for those interested in PrEP should focus on increasing awareness of PrEP as a prevention choice and helping the client to decide whether PrEP is right for them. For those who choose PrEP, counselling then continues into preparing individuals to start PrEP, explaining its use and making a specific plan for PrEP use. Also, counselling should inform PrEP users about issues such as:

- dosing requirements for greatest protection
- what to do if a dose is missed
- common adherence strategies
- the importance of ongoing monitoring while on PrEP
- side-effects and side-effects management
- how to safely discontinue and restart PrEP
- sexual health protection strategies beyond PrEP
- harm reduction for people who use drugs
- comprehensive HIV prevention planning.

For follow-up counselling, important goals are checking in on: current sexual health and/or drug use behaviours; intention to remain on PrEP; and facilitators and barriers to PrEP use. Follow-up counselling can also include problem-solving, such as addressing adherence problems and the challenges of disclosure to partner(s).

## PrEP and “seasons of risk”

People often move in and out of “seasons of risk” and “risky situations” for HIV infection.

For both antiretroviral therapy (ART) for HIV treatment and PrEP, adherence is crucial. However, adherence to ART involves lifelong therapy with daily doses. In contrast, among PrEP users, HIV exposure may be episodic. People often move in and out of “seasons of risk” and “risky situations” (1, 2). Thus, people taking PrEP will not take it all their lives. Learning how and when to start and stop PrEP is key to its effective use (3). PrEP counselling creates an opportunity for PrEP

users and their counsellors to recognize situations that may involve exposure to HIV and to use appropriate and effective prevention strategies, including PrEP.

Triggers or specific situations that may prompt a person to consider starting PrEP include sex without a condom (planned or experienced), diagnosis of an STI (in a partner or oneself), alcohol and recreational drug use before sex, leaving a long-term relationship, entering sex work, moving to a city having a high prevalence of HIV, starting a relationship with a person with HIV who is not virally suppressed on ART. Those who leave school or leave home early may have greater HIV vulnerability and may also want to consider using PrEP. Also, PrEP use may be part of a safer conception strategy for HIV serodiscordant couples. People who use drugs may have periods of injecting drug use where HIV risk is high and PrEP may be considered.

Similarly, a variety of reasons may prompt a person to stop PrEP. Seasons of risk end for various reasons – for example, when a partner with HIV achieves viral suppression on ART, when a mutually monogamous relationship becomes a long-term commitment, when drug injecting stops or when other risks change. A critical aspect of periods of PrEP use and non-use is education and support for safe stops and restarts of PrEP use, and engaging those currently on PrEP in discussions about plans for persistence (how long the person sees him- or herself using PrEP and what the person’s personal criteria are for deciding when PrEP is no longer needed or desired). PrEP providers should position themselves as a valuable part of this decision-making to the greatest extent possible.

## Who can counsel about PrEP?

Counsellors and health workers should be carefully trained on PrEP use before they counsel clients about PrEP. In addition, the user’s preferences should be considered. Some users may prefer talking with a peer or lay counsellor, who has some shared experiences. Others may prefer counselling from a medically trained counsellor (for example, a nurse, doctor or clinical officer). Integrating training on PrEP counselling skills into current HIV testing training and other relevant curricula can provide an opportunity to introduce PrEP in a range of settings such as primary health, STI and reproductive health services.

PrEP counsellors need refresher training regularly so that they can provide accurate and up-to-date information to clients who may ask about new medicines and methods as they become available. Refresher training may help to sharpen counselling skills and provides an opportunity to teach new approaches.

## A key role for peer and lay counsellors

Peer and lay counsellors may be the most acceptable persons to provide counselling that supports PrEP use and adherence.

In many instances involving peer and lay counsellors may be advantageous, for example peer and lay counsellors may be the most acceptable persons to provide counselling that supports PrEP use and adherence. WHO has previously recommended the use of trained and supported lay providers to perform certain HIV clinical services, including HIV testing, HIV counselling and support for delivery of antiretroviral treatment (4-6). Beyond providing services, lay workers can act as role models and offer non-judgemental and respectful support that

can help reduce stigma, facilitate access to services and improve their uptake. Young women, men who have sex with men, transgender people, sex workers, people who use drugs and other groups who fear stigma in health services may feel better connected to peers and near-peers. Lay providers may cost the programme less than using health workers to perform the same tasks. However, it is important that programmes compensate trained lay providers appropriately for their work. Otherwise, high turnover is likely. These workers should receive adequate wages and/or other appropriate incentives. The main reason for involving lay providers should be to increase access to and effective use of PrEP and not to reduce costs.

Lay provider: any person who performs functions related to healthcare delivery and has been trained to deliver specific services but has received no formal professional or paraprofessional certificate or tertiary education degree (7).

Creating spaces in clinical settings or elsewhere for peer and lay counsellors to conduct PrEP counselling is a crucial part of peer counselling. Often, the lack of such spaces prevents lay and peer counsellors from playing a key role. Supportive supervision and oversight of lay and peer counsellors by a professionally trained counsellor or healthcare provider is necessary to ensure that up-to-date and accurate information is routinely shared with the lay and peer counsellors, as with all counsellors.

## Counselling strategies

Specific information about PrEP in client-friendly language is available in the **module for PrEP users**. Topics covered include: *"What is PrEP?"*, *"How well does PrEP work?"*, *"Who can consider using PrEP?"*, *"Who cannot use PrEP?"*, *"How do I store the medicines?"*, *"When and how do I take PrEP?"*, *"How can I remember to take PrEP?"*, *"What if I miss a dose?"*, *"What if I have side-effects?"*, *"What about PrEP, pregnancy and breastfeeding?"*, and *"When and how can I stop PrEP?"*. This section describes the approaches to conveying those messages most appropriately and effectively.

