

Guidance for Providing
Informed-Choice Counseling
on Sexual Health for
Women Interested in
Pre-Exposure Prophylaxis (PrEP)

Kenya & South Africa January 2016









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# Acknowledgements

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# Introduction

# Pre-exposure prophylaxis – referred to as PrEP – is a new HIV prevention option

Several clinical trials have shown that an antiretroviral (ARV) drug called Truvada (emtricitabine/tenofovir disoproxil fumarate) reduces the risk of HIV infection in both women and men — an approach known as pre-exposure prophylaxis (PrEP). When taken regularly, PrEP can significantly reduce a person's risk of acquiring



HIV\*.<sup>4-5</sup> Emtricitabine/tenofovir disoproxil fumarate has been approved as PrEP in both South Africa and Kenya,<sup>6,7</sup> and numerous PrEP demonstration projects are planned or under way in these countries.<sup>8</sup>

### PrEP is one of several prevention options

Many HIV prevention options exist, such as using condoms consistently and correctly, abstaining from sex, and reducing the number of sexual partners. Having multiple HIV prevention options allows individuals to pick what works best for them at any given point in their lives. This can help individuals achieve better protection overall, even if they are not using all HIV prevention options all the time.

PrEP is not meant to replace existing HIV prevention approaches, but instead to complement them. Ideally, individuals will use a combination of prevention measures, such as using condoms consistently and correctly, reducing the number of sexual partners they have, and adhering to PrEP.

<sup>\*</sup>PrEP is an intervention to reduce the risk of HIV. Truvada is currently the only ARV drug approved as a PrEP intervention. In this guidance, we use the word "PrEP" to refer to both the intervention and the drug, for ease of reading.

In reality, however, perfect use of any prevention option is difficult for many people. Some individuals may have limited or no control over condom use with some or all of their partners, or may wish not to use condoms. Others may find it difficult to reduce their number of sexual partners or to refuse sex with unsafe partners. And, some individuals may have difficulties remembering to take PrEP every day without interruption. Having a range of prevention options to choose from ensures that everyone can find an approach that works best for them.



Guidance on PrEP-specific risk-reduction counseling must therefore address the possibility that some individuals who use PrEP may choose to discontinue condom use or to use condoms less consistently, even if they are encouraged to continue condom use while using PrEP.

#### Purpose of this guidance

The purpose of this guidance is to promote informed decision making on sexual health for women who have expressed interest in using PrEP as part of their HIV risk-reduction strategy.

#### The guidance is...

Written for service providers (e.g., counselors, nurse counselors) who provide HIV risk-reduction counseling at facilities that offer PrEP to clients.

#### The guidance is...

Specifically for women who are HIV-negative. Although HIV-negative men can also take PrEP, this guidance describes factors HIV-negative women should consider when taking PrEP.



#### The guidance is...

Founded on the informed-choice counseling approach traditionally used in family planning and on research on informed decision making.<sup>9-12</sup> It acknowledges and supports many different HIV risk-reduction approaches while encouraging women to consider how these approaches apply to their individual needs and circumstances.

#### The guidance provides...

Essential HIV prevention information in the context of PrEP. It helps counselors guide clients through decision making that affects their overall sexual health. It does this by describing the potential advantages and limitations of PrEP, asking essential questions that allow women to reflect upon the information within their own values and risk situations, and communicating key messages about sexual health.

#### The guidance is intended...

To be incorporated into standard risk-reduction counseling and evidence-based PrEP adherence counseling. It is not designed to replace these types of counseling. Also, it does not provide guidance on all HIV risk-reduction methods, as such materials can be found elsewhere. Rather, this guidance provides information on PrEP, focuses on decisions concerning PrEP and condoms, and places counseling about PrEP in an overall framework of informed and voluntary choice.

Programs interested in using this guidance will need to adapt it based on their national guidelines and their facility's standard operating procedures on HIV risk reduction.



# Background Research and Guidance Development

#### **Survey research and interviews**

In 2012, a survey was conducted in Bondo, Kenya, and Pretoria, South Africa, among 799 women who were not taking PrEP, to find out how their sexual behaviors might change if they were to start taking PrEP. The findings showed that 27% to 40% of the women, depending on their risk situations, would be inclined to reduce their use of other HIV risk-reduction measures (i.e., be less likely to use condoms, be more likely to have sex with a new partner) if they were to start taking PrEP.<sup>13</sup>

Qualitative interviews were then conducted among 60 women whose survey responses suggested that they would be more likely to reduce condom use or have sex with a new partner if they took PrEP. The purpose of the interviews was to explore motivations for their



anticipated behavior change. Three interrelated themes were identified:14

- "PrEP protects" PrEP was viewed as a highly effective HIV prevention method that will replace the need for using other HIV risk-reduction methods, such as condoms.
- Using PrEP will alleviate the challenges women face in negotiating the use of condoms, because PrEP can replace them.
- PrEP provides an opportunity for financial gain, because having sex without a condom or with a new partner was often necessary for receiving material goods and financial assistance; PrEP would provide reassurance in these situations.

