

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.



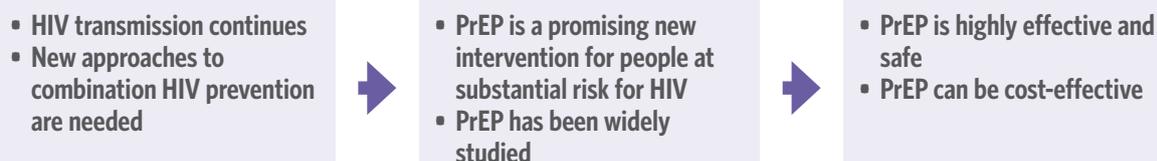
Module 12: Adolescents and young adults. This module is for people who are interested in providing PrEP services to older adolescents and young adults who are at substantial risk for HIV. It provides information on: factors that influence HIV susceptibility among young people; clinical considerations 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 leaders module



This module addresses leaders and decision-makers involved in making public policy on health, including ministers of health, ministers of finance and community advocates whose opinions and voices are essential to increase the focus on, funding for and delivery of effective HIV programmes.

United Nations 90 – 90 – 90 targets

- By 2020, 90% of all people living with HIV will know their HIV status.
- By 2020, 90% of all people with diagnosed HIV infection will receive sustained ART.

Prevention and treatment can be synergistic; both are needed to meet the United Nations fast-track 90 – 90 – 90 targets for ending the AIDS epidemic (1). The World Health Organization (WHO) recommends supporting and strengthening prevention alongside treatment. (See the WHO *Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV*.¹) Effective implementation of these recommendations, along with other existing prevention approaches, requires political and policy action at all levels.

In 2016, WHO also released the *Global health sector strategy on HIV 2016–2021*, which calls for rapid acceleration of the global HIV response over the coming few years followed by sustained action through to 2030 and beyond. This can only be achieved through renewed political commitment, additional resources, and

technical and programmatic innovations (2). The strategy promotes a people-centred approach grounded in principles of human rights and health equity.

WHO strongly recommends offering **antiretroviral therapy (ART)** to all individuals diagnosed as HIV-positive regardless of the duration of infection or the severity of their disease (3). This *Treat all* approach can save more lives, prevent both horizontal and vertical transmission, and reduce the spread of tuberculosis, which often occurs among people living with HIV who are not receiving ART (4–6).

WHO also recommends the use of **pre-exposure prophylaxis (PrEP)** for people at substantial risk of acquiring HIV (3). PrEP is the daily use of tenofovir (TDF) or a combination of tenofovir and emtricitabine (FTC) (also known as Truvada®) to prevent people who do not have HIV from acquiring it. These antiretroviral medicines used for PrEP have been shown to be safe and effective in preventing HIV infection when taken as prescribed.

People at substantial risk of acquiring HIV, who might benefit from using PrEP, include:

"I know condoms protect me from getting HIV and STI infection but I would like to have PrEP as I could control it by myself and it kills the fear of getting AIDS."

**Sex worker
Sonagachi brothel, India**

- people in serodiscordant couples (that is, when one person has HIV and the other person does not) until the person with HIV is fully virally suppressed on ART;
- people from key populations in many settings (such as sex workers, men who have sex with men, people who inject drugs and transgender people);
- young women in places with a high HIV incidence in southern and eastern Africa.

¹ Available at <http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>.

WHO recommendations

- **Antiretroviral therapy (ART)** should be initiated in all children, adolescents and adults living with HIV at any CD4 cell count.
- **Pre-exposure prophylaxis (PrEP)** containing an antiretroviral drug called tenofovir should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches.

Implementing PrEP involves more than just ensuring the supply of medicines. PrEP programmes also involve regular testing for HIV, screening for other sexually transmitted infections (STIs) and adherence support, and linking to treatment any people who receive a reactive result when they are tested for HIV before starting PrEP or who seroconvert (that is, who test HIV-positive for the first time while using PrEP).

PrEP is as an additional HIV prevention choice. It should not replace or undermine other effective and well-established HIV prevention interventions.

PrEP is intended as an additional prevention choice. Its implementation should not replace or undermine other effective and well-established HIV prevention interventions, such as condom programming and harm reduction for people who inject drugs. PrEP should be offered as part of a comprehensive testing, prevention and treatment service.