## Culturally relevant group activities

Providing and discussing general information about PrEP can work well with groups. Group sessions can be the first step in the counselling process, used to provide general information on PrEP, listen to questions and provide general answers. Then, clients can be invited to come into one-on-one sessions with a clinician, a lay or peer counsellor, or other counsellor.

Support groups of PrEP users can make important contributions to HIV prevention.

After people start PrEP, they can be invited to join support groups that help with adherence and retention. Support groups can address issues relating to empowerment and self-efficacy, beliefs about health issues, and stigma. Group activities can affect social behaviour, including communication with partners and potential partners about HIV and prevention strategies. Peer-led activities,

awareness campaigns and other community-based strategies can also support PrEP adherence and retention.

PrEP trials in the United States of America (ATN 082 and 110) used a group-based engagement strategy with young adults. These group communications sought to raise awareness of HIV risk, strategies for protection and how PrEP can be used (8, 9). The strategy was based on an evidence-based behavioural intervention called "Many Men, Many Voices" (10). This approach was highly acceptable among young adult black and Latino men in the USA who were anticipating starting PrEP (8). In sub-Saharan Africa, the FACTS 001 and ASPIRE (11) trials also used group strategies, as will the upcoming trial HPTN 082 (PrEP for young women in South Africa and Zimbabwe) (12).

## Principles for counselling individuals

Various models of counselling can be appropriate to support PrEP use. These models share the following characteristics: they are culturally sensitive, client-centred, problem-solving with emphasis on autonomy (client's choice) and affirmation (valuing each client's context, situation and decisions), and attentive to unmet needs that may challenge PrEP use or retention in PrEP-related care. The following counselling principles, methods and approaches are considered evidence-informed best practices (13):

## Culturally sensitive

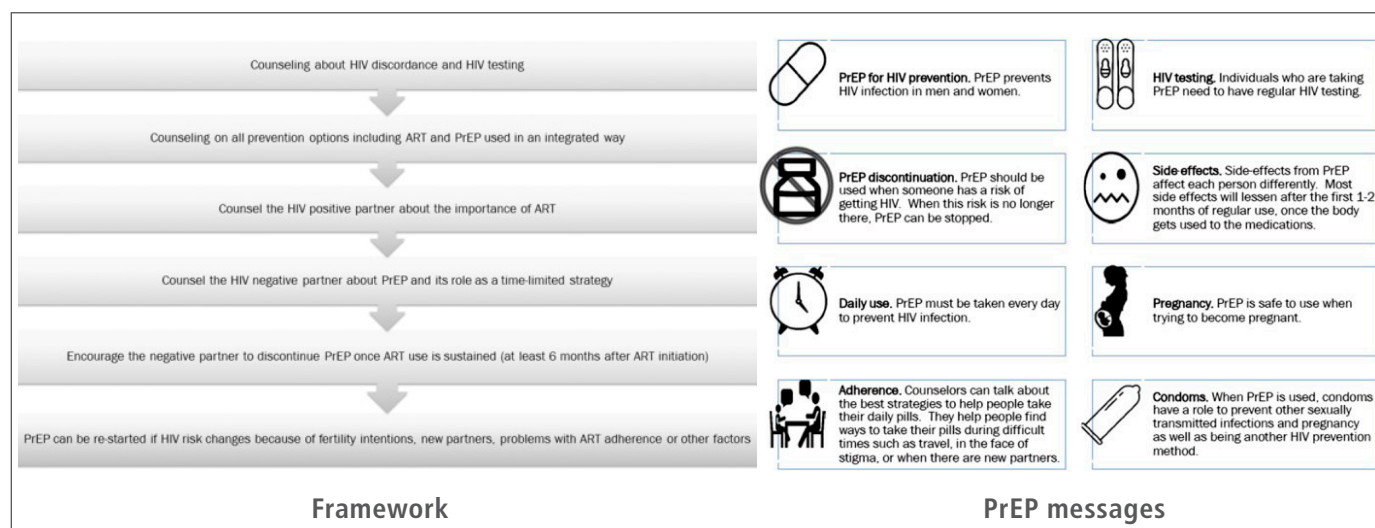
An approach of cultural sensitivity is critically important.

People at risk of acquiring HIV infection often experience stigma from multiple sources. Adolescent girls and young women often have special concerns about being judged negatively that could interfere with their use of sexual health services, contraception and/or their effective use of PrEP and other protective practices. The behaviours of men who have sex with men, sex workers, and

people who inject drugs are criminalized in many places, making them reluctant to seek HIV-related or other sexual health services. Transgender individuals, too, are subject to stigma, discrimination and violence. Understanding the social and cultural context and addressing barriers is critically important. In healthcare settings, it also means acknowledging and redressing the imbalance in power between the providers of services and those seeking services.



**FIGURE 1. EXAMPLE OF COUNSELLING HIV-SERODISCORDANT COUPLES ABOUT AN INTEGRATED PrEP AND ART STRATEGY (14)**



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## Individual discussions about PrEP

The term “client-centred counselling approaches” as used here refers to client-centred care strategies in which the client is seen as an expert on his or her life, desires and goals, while the counsellor serves as a guide who can assist clients in reaching their goals or setting new goals. Many counselling approaches used to support PrEP use draw on motivational interviewing strategies. These approaches are focused on enhancing motivation to use PrEP correctly by engaging clients in discussions covering all aspects of the PrEP experience, including perceived consequences of not only non-adherence but also the cost of being adherent. Autonomy and respect for a client’s decisions are paramount in this approach (see section below on fostering motivation). The counsellor allows the client to lead the conversation and offers reflective feedback. Client-centred counselling emphasizes:

- sharing knowledge
- respecting individuals’ experiences in the context of their social realities
- acknowledging and, as appropriate, involving the family and others who influence individuals’ lives
- building opportunities for autonomy and success.