These results highlight the need for guidance on how to counsel women who may reduce or discontinue their use of other HIV risk-reduction measures. Such guidance could help these women make informed choices about their overall sexual health when using PrEP.<sup>15</sup>

#### **Developing the guidance**

During the initial stage of guidance development, women's perceptions of the concept of an informed-choice approach for PrEP-specific risk-reduction counseling were explored. Eight focus group discussions (four in Bondo and four in Pretoria) were conducted with women at higher risk of HIV.<sup>16</sup> One purpose of the focus group discussions was to gauge the acceptability of the informed-choice approach among women who could be recipients of PrEP counseling in the future.

Several women said they believed an informed-choice framework was a good approach for PrEP-specific counseling; only one woman responded negatively to the approach, saying too much information would be provided to clients. Some women said they liked that a client being counseled could choose what risk-reduction strategy would be best for her. And, some said that by using the informed-choice approach, they believed counselors would provide clients with sufficient information that would allow a woman to make a good decision about her own health.

In-depth interviews with six risk-reduction counselors (three in Bondo and three in Pretoria) were also conducted to gather information to help shape the guidance. Counselors were asked to describe, for example, what questions they ask or would ask to facilitate discussions on women's risk perceptions or to help women identify their own HIV risk behaviors. They were also asked to describe the types of questions they would ask to help women determine if PrEP is the right HIV prevention option for them and what information they think women will want to know about PrEP in order to make informed decisions about its use. Counselors' suggestions informed the guidance.

The guidance also incorporates the counseling materials and messages developed for the Strategies to Combine PrEP with Prevention Efforts (SCOPE) demonstration study for women, for which protocol and materials development was sponsored by FHI 360 with funding from the U.S. Agency for International Development (USAID).<sup>17</sup>

In March 2015, six workshops were held in Bondo and Kisumu, Kenya, and in Pretoria, South Africa, to review and discuss the proposed guidance. Workshop participants included key stakeholders, members of community advisory boards, and HIV risk-reduction counselors. The guidance was finalized after the comments from the workshops were incorporated and the workshop participants were provided the opportunity to give feedback on the final draft of the guidance.

# **Guiding Principles**

The guidance is informed by two overall principles.

Principle #1: Enabling women to make an informed and voluntary choice of HIV prevention options is the foundation of effective counseling

Making an informed and voluntary choice about sexual and reproductive health is one of the human rights recognized by the international community and supported by many countries around the world. <sup>18</sup> Informed and voluntary choice (Box 1) means individuals are entitled to:

- Attain high standards of sexual and reproductive health.
- Receive relevant information and means to act on this information.
- Make their own decisions without discrimination, coercion, or violence.

A well-informed client who voluntarily chooses a course of action, preventive approach, or treatment (when appropriate) that best meets her needs is more likely to be satisfied and to adhere to her choice. 19-21

### Box 1. Informed and voluntary choice

Informed → A woman needs to have clear, accurate, and specific information to make an informed decision. Having this information will help her make many decisions about her health, including the most suitable approach for HIV prevention. While making these informed choices and decisions, a woman should be allowed to consider her unique health needs, risks, values, and preferences.

**Voluntary** → A woman needs to be encouraged to make her own decision — the one that may work best for her — and not be pressured to make a particular choice.

Choice → A woman must have a range of options in order to make a choice.

For HIV prevention, this means a woman should choose the risk-reduction option, or options, that will work best for her.

# Principle #2: Women are capable of making informed decisions about their overall sexual health

Counselors who believe that women can make the decisions that are best for them — including decisions on the use of other risk-reduction measures, particularly condoms, when they are using PrEP — will be able to facilitate informed and voluntary choice counseling on sexual health. This counseling style considers a woman's:

- Context and experiences with her sexual partners.
- Experiences with condom use prior to using PrEP.
- Intentions for condom use when taking PrEP.



The "one-size-fits-all" prevention message of "always use condoms" may not be realistic for many women. Although women who consider PrEP should be encouraged to also use or continue using condoms, simply telling women to "always use condoms" in addition to PrEP may suggest that PrEP is not effective for HIV prevention on its own. It can discourage some women from using PrEP at all, leaving them without protection in situations in which consistent condom use is not achievable.

Women who are unable or unwilling to use condoms consistently when taking PrEP need guidance to:

- Make informed decisions about contraception and about regular screening and treatment for sexually transmitted infections (STIs).
- Understand the importance of PrEP adherence, especially if PrEP will be used as the primary HIV prevention strategy.