The goal of this module, together with the other modules in this WHO *PrEP implementation tool* is to build on the WHO PrEP recommendations and help to ensure that PrEP is offered appropriately and for maximum benefit.

HIV epidemic continues to devastate

Despite progress against HIV, more than 2 million people still acquire HIV every year (7). Each person with HIV requires lifelong ART to stay healthy and alive and to prevent further transmission. In 2016, 18 million people in the world were on ART. This figure equates to half of the 36.7 million people with HIV now eligible for ART following the new WHO *Treat all* recommendation.

The HIV epidemic has had a devastating impact on humanity, disrupting families, contributing to unemployment, undermining productivity and interrupting schooling. In addition, it contributes to social marginalization and to stigma and discrimination against many vulnerable populations, including sex workers, men who have sex with men, people who inject drugs, transgender people and migrants.

Policies can help prevent HIV

Policy change can make a crucial difference in efforts to end the AIDS epidemic. Policy can assure that the national response to HIV broadens the reach of HIV treatment and includes PrEP within the context of a comprehensive prevention approach. Where people with HIV or at high risk of acquiring HIV are criminalized or discriminated against, reviewing and revising policies and laws as needed is important to establish the equitable access to services that is essential for an effective HIV response.

Policy change may be necessary at many levels, including making HIV prevention and treatment a national priority; revising policies on who can provide services (including task sharing so that nurses or other appropriate providers can deliver ART and PrEP services); introducing regulatory policies that allow antiretroviral drugs to be used for prevention; and improving procurement processes to ensure a consistent supply of medicines and laboratory reagents at affordable prices.

“How can you afford to implement this new intervention?’ I always reply, ‘How can we afford not to?’ Once you answer this question you will find the way to make it happen. However, we must ensure that the PrEP offer is part of a comprehensive approach to prevention.”

Dr. Aaron Motsoaledi
Minister of Health,
South Africa

Research shows that PrEP works when taken regularly

More than 10 rigorous clinical trials have shown that PrEP prevents HIV acquisition.

Unlike many other interventions, there is substantial evidence from research trials supporting the efficacy of PrEP. More than 10 clinical trials, with participants from a total of 18 countries, have shown that, used for PrEP, antiretroviral drugs containing TDF, or a combination of TDF and FTC, effectively prevent HIV acquisition. In these trials, the risk of acquiring HIV decreased by more than 90% when participants used PrEP consistently. The trials involved

both men and women in populations that carry a disproportionate burden of the HIV epidemic. The results of the trials have been published or presented at major meetings (8–17).

Medicines used for PrEP are safe for all populations

The medicines used for HIV treatment and PrEP have a good safety profile. Side-effects are not common; moreover, they are typically mild and resolve in the first few weeks of use.

Risk of drug resistance is uncommon, occurring in approximately one in every 1000 PrEP users in clinical trials, almost exclusively among people who already had acute, undetected HIV infection when they started PrEP. Therefore, testing people for HIV before they start PrEP is essential to avoid drug resistance. Offering PrEP reduces the number of new HIV infections, each of which would require lifelong ART with substantial ongoing risk of drug resistance. Thus, PrEP is expected to decrease the public health burden of HIV drug resistance.

PrEP appears to be safe during pregnancy and breastfeeding. The risk of HIV acquisition during pregnancy and breastfeeding and the accompanying increased risk of mother to child HIV transmission far outweigh any potential risk of fetal or infant exposure to TDF used for PrEP. Furthermore, PrEP can be an additional tool to help serodiscordant couples conceive safely.

Specific policies needed to expand HIV treatment and PrEP

Political leadership is needed to ensure that medicines regulatory authorities and public health officials review evidence for offering immediate ART to all people with HIV and offering PrEP to people who do not have HIV but face substantial risk of acquiring it.

Policies may need adaptation so that people who do not have HIV can use HIV treatment drugs for prevention.

Political leadership is also necessary to commit the resources required for effective implementation of these policies.

Regulatory policy and approval

Several countries already include PrEP in their national HIV strategies. In other countries, policies may need to be expanded or adapted to permit the use of HIV treatment medicines for prevention by people who do not have HIV. For example, in most countries post-exposure prophylaxis (PEP) is widely accepted for use in HIV prevention after needle stick injury among healthcare workers or after sexual assault or other sexual exposure. The

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