Content included in counselling discussions should address the specific needs of the client. Client-centred approaches adapt services to the needs and desires of the client. Depending on the client, counselling may address any of the following issues and services:

- HIV testing
- PrEP or PEP considerations
- HIV testing and treatment of partner(s)
- STI screening and treatment
- reproductive goals, safer conception, pregnancy and contraception
- hepatitis B and C prevention, testing and treatment
- provision of condoms and lubricant
- mental health screening and treatment (especially for depression)
- alcohol and substance use
- tuberculosis screening, testing and treatment
- counselling about intimate partner violence.

Counselling issues vary depending on the context; some population groups (14) and people in certain circumstances may find additional issues important. For example, serodiscordant couples should be briefed about the use of PrEP by the HIV-negative partner as a bridge to ART-driven viral suppression and about the benefit of mutual support for adherence. Further, in some areas consistent discussions about safety and efficacy may be warranted to help allay concerns about PrEP in the community (15).

**Here are some concerns and issues that may arise for counsellors working with different populations:**

**Transgender women and men.** Transgender women have an increased risk of HIV in all regions. Information about risks to transgender men is less available. The experience of transgender women and men is often obscured because they have often been grouped with men who have sex with men, whose situation is different.

#### **Does PrEP work for transgender women?**

PrEP works for transgender women when used consistently. In the iPrEx study (16), in a group of 339 transgender women, there were no HIV infections among those who took at least four PrEP tablets per week. However, overall adherence to PrEP was less among transgender women than among men who have sex with men, especially during periods of higher possible exposure to HIV. Ways to foster effective use of PrEP among transgender women may include offering gender affirming care such as feminizing hormone therapy.

#### **Does PrEP interfere with gender affirming hormones?**

Gender affirming hormones are processed in the body by the liver, while PrEP medicines are processed in the kidneys. Interference between sex hormones and ART has not been observed.

**Sex workers** bear a disproportionate burden of HIV infection particularly in places where their work is criminalized. Where sex work is legal, sex workers are better able to protect themselves through consistent use of condoms. Among sex workers, condom use is the mainstay of protecting sexual health. Sex workers may benefit from counselling about how to integrate regular PrEP pill-taking into a lifestyle with irregular working hours.

#### **Will PrEP undermine sex workers' or their clients' willingness to use condoms?**

Many sex workers do not use condoms with their primary partners (for example, spouses). Similarly, some sex workers are not able to negotiate condom use with all clients on all occasions. PrEP can serve as additional protection.

As for all people, each sex worker needs to consider if PrEP use is right for him or her. To date, no evidence with other at risk population groups has indicated that PrEP will undermine the use of condoms. Still, advocacy and community communication must continue to highlight the importance of condoms and lubrication as a critical component of combination prevention.

#### **Will sex workers be coerced to take PrEP?**

All use of medicines must be voluntary. Still, counselling must highlight that taking PrEP is always a voluntary choice.

**Men who have sex with men** have increased vulnerability to HIV infection in all regions. In many countries increasing numbers of men who have sex with men are becoming aware of the benefits of PrEP and are seeking PrEP through formal health services or informally through Internet sales and other venues. Men who have sex with men who obtain PrEP through informal sources should be encouraged and supported to link to clinical services so that they can receive regular HIV testing and other monitoring and support. Also, a number of men who have sex with men may engage in substance use during sex.

**People who use and/or inject drugs are often at substantial HIV risk.** WHO recommends a package of effective HIV services be provided for all people who inject drugs, including harm reduction (in particular opioid substitution therapy and needle and syringe programmes). When these interventions are available, the risk of HIV transmission is significantly reduced. Providing these should be a priority.

People who use and/or inject drugs may also be at risk of sexual transmission of HIV. In particular, this may be the case among people who use amphetamine type stimulants and engage in higher risk sexual practices (including among some subgroups of men who have sex with men in some settings). There may also be a link with sex work and not being empowered to use condoms consistently with all clients or with intimate partners.

Access to harm reduction remains the mainstay of HIV prevention for people who inject drugs. However, this population should not be excluded from PrEP services. PrEP can be considered for people who use drugs for whom harm reduction services – sterile injecting equipment and opioid substitution therapy – are not relevant, such as people using amphetamine type stimulants who are at substantial risk of HIV infection.

**Women expressing the desire to become pregnant or who are pregnant** need information about PrEP during pregnancy, and women who are breastfeeding need information about PrEP in that context.

### **Can PrEP be continued during pregnancy and breastfeeding?**

HIV infection can occur at high rates during pregnancy and breastfeeding. The risk of passing HIV infection onto a baby is higher if the mother becomes infected while she is pregnant. The existing safety data support the use of PrEP in pregnant and breastfeeding women who are at continuing substantial risk of HIV infection.

The choice to continue or discontinue PrEP when a woman becomes pregnant should be made by the woman herself, following discussion of the risks and benefits with her healthcare provider.

**If a woman wants to become pregnant and she has concerns that her partner may have HIV (or has HIV and is not virally suppressed on ART) can she consider PrEP?**

PrEP can be considered as part of a safer conception package for women wanting to become pregnant and who are at high risk of acquiring HIV.

**Adolescents.** In counselling for adolescents, relevant issues may include developmental needs such as establishing autonomy, privacy about medical decisions and consent to testing and HIV services. Providing a PrEP service for adolescents may have additional challenges. Adolescents may need more frequent contact and more support to help them adhere to PrEP (9). Issues around age of consent (and parental approval) for HIV testing and provision of PrEP will vary and need to be considered. Counsellors will need additional training to provide PrEP for adolescents.

## **Fostering motivation**

Communication strategies can foster the motivation to use PrEP effectively and to engage with follow-up services. Motivational interviewing can help PrEP users to explore the complexities of their feelings and motivations for PrEP use. This approach may also explore reasons for non-use of medicines and negative experiences with medicines.