# The Guidance

The guidance is divided into four sequential phases (Figure 1):

- First, in the introductory phase, a client expresses interest in learning more about PrEP.
- Second, in the information phase, the counselor provides accurate information about PrEP and condoms.
- Third, in the deliberation and decision-making phase, the counselor helps the client apply this information to her individual circumstances and to consider what the best option is for her overall sexual health.
- Fourth, in the concluding phase, the client finalizes her plan to reduce her risk of HIV and to maintain her overall sexual health. The counselor summarizes the client's plan and welcomes her to return if she would like to try another approach in the future.

At the end of these phases, the client has made an informed decision about PrEP and the use of other HIV risk-reduction methods.

#### How to read the guidance:

Each phase, except the concluding phase, begins with an overview of the phase and an outline of the steps within that phase. After that, detailed guidance is provided on how to carry out each of the steps. Programs interested in using this guidance must incorporate these steps into their current HIV risk-reduction standard operating procedures based on their country's national guidelines.

#### Figure 1. Phases of informed-choice PrEP counseling

#### **Introductory Phase**

#### The counselor:

- Informs client that another HIV prevention option, called PrEP, is available
- Briefly explains what PrEP is, so the client can decide if she is interested in learning more

#### The client:

- Expresses interest in PrEP → proceed to information phase
- Is not interested in PrEP → proceed to standard HIV risk-reduction counseling

#### **Information Phase**

#### The counselor:

- Explores the client's current context of risk and preventive behaviors
- Educates about what PrEP can and cannot do
- Educates about what condoms can do
- Educates on the benefits of using condoms and PrEP together
- Encourages client to ask questions and asks client questions to ensure comprehension

#### The client:

Helps the counselor understand her context of risk and preventive behaviors

### **Deliberation and Decision-Making Phase**

#### The counselor:

- Helps client apply information to her individual circumstances
- Provides other essential information and skills to prevent HIV and promote overall sexual health:
  - Stresses importance of PrEP adherence
  - Offers to help build skills to improve condom use
  - Addresses pregnancy risk and educates on contraceptive methods as needed
  - Discusses risk and screening for STIs
- Supports client in her informed decision about what risk-reduction method or combination of methods to use

#### The client:

- Considers what risk-reduction methods are best for her
- Makes an informed decision about what risk-reduction method or combination of methods to use

### **Concluding Phase**

- The client finalizes her decision.
- The counselor welcomes her to return in the future if she would like to try a different approach.



### **Introductory phase**

The introductory phase is likely the first time a counselor and a client have talked about PrEP. The discussion could be initiated by the client or by a provider. For example:

A client may come to the clinic to express her interest in using PrEP. In this situation, she may have already decided that she wants to use PrEP.

Or, a client may have heard about PrEP, but wants to learn more about it before deciding whether she wants to use it.

Or, a client may have never heard about PrEP, but has come to the clinic to learn more about HIV prevention, or has come to the clinic for another reason related to her health. In this situation, a counselor can inform her that a new HIV prevention option called PrEP is available and can briefly describe what it is.

In any of these situations, an opportunity exists for a counselor to assist the client in thinking about her overall sexual health while taking action to reduce her HIV risk.

#### We recommend three steps in the introductory phase:

Step 1: Set the agenda for the counseling session

Step 2: Inform the client that PrEP is available

Step 3: Briefly explain what PrEP is

#### Step 1: Set the agenda for the counseling session

#### Frame the discussion:

Client-initiated: I understand that you are interested in taking PrEP or in learning more about it. Today I will tell you all about PrEP, so you can decide if PrEP is a good HIV risk-reduction method for you. I would also like to talk about your risk for HIV and other things you are doing to prevent HIV. Together, we will think of actions that you can take to remain HIV-free. We will also talk about ways to keep you healthy overall.

**Provider-initiated:** Today I would like 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 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.

#### Suggested questions to ask:

- How do you feel about this discussion? Are you comfortable with this discussion?
- 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?

Proceed if the client agrees to continue with the discussion. If the client is uncomfortable with the discussion, explore what might make her feel comfortable. If the client does not want to proceed with the session or decides that she is not interested in PrEP, switch to standard HIV risk-reduction counseling, if the client agrees. Set up another time to meet if the client wants her partner to be involved in the counseling session.

Encourage the client to ask any questions that she has at any point during the session. Inform the client that everything that will be discussed will remain confidential.

### **Step 2: Inform the client that PrEP is available**

This step is simple and brief: inform the client that a new HIV prevention option called PrEP — short for pre-exposure prophylaxis — is now available at this clinic.



#### **Step 3: Briefly explain what PrEP is**

- Begin by asking the client to tell you what she has heard about PrEP.
- Explain that you will now provide her with a brief overview of PrEP, to see if she is
  interested in learning more. Also clarify any myths and misconceptions she may have.
- Explain, as needed, that:
  - PrEP is an ARV pill that HIV-negative people can take regularly 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.
  - Women interested in using PrEP are currently advised to take it daily.
- Show a PrEP pill to the client. Allow her to hold and look at the pill.
- Ask the client if she is interested in learning more about PrEP.

