

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; performing appropriate testing before initiating someone on PrEP and while the person is taking PrEP; and how to follow up PrEP users and offer counselling on issues such as adherence.



Module 2: Community educators and advocates. For PrEP services to reach populations in an effective and acceptable way, community educators and advocates are needed to increase awareness about PrEP in their communities. This module provides up-to-date 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 addressing issues around 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 most effectively implemented in their own settings. It also contains a series of frequently asked questions about PrEP, with related answers.



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 under a pharmacist's supervision. It provides information on the medicines used in PrEP, including the optimal storage conditions. It also 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 are responsible for providing testing services at PrEP sites and associated laboratories. It offers guidance in selecting relevant testing services, including appropriate screening of individuals before PrEP is initiated and monitoring while they are taking PrEP. Information is provided on testing for HIV, creatinine, hepatitis B and C virus, pregnancy and sexually transmitted infections.



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.

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 PrEP Users module

This module is for people who are considering starting PrEP or who are currently using PrEP. Countries and PrEP services can adapt its contents to provide information about PrEP availability and PrEP services that are more specific to their setting. For example, links to specific locations can be added to the section titled “Where can I get PrEP?”, and links to local community-based and other resources can be added to the list of annotated Internet resources in the annex.

The World Health Organization recommends that PrEP should be offered to people who are at substantial risk of acquiring HIV infection.

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*).

Questions that people raise when considering PrEP

What is PrEP?

Pre-exposure prophylaxis (PrEP) is when people take an HIV medication to reduce their chance of getting infected while they are at risk of acquiring HIV. WHO currently recommends the use of PrEP taken daily for both men and women who are at substantial risk of acquiring HIV.

How well does PrEP work?

- PrEP does not provide 100% protection, but it is highly effective and provides a great deal of protection against HIV. In some recent studies, PrEP has been shown to reduce the risk of HIV infection during sex by over 90% when used consistently.
- PrEP is more effective for those who take PrEP regularly (that is, who are adherent) than for those who often miss their daily dose.
- Taking PrEP *every day* is recommended because daily use of PrEP is effective, safe and the most convenient approach. Daily PrEP use provides the highest amount of medication in the blood and body tissues and, thus, the highest level of protection. If you take PrEP daily, you may still be protected, even if you miss a dose once in a while.
- Time is needed to build up protective levels of the medicine in the blood and other tissues. Additional HIV prevention should be taken for the first seven days when starting PrEP. Ways to lower risk during this period include: adopting safer sexual practices, such as not having vaginal or anal intercourse, or using condoms. It is suggested that PrEP should be continued for 28 days after the last potential exposure to HIV.

Who should consider using PrEP?

PrEP is for people in situations and times in their lives when they may have a high risk of HIV infection. PrEP may offer you a way to help manage your risk of getting HIV. ***If you think that you are at high risk of HIV infection***, and you live in a place or in a community with a high HIV prevalence, there are many reasons why PrEP could be something for you to consider. For example:

- You are not using condoms all the time with all sexual partners.
- You are having or have had sex with more than one sexual partner in a six-month period.
- You have a sexual partner who has other sexual partners and may be likely to have or be at high risk of HIV infection.

- You are having unprotected sex with a person who injects drugs and shares injection equipment with others.
- You inject drugs and share injecting equipment.
- You have sex when drinking alcohol and/or taking recreational drugs.
- You have been told that you have a sexually transmitted infection, such as gonorrhoea, syphilis, chancroid or herpes.
- You have a sex partner who was recently told that he or she has a sexually transmitted infection, including HIV.
- You are having unprotected sex with someone who has HIV and who is not on antiretroviral therapy, or who is on antiretroviral therapy but has not achieved suppression of viral load to undetectable levels.
- You and your sexual partner do not discuss your concerns about HIV, or your partner does not know his/her HIV status.

Most of these risks will be greater in places where HIV prevalence is high.

In addition, members of the following populations may want to learn more about whether PrEP is a good choice for them:

- men and transgender people who have sex with men
- sex workers, especially if not able to use condoms with every sex act
- people with a sexual partner who has HIV (that is, being in a serodiscordant couple) and who is not on antiretroviral therapy and virally suppressed
- people, including adolescent girls and young women, who live in areas with a high HIV incidence
- people who inject drugs.

Who cannot use PrEP?

- People who already have HIV should not take PrEP. Instead, they should be offered antiretroviral therapy.
- People with kidney disease should not use PrEP containing tenofovir.

What are different ways to stay free of HIV?

There are many ways to stay free of HIV infection. You should choose what best suits your own needs and personal situation. You may combine different ways of staying free of HIV, and you can change which strategies you use over time. Here are some of the other things you can do to protect yourself.