## **Problem-solving**

Problem-solving approaches help clients to identify factors that facilitate sexual health as well as those that are barriers to sexual health protection. Approaches may focus, as needed, on effective PrEP use, condom use, contraceptive use or further engagement in care, depending on the goal of counselling. Problem-solving approaches also play an important role in reducing the risks associated with drug use and accessing harm reduction and treatment services. Problem-solving is not a counsellor-driven assessment to identify barriers and tell clients what they must do to “fix” the problem. Rather, it is a discussion with clients to help them identify the factors that influence their protective behaviour and to help them develop strategies to reduce these barriers.

## **Neutral assessment of adherence**

Monitoring PrEP use is advisable. However, asking clients to report on missed doses, with possible negative consequences such as rebuking those for not taking the doses as prescribed or withholding further medicines, is generally not productive.

Neutral assessment (17) of adherence allows a constructive discussion that can support the client in finding solutions to their difficulties in adhering.

## **Offering choices**

Offering a menu of choices for HIV protection will increase the chances that a client will adopt one or more protective strategies. The counsellor should consider the factors that place the client at risk at different levels, including individual,

partner, family, school situation, work situation, and the societal levels, involving stigma or criminalization. PrEP is one of several possible options, and the client's right to choose should be emphasized. In addition to PrEP, other options that decrease risk may include the following, depending on the client's situation:

- **Consistent use of male or female condoms** provides a high degree of protection if used consistently – with all partners and at every act of penetrative sex, starting before intercourse and continuing throughout. Water-based lubricants should be provided with condoms, especially for men who have sex with men, transgender people and sex workers. Condoms also protect against other STIs and pregnancy.
- **Non-penetrative sex**, including mutual masturbation, is safe.
- **Delaying sexual intercourse** may be a viable choice for some adolescents and young adults who have not yet started to have sexual intercourse. However, adolescents and young people who are asking about PrEP may have already engaged in intercourse or else are preparing to do so safely. For them, a delay or even a return to abstinence is likely to be unacceptable or not feasible.
- **Diagnosis and treatment of STIs** decreases the risk of HIV acquisition. A sore or inflammation from an STI may allow infection with HIV that would otherwise have been stopped by intact skin.
- **Voluntary medical male circumcision** decreases the risk of acquiring HIV by about 60% for men whose exposure to HIV is primarily through heterosexual intercourse and is recommended in 14 priority countries in East and southern Africa (18-20).
- **Mutual monogamy** (when neither person has other sexual partners) can be an effective strategy if the relationship is stable and the partner has recently tested HIV-negative or else is HIV-positive, on antiretroviral therapy and has achieved viral suppression. Intimate partner violence or emotional abuse in the relationship could make this option unfeasible.
- **Post-exposure prophylaxis (PEP)** started within a few hours of exposure (and no later than 72 hours) and continued for 28 days. If the client has used PEP more than once, PrEP may be considered.
- **Having a partner/partners with HIV on ART and virally suppressed** makes HIV transmission to an HIV-negative partner unlikely.
- **Needle and syringe access programmes, opioid substitution therapy and other harm reduction strategies** will not protect from sexual transmission of HIV, but they will protect against HIV and other bloodborne infections transmitted by contaminated needles, syringes and other injecting equipment.

## Brief discussions

Multiple brief counselling sessions may be preferred by some clients over longer sessions. However, longer discussions for those in need of additional assistance or services should also be made available. PrEP clients will usually be seen every three months for HIV testing and other monitoring. This is an opportunity for regular check-ins on their sexual health and drug use protection plans and behaviour, and confirmation of their desire to continue PrEP. In most cases, discussions of 10–15 minutes will be adequate. More detailed discussions (for example, at the first PrEP consultation or when the client is experiencing difficulties with adherence) are expected to be less common and may take about 30 minutes.

## Prompts for counselling

In interactive counselling the client speaks more than the counsellor.

Interactive discussions about PrEP have been used in numerous studies and programmes. How one begins that conversation sets a tone for the entire discussion. To promote open exploration of PrEP, consider the lead-ins used in different projects presented below. These are a compilation of counsellor guidance and inquiries adapted from prompts used by a PrEP demonstration project in the United States of America (21, 22). They can be adapted for other communities. Other projects have used different approaches, such as *Integrated*

*Next Step Counselling (iNSC)* or informed choice counselling. These examples can be found in the supplementary information at the end of this module. **Not all these prompts can or should be used for all people or in a single session.** The counsellor can select from them based on the client's circumstances.

## Discussion prompts or questions for initial PrEP appointments

**Opener:** Let's talk about your sexual health for a few minutes.

"Assess client understanding that the protection provided by PrEP is not complete, and does not prevent other STIs or unwanted pregnancies, and therefore PrEP should be used as part of a package of HIV prevention services (inclusive of condoms, lubrication, contraception, risk reduction counselling and STI management)."

*Southern African Clinician Society guidelines for provision of PrEP*

### Sexual behaviour

- What has been going on for you sexually in the past couple of months?
- How much of the time did you use condoms?
- What has made it easier to use condoms during sex? What has made it more difficult?
- What concerns do you have about your sexual activities?
- How might taking PrEP impact your sexual activity?

### Drug use

- Did you use any drug in the last 12 months?
- If yes, which drug (alcohol as well as opioids, stimulants, cannabis, etc.)?
- And how did you use it (smoking, orally, injecting)?
- When did you last use drugs (specify which substances)?
- How often do you use drugs (once a year, month, week, day or more frequent)?
- Has your drug use ever been a problem for you? [*Note: referral to drug services may be appropriate if locally available.*]
- Do you think it may put you at risk of becoming infected or transmitting HIV?

