



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

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WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 5: Monitoring and evaluation.

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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 antiretroviral medicines.

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 monitoring and evaluation module

Oral pre-exposure prophylaxis (PrEP) is a new and empowering prevention option for people at substantial risk of HIV acquisition (see WHO recommendation, box). Among biomedical prevention interventions, PrEP is one that requires high adherence in order to be effective, needs on-going monitoring for safety through laboratory tests and repeated HIV testing and is more costly than options such as condoms.

Routine monitoring of PrEP programmes will be essential to assess uptake, effective use and safety.

Routine monitoring of PrEP programmes will be essential to assess uptake, effective use and safety, as well as to forecast demand and to ensure a sufficient, uninterrupted supply of required commodities. Furthermore, active surveillance during the early stages of implementation may be necessary to identify adverse events among pregnant and breastfeeding women and their infants, other adults and adolescents. Currently, in most countries there has been limited experience with providing PrEP outside small-scale research and demonstration projects. As health services offering PrEP expand, surveillance, monitoring and reporting systems will need to be implemented alongside PrEP services, and their progress evaluated periodically. Monitoring and evaluation (M&E) will make sure that PrEP is being delivered safely and effectively and that services focus on those who would benefit most.

PrEP services will need to be focused strategically to maximize impact with available resources (see strategic planning module). As far as possible, PrEP services should be integrated within existing services and with existing reporting systems. Programmes may choose different PrEP service delivery points depending on which populations are a priority for PrEP. These could include broader services for sexual and reproductive health, family planning, antenatal care (ANC), HIV services for serodiscordant couples, sexually transmitted infections (STIs), tertiary educational institutions and other clinical or, particularly for key populations, community outreach settings, with access to laboratory services. Integrating PrEP monitoring and reporting into existing monitoring of health services may be complex, but it is beneficial to link or integrate services where possible to make it easier for people to obtain care.

This module addresses those responsible for monitoring HIV combination prevention strategies that include PrEP at the national and site levels and those who will be implementing and overseeing the collection and analysis of data to assess PrEP services. It provides information on how to monitor the safety and effectiveness of PrEP, suggesting core and additional indicators for site-level and national monitoring and reporting. It also focuses on considerations for measuring programme performance, recognizing early challenges and using actionable data for decision making and quality improvement.

WHO Recommendation for PrEP

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

Source: Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva, World Health Organization, September 2015. <http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>

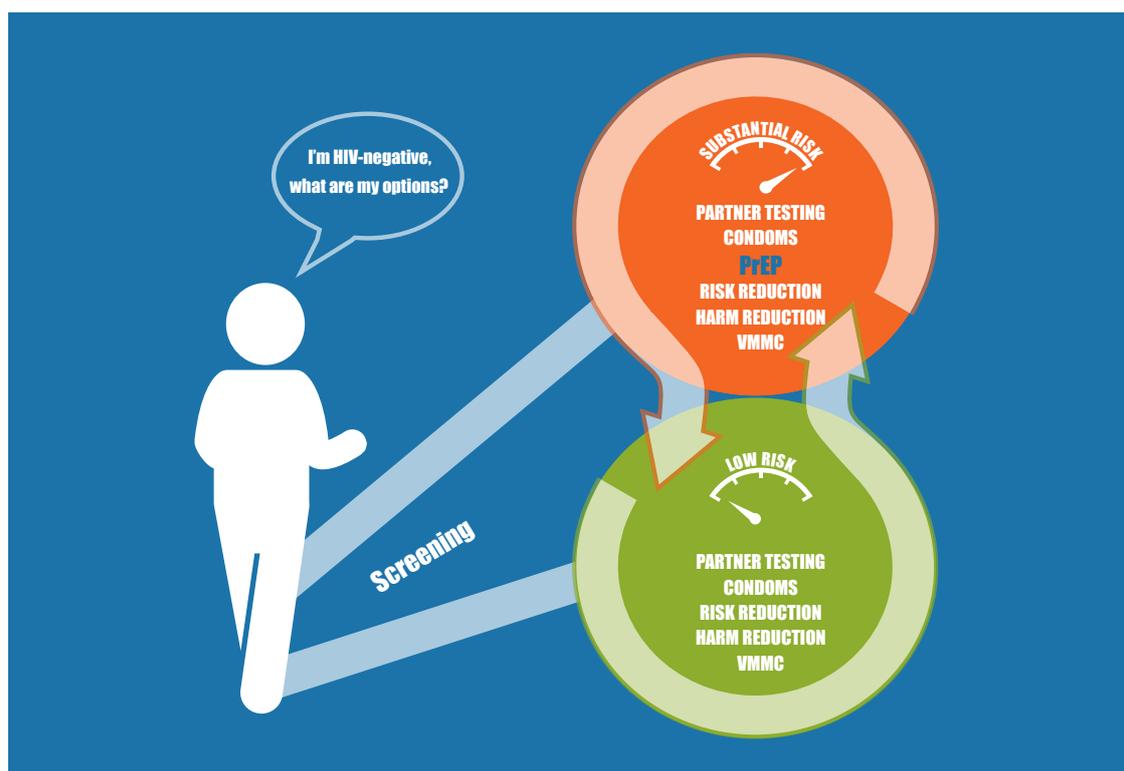
1. Overarching goals for monitoring and evaluating PrEP services

The global goals for PrEP services are to increase the effective use of PrEP among people who would most benefit from it, to enable policies that facilitate availability and access, and to contribute to UN targets to end the AIDS epidemic by 2030 (1). Goals for national programmes will include increasing coverage of PrEP among priority populations, setting service delivery targets, monitoring the PrEP cascade, identifying clinical or structural areas for improvement of services, and evaluating programmes and impact.