- **Male and female condoms (with lubricants)** are effective when they are used consistently, with all sexual partners. Condoms also protect against other sexually transmitted infections and pregnancy.
- If you have a partner who has HIV, **treatment** of his or her infection with antiretroviral therapy can nearly eliminate the risk of transmission. For your partner's HIV treatment to protect you from HIV infection, your partner should have a viral load test that shows that their HIV has been suppressed to "undetectable" levels. If you have doubts about your partner's adherence to HIV treatment or the result of his or her viral load test, it is best to protect yourself in additional ways.
- **Post-exposure prophylaxis (or PEP)** 'is antiretroviral medication that can be taken after you have an exposure to body fluids containing HIV. For PEP to work well, you must start PEP as soon as possible after the exposure and no later than 72 hours after exposure. PEP should be continued for 28 days after the exposure.
- Being in a sexual relationship with **only one partner** can be helpful for preventing HIV infection if both partners have been tested and disclosed their HIV status to each other, and if they have agreed to have no other sexual partners. This applies when both partners are HIV-negative, or when one partner is negative and the other has HIV and is on antiretroviral therapy and virally suppressed. Such relationships are safer if you and your partner can discuss your agreements and expectations often. It is not reliable to simply assume, without any discussion, that your partner is not having sex with anyone else.
- If you inject drugs, it is recommended to use **new or sterile injection equipment, whenever possible**. This will prevent HIV transmission as well as other transmissible blood-borne infections such as hepatitis B and C.

Where can I get PrEP?

- PrEP is relatively new. Although an increasing number of clinics are offering it, it may be difficult to find a clinic that offers it in your area and in some countries PrEP is not currently available.
- Ask at your local clinic. If they do not know about PrEP, you can show them this publication. You can also ask them to help you find out where you can get it.
- Ask your friends about PrEP and if they know where to get it.

Do I have to use condoms while I am taking PrEP?

- PrEP does not require the use of condoms to be effective. However, condoms provide additional protection against HIV and protect you from other sexually transmitted infections and unplanned pregnancies:
 - PrEP does not prevent sexually transmitted infections, such as syphilis, gonorrhoea, chlamydia and hepatitis. Condoms, however, do provide protection against these other infections as well as against HIV, and so they protect your overall sexual health.
 - PrEP does not prevent pregnancy. When used consistently, condoms prevent pregnancy. There are many other ways to prevent pregnancy, including oral contraceptive pills and injectable hormones, implants, intrauterine devices and diaphragms. PrEP does not interfere with any contraceptive method.

Questions that people raise while using PrEP

How do I store my PrEP medication?

- There are usually 30 pills in each bottle (30 days of PrEP). Store the bottle at room temperature (not in a refrigerator and not in a hot place such as a car).
- Keep the pills in the bottle with the desiccant (the small bag or round plastic capsule that comes with the bottle to keep the medicine dry). If you wish, you can remove pills from their bottle and place them in a seven-day pill box, since this is only for a short time.

When and how do I take PrEP?

- WHO recommends that you take PrEP once a day every day. Daily use is safe and convenient and it provides the best protection against HIV.
- PrEP can be taken at any time during the day and at different times on different days.
- It is helpful to link taking PrEP with something that you do every day.
- PrEP can be taken with or without food.
- PrEP can be taken when drinking alcohol or using recreational drugs.
- PrEP can be taken if you are taking hormonal contraceptives, sex hormones or non-prescription drugs.
- It takes about seven days of taking PrEP daily before there is enough medication in your body to provide protection against HIV.
- Before you start PrEP, you will be tested to make sure that you do not have HIV. If the test finds that you have HIV, you will be linked to HIV treatment services.
- While taking PrEP, you will need to be retested for HIV every three months to be sure that you remain free of infection.
- Risk for infection with HIV is not constant. A person's risk may vary over time as circumstances change. For example, the break-up of a stable relationship may start a time of higher risk. These are what are sometimes called "seasons of risk". You may choose to stop using PrEP at certain times and to start again as your situation changes.

How can I remember to take PrEP?

- Many people find it helpful to take their pill at the same time as something else they regularly do each day (for example, eating breakfast, brushing teeth, watching a daily TV programme).
- Reminders also can help – for example, mobile phone alarms or seeing the bottle somewhere that you look at each day.
- Support from a trusted partner, family member or friend can help you to take PrEP regularly.
- When routines are disrupted (for example, staying out overnight, going on holiday, skipping meals), consider carrying extra pills with you.
- Running out of medication is a common cause of missing doses. It is a good idea to plan ahead to refill your medications. If you wait until the last minute to make an appointment, you may find that the clinic cannot see you before you run out.