### Plan(s) for staying HIV- and STI-negative

- In what ways are you reducing your risk of getting HIV and other STIs now?
- What steps have you considered for the future?
- You are reducing your risk for HIV by deciding to take PrEP. Let's talk about how PrEP fits into your risk reduction efforts. [*Note should be made that PrEP will reduce the risk of acquiring HIV, but it will NOT reduce the risk of acquiring other STIs.*]
- What other ideas/plans, if any, do you have for staying HIV/STI-negative?

### HIV testing and results

- How are you feeling about getting your HIV test result in a few minutes?
- What would you like to discuss before I provide your results?
- [*After negative results are given:*]
  - What are your thoughts and feelings about your negative test result?
  - How does this negative test result impact your plans or efforts to remain HIV-negative?
- [*After positive results are given, provide post-test counselling and linkage to treatment.*] (5)

### Preparing for effective PrEP use

- Do you have any experience with taking a daily medicine?
  - What is your experience with taking a daily medicine?
  - Are you currently taking daily medicines on a long-term basis? [*If so, may need to refer to a pharmacist or other healthcare provider.*]
  - What helps you remember to take your pills?
- When you have taken medicines in the past, how did you remember to take them?
- What is your plan for taking PrEP daily?

- What will you do about taking your pill if you are away from home for a night or two?
- What will you do if you miss a dose of your PrEP pill?
- What is your understanding of possible PrEP side-effects? How will you cope with side-effects if you have them?

## Discussion prompts for follow-up PrEP appointments

**Opener:** Let's check in about your sexual health and what it has been like taking PrEP since your last visit.

### Pill-taking experience

- How has it been for you to take PrEP?
- What side-effects have you had, if any?
- What helps you remember to take your pill?
- What challenges do you experience in taking the pills? When are you more likely to forget?
- What are your concerns about missing PrEP pills?
- What have been your experiences with missing PrEP doses?
- What helps or might help you to take your pills regularly? Helpful strategies may include:
  - using a pill box
  - taking PrEP pills with other daily medicines
  - using a phone alarm
  - marking doses taken on a calendar
  - keeping the bottle in a visible location associated with a daily activity such as brushing teeth or watching a daily TV programme
  - having more support from your partner, a family member or a friend
- What keeps you motivated to take the PrEP pills?
- What might help make taking PrEP even easier?

### Discussing PrEP with others

- Have you discussed your PrEP use with others? Why or why not? With whom have you discussed it?
- Since your last visit have you had any social experiences, positive or negative, that you think are related to taking PrEP?  
*[Note to counsellors and health workers: These social experiences might include an improved relationship with a friend or sexual partner, such as the ability to have a more open discussion with a partner about HIV status; or stigma and discrimination, such as someone not wanting to use condoms after learning that you are using PrEP.]*

### Behaviour and activity

- What has been going on for you sexually since your last visit?
- How has PrEP changed your social and sexual goals? Have you noticed changes in your usual sexual activities? What are your thoughts about condoms? What about sexual partners: Are you having different kinds of conversations with sexual partners? Have you increased or decreased the number of sexual acts and/or the number of partners?
- Has taking PrEP changed what else you do to protect yourself from getting HIV and STIs (for example, topping versus bottoming, condom use, discussing HIV and STI status and/or testing with partners)?
- Has PrEP made you feel safer about sex?
- Has PrEP made it easier for you to take charge of your health?
- In addition to taking PrEP, what are your plans to stay HIV-negative?

### HIV testing and results

- How are you feeling about getting your HIV test result in a few minutes?
- What, if anything, would you like to discuss before I provide your results?
- *[After negative result obtained:]*
  - What are your thoughts and feelings about your negative test result?
  - How, if at all, does this negative test result impact your plans and efforts to remain HIV negative?
- *[After positive result obtained, provide post-test counselling and linkage to treatment.]*

### Confirm clear plan for staying HIV/STI-negative

- What I hear you saying is that you currently reduce your risk for HIV by [fill in protective behaviours] and also you talked about your desire or plan with [fill in name of person(s)]. Have I understood you correctly?
- What other ideas or plans, if any, do you have for staying HIV- and STI-negative?

## Differentiated care

As with HIV and TB care, PrEP programmes could consider the potentially facilitating role of differentiated care. To date there is little experience of differentiated care approaches in PrEP services, but this is something that could be explored as services evolve and mature. PrEP programmes are comparatively new, and patterns of adherence and, thus, in many regions the need for intensive adherence support remains to be determined. Strategies to deliver PrEP can recognize that some PrEP users need basic kinds of support and others need more intensive support to achieve and maintain effective levels of PrEP adherence. Programmes should monitor the burden of attending health facilities on clients – for example, how often are PrEP users asked to come to the clinic/centre, how long are appointments, how are the health facilities perceived by clients, and how well-resourced are the clinics/centres to meet the needs of clients? The central question is whether everyone receiving PrEP needs to engage with health facilities in the same way, as is currently required. Can the profile of a client doing well with PrEP be identified, and can those clients obtain sufficient PrEP care with the minimal necessary burden? Programmes could consider strategies used for ART delivery such as Adherence Clubs, where one group member in rotation collects prescriptions for all members and distributes the medicines to them; shortened or streamlined visits; and longer intervals between care visits for adults who are doing well with PrEP and adhering well to the regimen.

## Monitoring efforts

As noted, developing strategies and programmes that are tailored to the needs of the specific community or PrEP user population presents the best opportunity for high quality, client-centred care. The entry point into planning and development of this approach is familiarity with community needs. As part of continuous quality improvement cycles, programmes should consult with community stakeholders to determine the most acute needs and desires of PrEP users. Programmes can prepare for or adapt to address these needs and monitor outcomes closely to determine if needs are in fact being addressed. Local experience can be used to design and improve monitoring of PrEP, including adherence, retention, and stopping and restarting PrEP as needed. Local experience can guide improvements in programme services.