Based on the client's interest, proceed to the information phase of the guidance or switch to standard HIV risk-reduction counseling. Inform her about how long the counseling session is anticipated to last.

## **Information phase**

During the information phase, the counselor learns about the client's current context of risk and preventive behaviors and provides essential information on PrEP and other preventive options.

We recommend four steps in the information phase:

- **Step 1: Explore the client's current context of risk and preventive behaviors**
- Step 2: Educate about what PrEP can and cannot do
- Step 3: Educate about what condoms can do
- Step 4: Educate on the benefits of using PrEP and condoms together

### Step 1: Explore the client's current context of risk and preventive behaviors

#### Frame the discussion:

Sometimes people find it hard to practice safer sex on a day-to-day basis. Also, some partners do not want to use condoms or will use them only occasionally. I would like to hear from you about what your experience has been like.

#### Suggested questions to ask:

- For clients who came to the clinic wanting to use PrEP or to learn more about it:
  - ✓ What are the reasons you are considering a new HIV prevention method?
  - ✓ What are you currently doing to reduce your risk of HIV?
    - What has worked for you when it comes to safer sex?
    - What has not worked?
    - When is safer sex most difficult for you to achieve? [Explore experiences in using condoms and partner reduction, as appropriate.]
- For provider-initiated discussions on HIV risk reduction:<sup>1</sup>
  - ✓ Let us first talk about whether you might be at risk for HIV. How at-risk do you think you are for HIV?
  - ✓ Your risk for HIV depends on several things. Some sexual practices are more risky than others. The sexual behavior and HIV infection status of your partner can increase your risk of HIV. Let us now talk about your sexual partner or partners.

<sup>&</sup>lt;sup>1</sup> This step is typically conducted as part of HIV risk-reduction counseling. It is not a new step with the introduction of PrEP. You can modify this step as needed when incorporating this guidance into your facility's standard operating procedures on HIV risk reduction.

- Explore with the client whether she has a primary partner or any casual or once-off partners. Ask the client for the possibility that any of her partners:
  - Was diagnosed with HIV.
  - May have sexual partners other than her.
  - Is HIV-negative but routinely undergoes testing for HIV.
  - Does not know his HIV status or refuses to share it with her.
  - Is uncertain about his HIV status and refuses to test.
  - Was recently treated for an STI.
- ✓ It is also possible that your sexual behavior or practices could put you at risk. What sexual behaviors or practices of yours do you think might put you at risk of HIV?
- ✓ What would you like to do to reduce your risk of HIV?
- ✓ What are you currently doing to reduce your risk of HIV?
  - What has worked for you when it comes to safer sex?
  - What has not worked?
  - When is safer sex most difficult for you to achieve? [Explore experiences in using condoms and partner reduction, as appropriate.]
- Consider the client's individual factors and circumstances that facilitate or prevent the use of HIV risk-reduction methods, particularly condom use. Tailor the discussion to:
  - Acknowledge and support any positive steps the client has already taken to reduce her risk of HIV.
  - Clarify sexual practices and behaviors that are riskier based on the client's answers.

- Ask and answer any questions the client may have before proceeding with the next step:
  - Based on what we have discussed this far, what questions do you have for me before we continue?

### Step 2: Educate about what PrEP can and cannot do

#### Frame the discussion:

Let us talk first about PrEP. Any time a person is thinking about starting something new, it is common to have questions, concerns, or even troubles using the new method or approach correctly. Together we can make sure that you understand what PrEP can and cannot do. And, we can make sure that you are comfortable using PrEP, if you decide that PrEP is a good option for you.

#### Suggested questions to ask:

- Earlier you said that you heard \_\_\_\_\_ [from introductory phase] about PrEP. Based on what you have heard, what do you like about PrEP?
- What questions or concerns do you have about PrEP?
- Acknowledge the client's knowledge about PrEP. Provide additional information and clarify myths and misconceptions as needed:
  - PrEP stands for Pre-Exposure Prophylaxis, where "prophylaxis" means "prevention of disease."
  - PrEP is a pill that, if taken daily by HIV-negative women, can significantly reduce their chances of getting HIV. HIV-negative men can also take PrEP. PrEP can help women and men who are HIV-negative remain HIV-negative.
  - Sometimes PrEP is referred to as Truvada (which is the brand name). Truvada combines 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. The names of the ARV drugs are emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF).
  - PrEP does not cure HIV, but it can prevent it in people who are HIV-negative.