Measuring the performance and effectiveness of PrEP programmes is challenging because individuals may appropriately or inappropriately choose to cycle on and off PrEP during perceived periods of differing HIV risk (Fig. 1). While PrEP needs to

be used appropriately in order to be effective against acquiring HIV, it does not need to be used during periods of no/low risk. Counting the number of people newly prescribed PrEP over time will provide an indication of trends in PrEP use and potential demand. However, other indicators, such as loss to follow-up, will be more difficult to measure due to differing durations of use and follow-up of PrEP users. Furthermore, where PrEP is obtained from private providers or direct online purchasing, with or without prescription, usage may be much more difficult to track. Routine monitoring systems will need to balance capturing the information needed for decision-making to improve the quality of PrEP services with avoiding undue burden on health-care providers or other service delivery staff.

Fig. 1. Risk-based HIV prevention choices in geographic regions of high HIV prevalence or for key populations



2. The PrEP cascade

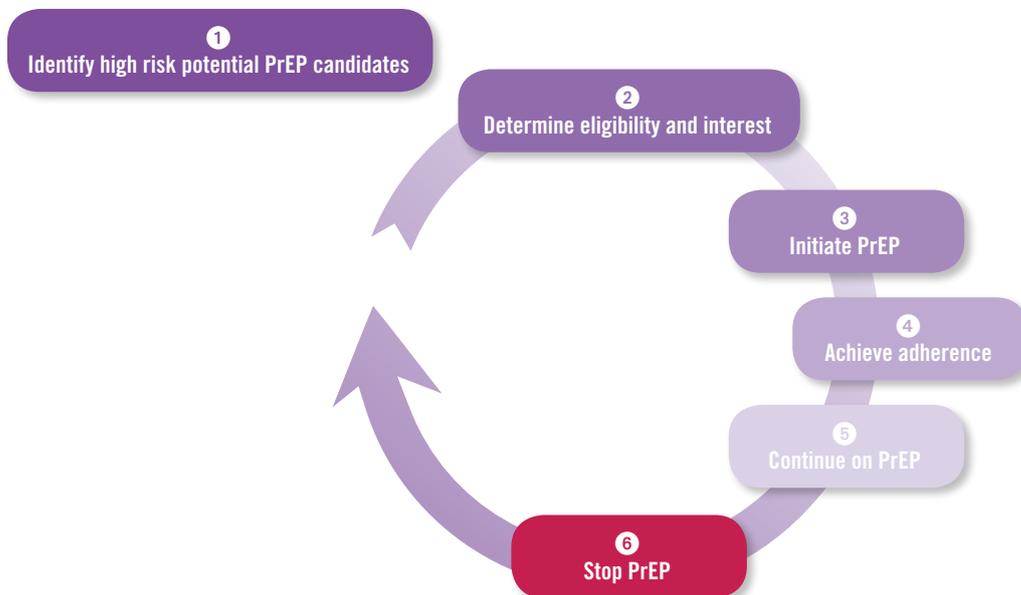
An effective PrEP programme is one in which people at substantial risk of HIV are appropriately identified, offered PrEP and then use PrEP as directed. In order to do this, PrEP programmes need to be appropriately focused according to the epidemiological profile in a given country or setting to reach the highest-risk population groups and individuals. PrEP service delivery follows a cascade that is analogous to the HIV treatment cascade (Fig. 2) and includes the following steps:

WHO defines a population at substantial HIV risk as one where the incidence of HIV infection in the absence of PrEP is sufficiently high (>3% incidence) to make offering PrEP potentially cost-effective.

1. screening individuals for HIV risk to identify potential PrEP candidates;
2. determining eligibility and interest in PrEP;
3. initiating PrEP;
4. achieving adherence (that is, taking medicines as prescribed);
5. continuing to take PrEP over time (including clinical monitoring) if risk continues;
6. stopping PrEP.

Individuals who stop PrEP may restart again at step 2 if they are still eligible and are interested in taking PrEP. Stages along this PrEP cascade can be measured through indicators (see section on indicators), which provide a programmatic overview of who is accessing PrEP and how PrEP is being used.

Fig. 2. Steps in the oral PrEP cascade to be considered for monitoring and evaluation



Source: Adapted from Liu et al. (2)

A critical first step in the oral PrEP cascade is identifying people at substantial HIV risk. WHO defines a population at substantial HIV risk as one where the incidence of HIV infection in the absence of PrEP is sufficiently high (typically considered >3% incidence) to make offering PrEP potentially cost-effective. Some countries, such as the United States of America, have used lower thresholds (3). Prioritizing the offer of PrEP to people at substantial risk of HIV infection maximizes the benefits relative to the risks and costs. The strategic planning module of this implementation tool details how to use epidemiologic data to guide decision-making on which populations are highest priority, where PrEP services could be provided, and how PrEP could be integrated into other health services. This step in the cascade is typically quantified by the number of people who are estimated to need PrEP (see section on setting PrEP targets).

To help identify potential PrEP candidates (step 1 in the cascade), some programmes use HIV risk assessment tools. These tools help providers work with clients to assess their risk for HIV, help clients to assess their own risk or help to assess and document various criteria that may indicate a person is a potential PrEP candidate (for example, the person has used post-exposure

Risk assessment tools should not be used to exclude people from PrEP services, especially if they consider themselves at risk and want to take PrEP.

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