## Supplementary information

The examples provided in the supplementary information section were provided by Iprex and FHI360.

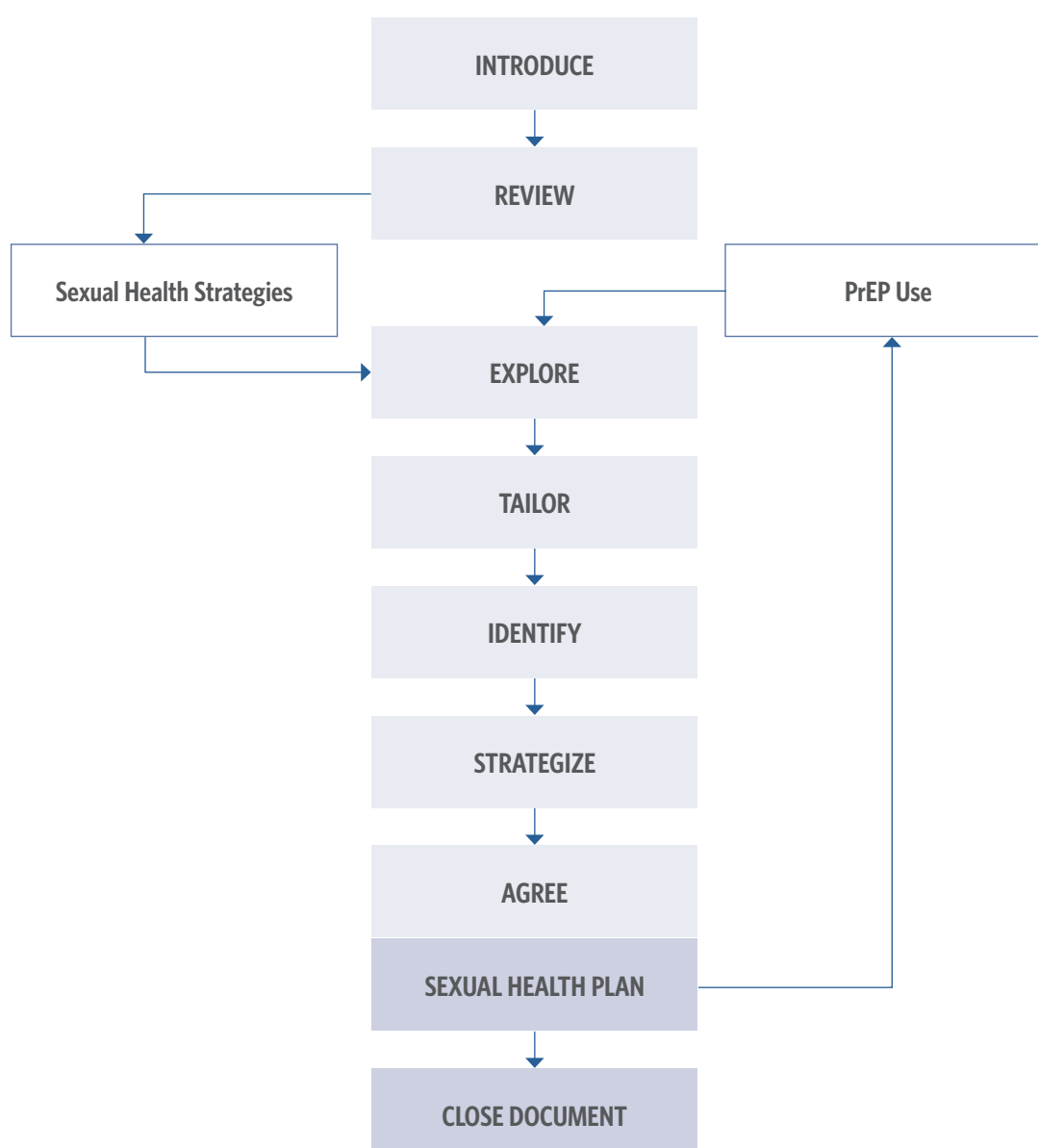
### Counselling example I: Integrated Next Step Counselling (iNSC)

This method was developed to address the challenges of informing the choice of PrEP, developing a plan for adherence, and developing broader plans for sexual health (17). The method is interactive, brief, client-centred and focused on problem-solving, starting with the client's identification of personal goals and the barriers and facilitators to achieving those goals. The method was developed for the iPrEx study conducted in Thailand, South Africa, Brazil, Peru, Ecuador and the USA. This counselling method has been used to support adherence in the iPrEx Open Label Extension, especially in regions working with younger participants in resource-poor areas (23).

#### Next step counselling process

Next step counselling (NSC) is a series of steps designed to help the counsellor achieve a more interactive and client-centred approach focused specifically on PrEP adherence (17) (Fig. 2).