- PrEP is not 100% effective at preventing HIV. But it can be around 90% effective in women when taken very regularly (i.e., every day).<sup>22</sup> If PrEP is not taken every day, it is much less effective. Because PrEP is not 100% effective, it is recommended that people still use condoms when they have sex, even if they are taking PrEP, for the best protection against HIV.<sup>23</sup>
- HIV-negative people do not need to take PrEP for the rest of their lives (unlike HIV-positive people, who do need to take ARV drugs for the rest of their lives, to treat HIV).
   PrEP should be taken only for as long as the HIV-negative person remains at high risk for HIV. This could be for only a few months or it could be for years.
- For women, PrEP must be taken every day. During the times in a woman's life when she is at risk for HIV, she should take PrEP daily, even if she does not have sex every day. This approach is similar to that for the contraceptive pill, which women must take every day to prevent pregnancy. For PrEP, taking the drug every day ensures that enough of the drug is present in the body at all times to prevent infection.
- PrEP does not provide any protection against pregnancy and most STIs. PrEP provides some protection against a certain type of herpes simplex virus<sup>24</sup> but no protection from other STIs.
- Provide detailed information about PrEP as needed based on the client's current knowledge:
  - Explain how PrEP works:

HIV can still enter the body of a person taking PrEP, if she or he comes into contact with semen or vaginal fluids from someone with HIV. PrEP keeps the virus from making copies of itself once inside the person's body. Without making copies, the virus cannot stay in the body for long and the person does not get HIV infection.

- Describe when individuals should consider taking PrEP:
   Being HIV-negative doesn't mean one needs PrEP PrEP is not for everyone. It is most appropriate for people at increased risk of being exposed to HIV. You should consider taking PrEP if:
  - ✓ You know or are concerned that your main sexual partner is HIV-positive.
  - ✓ You have multiple sexual partners.

- ✓ You know or are concerned that your partner has other sexual partners.
- ✓ You have sex with partners whose HIV status is unknown and you do not use condoms.
- ✓ You engage in riskier sexual practices (e.g., anal sex).
- ✓ You or your partner was recently treated for an STI.
- ✓ You have used post-exposure prophylaxis called PEP more than once in the past year.
- ✓ Before having sex, you use alcohol or drugs (or have sexual partners who do), which can impair your ability to practice safer sex or make you more likely to take sexual risks.
- ✓ You are willing to come back to the clinic regularly to get a new supply of PrEP
  [describe program's schedule for getting PrEP refilled].
- ✓ You are willing to be tested for HIV (and have the other necessary laboratory tests) before starting PrEP and regularly as you are taking PrEP [describe your program's schedule for HIV and other laboratory testing for PrEP users, for example, every 2, 3, or 4 months].

#### • Explain who should not use PrEP:

PrEP should not be used by people who:

- ✓ Are HIV-positive or do not know their HIV status.
- ✓ Are HIV-negative but have been diagnosed with serious kidney disease (a condition in which kidney function suffers). This is because decreased kidney function has been seen in some HIV-positive people whose HIV treatment regimen contained one of the same drugs that is in PrEP (i.e., Truvada).
- ✓ Do not think they can take a pill every day. Women should carefully consider if they want to take a pill daily before they start using PrEP. This is because PrEP is not as effective at preventing HIV among women when it is not taken regularly, based on current research.

#### • Explain how PrEP should be taken:

PrEP should be taken once a day for as long as a person remains at high risk for HIV infection. It can be taken with or without food. Alcohol use does not affect how safe or effective the pill is.

#### • Explain what the side effects of PrEP are:

PrEP may cause side effects in a small number of people who use it. The most common side effects are headache, weight loss, nausea, vomiting, and abdominal discomfort.

These side effects may be unpleasant, but they are not harmful.

In most cases, the side effects diminish with time — often after a few weeks of taking PrEP. If you find them hard to tolerate, tell your health care provider, who can help you manage and minimize some of them.

In addition, a very small number of people who take PrEP can develop kidney problems, which usually disappear after stopping the pill. Before people start PrEP, they will be tested to ensure that their kidneys are healthy. After they start PrEP, they will have their kidney function monitored regularly to ensure that they remain healthy.

#### • Explain how long people can take PrEP:

People do not need to take PrEP for the rest of their lives. They can take PrEP for as long as they remain at high risk of getting HIV. This could be for months or possibly years. However, they will need to continue coming to the clinic for periodic checkups for as long as they take the pill. This way their doctors can make sure PrEP is still a good option for them.

#### • Explain what might happen if PrEP is not taken regularly:

Women taking PrEP should take it every day. This is because PrEP is most effective against HIV among women when it is taken daily. If PrEP is not taken daily by women, it is much less effective. If a woman takes PrEP occasionally and is not using other HIV risk-reduction methods, she could become infected with HIV if she is exposed to virus.

In addition, because PrEP is not 100% effective, some people can still become infected with HIV when taking PrEP. If this happens, the virus could develop resistance to the ARV drugs found in PrEP (i.e., Truvada). This means that HIV could stop responding to those drugs. If the person later uses the same ARV drugs as part of her HIV treatment regimen, the drugs will have little or no effect on the virus. Developing drug resistance means that the person will have fewer effective options for HIV treatment.