What if I miss a dose?

- People sometimes forget or skip doses. If you forget a dose, just take it when you remember. For example:
 - If you usually take PrEP in the morning, but one day you realize at 10 o'clock in the evening that you forgot, it is okay to take one pill then and continue with your usual morning schedule the next day.
- It is safe to occasionally take two tablets in one day. If you are not sure whether you took a PrEP tablet today, take another one.
- If you usually take PrEP daily, you will still have high levels of protection if you occasionally miss a dose. If you usually miss more than one dose per week, you should think about other ways to help you take PrEP every day.

What if I have side-effects?

- Some people experience side-effects when starting PrEP. These may include abdominal bloating, softer/more frequent stools or nausea.
- These symptoms are usually mild and go away in the first few weeks.
- Strategies that some people find helpful to reduce stomach-related symptoms:
 - take the pill with food
 - take the pill at night before bedtime.
- For a few people, PrEP affects how well their kidneys work. Your blood will be tested to measure kidney function before you start PrEP. If the test shows a problem, this kidney test may be repeated. If the test continues to show a problem, you will be referred for further testing. Once you start PrEP, the clinic providing your PrEP will offer you blood tests to monitor your kidney function. If your blood test shows a problem, you may be asked to stop taking PrEP for a while. Kidney function usually will quickly return to normal, and then you can restart PrEP.
- PrEP can have a small effect on bone mineral density (how strong bones are). The change occurs in the first few months of PrEP use and does not continue after that. PrEP users do not experience more broken bones than is usual. If you stop taking PrEP, bone mineral density usually returns quickly to normal.

What other service may be available for me when I take PrEP?

- Contraception to prevent unwanted pregnancy
- Screening and treatment for sexually transmitted infection
- Testing for hepatitis B, and hepatitis B vaccination
- Male and female condoms and lubricants
- Counselling to support you to take PrEP regularly and help with other issues – for example, relationship issues
- Harm reduction and drug treatment services for people who use drugs.

Other services may also be available, for example:

- Support groups: Some PrEP services have support groups for people who are taking PrEP, or they have a peer support (or “buddy”) programme.
- Special support for people who face intimate partner violence or legal issues or who want help with alcohol or drug use.

What if I want to become pregnant while taking PrEP?

- You or your partner may want to become pregnant. If this is the case, please tell your doctor or nurse.
- There are two main ways to safely have babies with a partner who has HIV (or if you might have HIV). These are:
 - Treatment of the partner who has HIV with antiretroviral therapy, and checking to make sure his or her viral load is suppressed.
 - Taking PrEP is a way to safely conceive a child with a partner who has HIV and is not virally suppressed on antiretroviral therapy or with a partner who has not been tested for HIV.
- Both ways of having a baby with a partner who has HIV are effective. They can be used together. PrEP for the uninfected partner and antiretroviral therapy for the partner with HIV should both be used.

Can I keep taking PrEP while pregnant and breastfeeding?

In places with high HIV incidence, HIV infection can also 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.

- If you are taking PrEP and you find out that you are pregnant, you may want to continue to use PrEP if you continue to be at risk for HIV infection.
- You may also consider continuing to take PrEP while breastfeeding.

What can I say to others about my PrEP use?

- People sometimes find it helpful to tell a partner, friend or family member that they are taking PrEP so that people can help support their PrEP use.
- At the same time, you should not feel pressured to tell anyone that you are taking PrEP. If you choose not to tell anyone, however, you may find it harder to remember to take a pill every day. Also, you may want to make a plan about what to say if someone finds your PrEP pill bottle.
- Many people feel very positive about PrEP use because it is a responsible way to take care of themselves, their partners and their community.
- Some people still do not know about PrEP and may not understand why you use PrEP. They may have many questions for you. You can tell them that the World Health Organization recommends PrEP and that many national governments and services in your community provide PrEP. *(See the list in the annexes for sources of useful information about PrEP.)*

When and how can I stop PrEP?

- People’s sexual and drug using lives change over time due to changes in their relationships, living situation, substance use, occupation and other factors. Starting PrEP does not mean that you will take PrEP for the rest of your life.
- You may stop PrEP if you are no longer at substantial risk of acquiring HIV. This could be because you are not having sex or you have stopped using drugs or that you are consistently using other ways to protect yourself.
- After the last potential exposure to HIV, you should keep taking PrEP – ideally for another 28 days.
- If you decide to stop PrEP, please tell your doctor or nurse.
- Please see your healthcare provider and get an HIV test before restarting PrEP. You could have acquired HIV during that period of time while not protected by PrEP.



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