**FIGURE 2. FLOW OF INTEGRATED NEXT STEP COUNSELLING (iNSC)**





The table below adapts the Next Step method for use in clinical practice

STEP	KEY COMPONENTS	EXAMPLES OF PROMPTS
Introduce the counselling session	Explain what you are going to talk about and why. Get permission to proceed.	<i>I would like to take a few minutes to check in with you about your goals and how you will meet your goals. Is that OK?</i>
Review client's experiences	Ask about what client already knows concerning PrEP and how they learned it and about their experiences with PrEP, if any.	<i>Thank you. Can you tell me a little about what you have heard about PrEP and about your experiences with PrEP, if any?</i>
Explore the context of the client's specific facilitators and barriers	Use open-ended questions to explore factors or situations that help to make pill-taking easier and those that make it a little more difficult.	<i>Can you tell me about your experience with PrEP since you were last here? What seems to make PrEP easy to take? What makes it harder to take?</i>
Tailor the discussion to focus on increasing ease of pill-taking	Pause to consider how information gathered in earlier steps helps to tailor the next question.	<i>Let me think for a moment about what you have said.</i>
Identify adherence-related needs	Guide the conversation towards identifying participant's perceptions of what would best help to integrate PrEP use into daily life.	<i>Given everything going on right now, what would need to happen for it to feel a little easier to work this regimen into your daily life?</i>
Strategize with the participant on the next step	Work with participants so that they identify one or a few viable strategies for increasing effective PrEP use.	<i>How could that happen? What are some ideas for how you could approach that?</i>
Agree on which strategies will be tried next	Ask which strategy (or strategies) the participant is willing to try or continue using.	<i>Of the things we have talked about, which might you be willing to try between now and the next time we meet?</i>
Close/record	Provide a summary of what was discussed and thank the participant.	<i>You noticed that ... would really make it feel easier to work this into your life and that ... is something that will help with that. You'll give that a try between now and the next time we meet. Thank you for talking with me. I look forward to talking again when you come in next.</i>

## Integrating next step counselling for PrEP use and sexual health

NSC was adapted in the iPrEx Open Label Extension to counsel individuals on sexual health promotion generally, with specific emphasis on PrEP adherence for individuals on PrEP. This counselling included a conversation about all the things someone is doing or considering doing to protect their sexual health, confirmation of the desire to receive PrEP (or not, as the case may be) and, for PrEP users, a discussion of experience with PrEP. Implementation of iNSC is linked to the delivery of negative HIV test results and serves as pre/post-test HIV counselling as well as adherence counselling in one brief, targeted, tailored conversation.

## Counselling example II: Informed choice counselling

Best practices in counselling are also incorporated into a PrEP counselling plan that was developed by FHI360 for a study looking at PrEP use and risk compensation among women at higher risk for HIV infection at sites in Kenya and South Africa (24, 25). More information on this approach can be found in the following document *Guidance for providing informed-choice counseling on sexual health for women interested in pre-exposure prophylaxis (PrEP)*, available at <https://www.fhi360.org/projects/prep-and-risk-compensation-assessing-effect-and-preparing-rollout>.

This approach builds on informed choice as a principle for selecting strategies for preventing HIV infection, modelled on guidance for informed choices for contraception and safer conception. This approach can be adapted for all populations. It is based on two client-centred principles:

- Principle #1: Enabling people to have an informed and voluntary choice of HIV prevention options is the foundation of effective counselling.
- Principle #2: Given the information they need, people can make good decisions about their overall sexual health and HIV prevention.

As with integrated Next Step Counselling, the informed choice counselling scheme identifies a series of steps to guide the counsellor and client through a process of making a choice. The process is divided into four phases: (1) the introductory phase, (2) the informational phase, (3) the deliberation and decision phase, and (4) the confirmation phase. The authors suggest prompts for each of these phases. A link to a detailed online description of the counselling method can be found at the end of this module.

1. In **the introductory phase**, when a client expresses interest in learning more about PrEP, the counsellor can prompt as follows:

- “Today I would like to talk to you about HIV prevention and to tell you about a new HIV prevention method called PrEP. I would also like to talk about your risk for HIV and about other things you are doing to prevent HIV. Together, we will think of actions that you can take to remain HIV-free, and you can decide if PrEP might be a good approach for you. We will also talk about ways to keep you healthy overall.”
- “How do you feel about this discussion? Are you comfortable with this discussion?”
- [If partner is present:] “I would like to continue speaking with you individually now. But, if you prefer, we can talk about HIV risk reduction and PrEP together with your partner. The decision is yours.”
- “May I proceed with the session?”

2. In **the information phase** the counsellor provides accurate information about PrEP. Begin by asking the client what she has heard about PrEP.

- Explain, as needed, that:
  - “PrEP is an ARV pill that HIV-negative people can take daily to significantly reduce their chances of getting HIV.”
  - “People do not need to take PrEP for the rest of their lives. They need to take PrEP only during periods in their lives when they think they may be at risk of HIV.”
- Show a PrEP pill to the client. Give the client a pill to hold and look at.
- “Are you interested in learning more about PrEP?”
  - “PrEP stands for Pre-Exposure Prophylaxis, where “prophylaxis” means “prevention of disease”.
  - “PrEP is a pill that, if taken daily by an HIV-negative person, can significantly reduce the chances of getting HIV. PrEP can help women and men who are HIV-negative remain HIV-negative.”
  - “PrEP pills combine two different ARV drugs in one pill. These are the same ARV drugs that are commonly used as part of a drug regimen to treat HIV infection in HIV-positive people.”
  - “PrEP does not cure HIV. Instead, it can prevent HIV infection in people who are HIV-negative.”
  - “PrEP is not 100% effective at preventing HIV. However, it can be highly effective when taken every day.”
  - “One PrEP pill must be taken every day. During times in a person’s life when he or she is at risk for HIV, he/she

should take PrEP every day, even if the person does not have sex every day. This is like the contraceptive pill, which a woman must take every day to prevent pregnancy. For PrEP, taking the medicine every day ensures that enough of the medicine is in the body at all times to prevent infection.”