While you are taking PrEP, it is therefore important that you are regularly tested for HIV [describe your program's schedule for HIV testing for PrEP users], particularly after you think you may have been exposed to HIV.

• Explain how soon PrEP becomes effective after a person starts taking it (i.e., how long it might take before PrEP works to prevent HIV):

PrEP is not protective right after the first pill is taken. The amount of drug in a person's body has to reach a certain level to effectively prevent HIV.

Current guidance<sup>23</sup> recommends that women should take PrEP every day for about 3 weeks before it can be relied on for HIV prevention. This is because the maximum, steady concentration of drug in the blood and in vaginal tissue occurs after about 20 days of daily use. <sup>25-26</sup>

#### • Explain how to safely stop taking PrEP:

Stopping PrEP will not cause any harm or make one more likely to get HIV than before she or he started taking PrEP. However, for men who have sex with men, current research suggests that PrEP should be taken for 4 weeks after the person last had sex with someone who might be HIV-positive.<sup>27</sup> It is believed that taking PrEP during this time (while using other approaches to reduce risk, such as condoms or abstinence) will provide protection against any HIV that may still be in the person's body. Similar research is not available for women. [Until more evidence on PrEP in women is available, it seems reasonable to counsel women who think they are no longer at risk of HIV (e.g., they entered into a mutually faithful relationships with an uninfected partner) and who want to stop taking PrEP to continue to take it daily for at least 4 weeks after they last had sex with someone who might be HIV-positive. At the same time, it is important to keep in mind that this guidance may change in the future (depending on any new study results) and counselors will have to adjust their counseling messages accordingly.]

Stopping PrEP also takes away an effective method of HIV protection. For people who used to rely on PrEP and remain at high risk of HIV, this could mean a greater risk of infection if other means of HIV protection are not used, such as using condoms consistently with all partners, avoiding risky sex practices, and reducing one's number of sexual partners. People who are at risk of HIV but stopped using PrEP will have to consider what other HIV prevention approaches to use and how to use them effectively.

Explain the difference between PrEP and post-exposure prophylaxis (PEP):
 PrEP is not the same as PEP (which stands for Post-Exposure Prophylaxis). Although both are taken by HIV-negative people to prevent HIV, PrEP is taken to reduce the risk of getting HIV before someone might be exposed to HIV.

PEP, on the other hand, is taken **only after** a person might have been exposed to HIV (e.g., if a condom broke or was not used with a partner who is possibly HIV-positive, if a person was raped). PEP must be started within 3 days after possible HIV exposure and it involves taking a full treatment dose of ARV drugs two or three times a day for 28 days.

Because of the higher dose of ARV drugs in PEP, side effects are more common with PEP than with PrEP, and they are more pronounced.

PEP is a good choice for those who may experience rare, accidental exposure to HIV, while PrEP is a good choice for people who have an ongoing high risk of HIV exposure.

- Explain whether PrEP is needed when a partner is taking treatment for HIV:

  For serodiscordant couples when one partner is HIV-negative and the other is HIVpositive the HIV-negative partner can be at reduced risk of acquiring HIV if the HIVpositive partner is on ARV treatment and her or his viral load is suppressed. This
  prevention approach (also called treatment as prevention) can only work when the HIVpositive partner always takes her or his ARV drugs as prescribed and the couple is having
  sex only with each other and have no other sexual partners. In these situations, the HIVnegative partner may not need PrEP if she is comfortable with relying on her partner to
  adhere correctly to HIV treatment.
- Ask and answer any questions the client may have before proceeding with the next step:
  - Based on what we have discussed this far, what questions do you have for me before we continue?

#### Step 3: Educate about what condoms can do

#### Frame the discussion:

Now let us talk about condoms. Many people rely on condoms for HIV prevention. But, at the same time, a lot of people find it difficult to use condoms consistently. Many women have trouble discussing or negotiating condom use with their partners. Together, we can explore how you feel about condoms and think about what kind of protection condoms can offer you.

- Suggested questions to ask:
  - Can you tell me what you know about male condoms? Female condoms?
  - What are the advantages of using condoms? What do you like about condoms?
  - What might be the disadvantages of using condoms? What have you found challenging about condoms? What strategies, if any, have you used to overcome these challenges?
- Acknowledge the client's knowledge about and experience with condoms. Provide additional information as needed:
  - When used correctly and every time you have sex, condoms:
    - ✓ Provide a high level of protection against HIV about 98%.
    - Provide a high level of protection against other STIs and pregnancy.
  - When not used every time or used incorrectly, condoms are much less effective.
  - Using condoms only some of the time with partners who have HIV or whose HIV status is unknown may be as risky as using no condoms at all.
- Ask and answer any questions the client may have before proceeding with the next step:
  - Based on what we have discussed this far, what questions do you have for me before we continue?