- “PrEP protects against HIV, but it does not provide any protection against most other sexually transmitted diseases or against pregnancy.”
- Explore the person’s risk of HIV and his or her prevention strategies.
  - “Let us first talk about whether you might be at risk for HIV now. How much at risk do you think you are for HIV?”
  - “Your risk for HIV depends on several things. Let us now talk about your sexual partner or partners.” Ask the client about the possibility that any of his/her partners:
    - » was diagnosed with HIV
    - » may have other sexual partners
    - » is HIV-negative and routinely undergoes testing for HIV, does not know his or her HIV status, or refuses to share it
    - » is uncertain about his or her HIV status and refuses to test
    - » was recently treated for an STI.
  - “What are you currently doing to reduce your risk of HIV?”
  - “What would you like to do to reduce your risk of HIV?”
  - “When is safer sex most difficult for you to achieve?”
- 3. In the **deliberation and decision-making phase**, the counsellor helps the client apply this information to his or her individual circumstances and to consider what is the best option for his or her overall sexual health.
  - “Using PrEP could be something to help you reduce your risk for HIV. Together, we will discuss the HIV prevention options that can be best for you, and you can make an informed decision if PrEP or another prevention method is best for you.”
  - “Given everything that we have discussed, is PrEP an HIV prevention method that you would like to try? [If yes:] How do you think PrEP can help you continue to stay safe?”
  - “Are there HIV risk reduction approaches that you may want to use in addition to PrEP? [If yes:] Which ones?”
  - “Up until now we have talked about preventing HIV. But being sexually active means that you [if the client is a woman] must also think about whether or not you want to get pregnant. You must also think about ways to prevent other STIs. To use your chosen preventive approaches effectively, you need accurate information and practical skills. Let us focus on this now and talk about ways to ensure your overall sexual health.”
  - “What questions do you have for me before we continue?”
- 4. In the **confirmation phase** the client confirms his or her plan to reduce the risk of HIV and to maintain overall sexual health. The counsellor summarizes the client’s plan and makes a follow-up plan.

**FIGURE 3: ABC CARDS - PRESCRIBER DELIVERED INTEGRATED NEXT STEP COUNSELLING INFORMED PREP DISCUSSIONS**

# ABC

**ALIGN • BRAINSTORM • COMMIT**

## COMBINATION PREVENTION COUNSELING

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SEXUAL RISK REDUCTION COUNSELING  
PrEP ELIGIBILITY ASSESSMENT  
PrEP USE PLAN

KR Amico, JC Hojilla, RM Grant. (July 2015). v1.1. Based on Integrated Next Step Counseling (iNSC), a strategic counseling model developed in iPrEx; additional information from New York Department of Health and Mental Hygiene. For further information, contact: ramico@umich.edu or carlo.hojilla@ucsf.edu

### Sexual Risk Reduction (SRR) Counseling

**ALIGN**

- ▶ **Ask & Explore**  
*How would you describe your current sexual health situation?*
- ▶ **Summarize Strengths & Challenges**  
*It sounds like your strengths are... (being motivated, current protection strategies, positive attitude)*  
*And some challenges you face are...(recent breakup, difficulty accessing services, intimate partner violence, drug use, depression)*

**BRAINSTORM**

- ▶ **Identify**  
*What do you think would need to happen for it to feel a bit easier to (stay HIV-negative, reduce risk)*
- ▶ **Strategize**  
*How could you see that happening?*  
*There are a few things you may want to consider. Can I share those with you? ▶*

**COMMIT**

- ▶ **Commit or Continue**  
*Of these strategies, what would you be willing to try or continue doing from now until your next visit?*

Generate menu of options.

MENU OF SAFER SEX STRATEGIES TO CONSIDER

- Regular HIV/STI testing
- Using water-based lubricants
- PrEP or pre-exposure prophylaxis
- PEP or post-exposure prophylaxis
- Reduce number of partners
- Reduce drug/alcohol use
- Using clean needles and not sharing
- Discuss HIV status with sex partners
- Safe pregnancy/conception plan
- Condom use (male & female condoms)

### PrEP Eligibility Assessment

- Do you use condoms only sometimes or not at all?
- Are you having sex with more than one person?
- Do you have sex with people whose HIV status you don't know?
- Are you in a relationship with an HIV-positive partner?
- Do you desire pregnancy with an HIV-positive partner?
- In the past year, have you:
  - Taken PEP to prevent HIV infection?
  - Had a sexually transmitted infection?
  - Used drugs like poppers, cocaine, ecstasy, or others?
- Do you inject drugs?

**PrEP**

- ▶ **Introduce PrEP**  
*PrEP is proven to reduce the risk of HIV in men and women if taken daily. Common side effects include nausea or cramping in 1:10, kidney dysfunction in 1:200, or a small decrease in bone density.*
- ▶ **Assess Patient Interest**  
*Are you interested in trying PrEP?*

**YES**  
Develop PrEP  
use plan

**NO**  
Summarize  
SRR plan

### PrEP Use Plan

**ALIGN**

- ▶ **Ask & Explore**  
*How would taking a pill everyday fit or not fit in your life right now?*
- ▶ **Summarize Strengths & Challenges**  
*It sounds like your strengths are... (already taking a medication daily, easy to link to daily event, positive attitude)*  
*And some challenges you have with daily pill taking are...(away from home, busy schedule, substance use, toxicity concerns, lack of privacy)*

**BRAINSTORM**

- ▶ **Identify & Strategize**  
*Given what we just talked about, what kinds of things need to happen for you to take PrEP everyday?*  
*I have some ideas from other PrEP users that may help.*  
*Can I share those with you? ▶*

**COMMIT**

- ▶ **Commit or Continue**  
*You said you'll use this strategy. I'll check in on you about this at your next visit.*

Generate menu of options.

MENU OF STRATEGIES TO CONSIDER

- Link PrEP to daily routine or event (like brushing teeth)
- Take at same time everyday
- Identify what to do if dose is missed
- Using a pillbox
- Understand side effects & how to manage side effects
- Disclose PrEP use to significant other
- Plan for intentional discontinuation
- Using reminder alarms/texts or calendar
- Have back-up supply in bag/purse

## Further reading

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**For more information, contact:**

World Health Organization  
Department of HIV/AIDS  
20, avenue Appia  
1211 Geneva 27  
Switzerland

E-mail: [hiv-aids@who.int](mailto:hiv-aids@who.int)

[www.who.int/hiv](http://www.who.int/hiv)