#### Step 4: Educate on the benefits of using PrEP and condoms together

#### Frame the discussion:

It is good to have more than one option for protecting yourself from HIV, but managing several methods requires more commitment than managing just one. It may be easier to commit when a person has a better understanding of why multiple methods are important. So let us talk about the benefits of using PrEP and condoms together.

#### Suggested questions to ask:

- Can you tell me why it might be good to use both PrEP and condoms to prevent HIV?
- What do you think may be challenging when using PrEP and condoms together?
- Acknowledge the client's knowledge about the benefits of using PrEP and condoms together. Provide additional information as needed based on her knowledge:
  - Using PrEP and condoms together leads to the best protection. This is because:
    - $\checkmark$  Using prevention approaches in addition to PrEP such as condoms improves overall protection from HIV.
    - ✓ Taking a pill every day may be difficult to remember. Condoms provide protection if pills are missed, and PrEP provides protection on occasions when condoms are not used.
    - ✓ Continuing to use condoms while taking PrEP has an advantage because even if one method fails, another one still provides protection from HIV.
    - ✓ PrEP does not protect against most other STIs and against pregnancy. Condoms provide protection from STIs and can also be used for pregnancy protection.
- Ask and answer any questions the client may have before proceeding with the next step:
  - Based on what we have discussed this far, what questions do you have for me before we continue?

### **Deliberation and decision-making phase**

During the deliberation and decision-making phase, the counselor helps the client think about her overall sexual health while applying what she has learned about HIV prevention during the information phase to her individual circumstances.

The counselor and client will also discuss — and the client will likely choose among — multiple HIV risk-reduction approaches in which she may rely on PrEP alone or PrEP in combination with other HIV prevention approaches. Special emphasis is given for clients who are unable to use condoms consistently or are planning to use PrEP without condoms or other HIV risk-reduction methods.

To be effective, counselors should be prepared to consider and accommodate all women's individual situations and preferences.

We recommend two steps in the deliberation and decision-making phase:

- Step 1: Help the client apply the information to her individual circumstances
- Step 2: Provide other essential information and skills to prevent HIV and promote overall sexual health

Throughout this phase, the counselor supports the client in her informed decision about what risk-reduction method or combination of methods to use.

#### **Step 1: Help the client apply the information to her individual circumstances**

#### Frame the discussion:

You have the power to take steps to reduce your risk for HIV, even if you do not have the power to change all things for the better. Every step you take to reduce your risk of HIV — big or small — helps. Using PrEP could be one such step. Together we will explore what steps may work best for you and what may help you to take these steps. Based on what we have discussed and what you have learned today, you can make an informed decision about what methods will work best for you to reduce your risk of HIV and maintain your overall sexual health.

#### Suggested questions to ask:

- 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 any other HIV risk-reduction approaches that you think may work better for you? (e.g., using condoms alone, practicing mutual monogamy after you and your partner both test HIV-negative). (If yes) Which ones?
- Are there HIV risk-reduction approaches that you may want to use in addition to PrEP?
   (If yes) Which ones?
- If the client would like to use PrEP, help her consider which HIV risk-reduction approaches are realistic for her:
  - Taking PrEP daily + using condoms consistently with all partners.
  - Taking PrEP daily + using condoms only with certain categories of partners (e.g., partners who are known to be infected, high-risk partners such as partners who have other partners, partners whose HIV infection status is unknown, new partners).
  - Taking PrEP daily + avoiding or minimizing sex with high-risk partners.
  - Taking PrEP daily + reducing the number of sexual partners.

- Taking PrEP daily + minimizing high-risk sexual practices (e.g., anal sex) or using condoms in such cases.
- Taking only PrEP daily in other words, using PrEP alone.

The client may also decide at this point that she does not want to take PrEP. If this is her decision, transition to standard HIV risk-reduction counseling.

#### Tailor the discussion:

- Discuss possible advantages and limitations of the client's preferred approach.
- Identify doable, realistic HIV risk-reduction steps that the client can try.
- Provide support in her informed decision about what risk-reduction method or combination of methods to use.
- Ask and answer any questions the client may have before proceeding to the next step:
  - Based on what we have discussed this far, what questions do you have for me before we continue?

# Step 2: Provide other essential information and skills to prevent HIV and promote overall sexual health

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Fra	me	the	disc	ussion:

You have chosen to try \_\_\_\_\_\_ to reduce your risk of HIV. I support you in your decision. Let us now talk about other things you need to think about to prevent HIV and ensure your overall sexual health.

- Provide additional knowledge and skills based on the client's chosen HIV risk-reduction approach:
  - If the client choses to use PrEP alone, without condoms:
    - Acknowledge that if she wants to rely on PrEP alone, it is better than not using any method to prevent HIV.
    - ✓ Stress the importance of daily adherence to PrEP, since it will be her only method for reducing her risk of HIV:
      - The pill should be taken every day. This is because in women, PrEP is most effective at preventing HIV when it is taken daily.
      - Although it is best to take PrEP every day, missing a pill occasionally still provides some protection — it is better than not using any risk-reduction measure at all. However, if you miss a pill often, your protection from HIV may decrease significantly.
    - Explore the feasibility of adherence to PrEP, particularly her confidence in being able to take a pill daily (e.g., maintaining privacy when desired, getting pills refilled on time, ability to establish a daily routine). If the client believes it may be difficult for her to take a daily pill, explore other potential HIV risk-reduction options.
    - If the client believes daily PrEP is the best approach for her, provide evidence-based PrEP adherence counseling following your facility's standard operating procedures.

• If PrEP will be used in combination with condoms (regardless of the consistency of condom use):

Follow your facility's standard operating procedures and offer skills-building activities to support condom use (e.g., male and female condom demonstration and practice, condom negotiation).

Initiate discussion on the prevention of pregnancy and other STIs:

Up until now, we have talked about preventing HIV. But being sexually active means that women must also think about whether or not they want to get pregnant. Women also must think about ways to protect themselves from other STIs. To use their chosen preventive approaches effectively, women need accurate information and practical skills. Let us focus on this now and talk about ways to ensure your overall sexual health.

- Assess the client's fertility intentions (i.e., whether or not she wants to become pregnant):
  - If the client does not want to become pregnant but is not using a contraceptive method, emphasize that condoms provide protection from pregnancy but that other, more effective contraceptive methods are available.
  - Follow your facility's standard operating procedures and initiate contraceptive counseling or provide referrals for contraceptive counseling and methods as needed.
- Provide information about and discuss risk for other STIs:
  - Describe to the client that:
    - ✓ If someone is at risk of HIV, the person is also at risk of other STIs.
    - ✓ PrEP (i.e., Truvada) provides some protection against a certain type of herpes simplex virus<sup>24</sup> but no protection from other STIs — only abstinence and condoms do, if used correctly and consistently.
    - ✓ STIs can also increase risk for HIV infection and cause other serious, long-term health problems, including infertility.

- Describe common STI symptoms and stress the need to come back right away if any of these occur:
  - ✓ Lower abdominal pain.
  - ✓ Unusual vaginal discharge.
  - ✓ Painful or frequent urination.
  - √ Vaginal bleeding or spotting during or after sex.
  - ✓ Bleeding between menses.
- Explain that many women with STIs have no symptoms at all and that regular STI testing may be the only way to diagnose STIs and provide timely treatment.
- Describe your facility's program for regular STI screening for PrEP users. Make a plan for the client's regular STI screening.
- Ask and answer any questions the client may have before concluding:
  - What questions do you have for me before we wrap up today's session?

### **Concluding phase**

By the end of the deliberation and decision-making phase, the client will have likely made an informed decision about what HIV risk-reduction method or combination of methods are best for her. Additional information and skills necessary to carry out her approach have also been discussed and practiced. To conclude the session, summarize the client's HIV risk-reduction plan.

#### Frame the discussion:

I support you in the decisions you have made to reduce your risk of HIV and maintain your overall sexual health. I would like to make sure that I have a clear understanding of the steps you are planning to take. Then we can conclude the session.

- Suggested question: Would it be okay if I quickly summarize what we just discussed?
- Summarize plan: Provide a brief summary of the client's plan for HIV risk reduction, PrEP adherence, and overall sexual health.

#### Probe:

- Did I understand it correctly?
- Did I miss anything?
- Is there anything else you are planning to do?

#### Conclude the session:

- Ask the client if she has any remaining questions. Provide any clarifications as needed.
- Acknowledge that the client's HIV risk-reduction needs will likely change over time.
   What works for her now might not work for her in the future. Let the client know that
   she is welcome to talk with you again the future if she would like to discuss different HIV
   risk-reduction options if her current situation changes or if she would like to try a
   different approach.

- Provide any additional PrEP-specific guidance per clinic guidelines. This may include:
  - ✓ Where to pick up her PrEP pills.
  - How often to return to the clinic for PrEP adherence and HIV risk-reduction counseling, for contraceptive counseling, and to refill her PrEP pills and contraceptive method.
  - ✓ HIV and STI testing recommendations.
  - ✓ Recommendations for clinical and laboratory monitoring.
- Thank the client for her time.

Additional resources are located in Appendix B.

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# Appendix A

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# Appendix B

### **Additional Resources**

- National AIDS and STI Control Programme (NASCOP) in Kenya: http://nascop.org/nascop/about-us.html
- Southern African HIV Clinicians Society: www.sahivsoc.org
- U.S. Centers for Disease Control and Prevention: http://www.cdc.gov/hiv/prevention/research/prep/





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