MODULE 9

STRATEGIC PLANNING

# 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 strategic planning module

When a country decides to include PrEP in its national HIV programme, a range of implementation issues have to be considered, such as cost-effectiveness, safety, and epidemiological impact. This strategic planning module is for public health officials and policymakers responsible for deciding to whom to offer PrEP for HIV prevention as a priority, where PrEP services could be provided, and how PrEP could be integrated into other health services *(1)*. In this module, strategic decision-making practices are described on how to identify people at substantial risk of HIV who could benefit from being offered PrEP.

**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)*.

## Defining "substantial HIV risk"

**Substantial risk of HIV infection** is defined as an incidence of HIV infection typically considered to be higher than three per 100 person-years in the absence of PrEP *(2)*. By offering PrEP to people at substantial risk of HIV, the greatest epidemiological impact and value for money can be obtained, although PrEP may be cost-effective at lower incidence rates in some settings *(3)*.

A number of different factors can influence whether people are at substantial risk for HIV, the most important of which are their own and their partner(s)' sexual and drug using behaviour and HIV status, and the overall background HIV prevalence and incidence where they live. People considered to be at substantial risk of HIV reside in most countries *(4)*, in particular:

- men who have sex with men
- people who inject drugs
- transgender women, and
- sex workers in many countries of sub-Saharan Africa

Specific population groups in southern and eastern Africa at substantial risk of acquiring HIV include:

- adolescent girls and young women
- people with concurrent or a high number of sexual partners
- people who have another sexually transmitted infection (STI), and
- serodiscordant couples, where evidence shows that the HIV-negative partner can benefit from taking PrEP when the partner with HIV is not virally suppressed on antiretroviral therapy (ART).

However, not all people within these groups may be at substantial risk for HIV acquisition, and identifying these groups and individuals can be challenging.

## Prioritizing PrEP for those at substantial risk of HIV

Reducing HIV transmission among groups with high HIV incidence is a priority for public health programmes. Epidemiological research conducted through national surveys, clinical trials and cohort studies has shown that HIV incidence varies considerably between and within different population groups. In order to make the most efficient use of resources, it is particularly important that more costly interventions such as PrEP are focused in geographical areas with

high HIV incidence (and prevalence), and within key and vulnerable subpopulations, as well as among people at substantial individual risk (regardless of geography or population group). The populations at risk, health system capacity, and available resources for HIV prevention will determine where and to which groups PrEP should be offered; in low-resource settings other HIV prevention interventions may prove more cost-effective *(5)*. Nevertheless, in most settings, PrEP will likely be cost-effective for people identified at substantial risk of HIV *(3, 6)*.

PrEP can still be considered in settings where HIV incidence and prevalence data are lacking. In those instances, local level data from a range of sources such as HIV testing services may allow for making estimates of HIV prevalence in order to identify people at high risk for HIV, although these sources have limitations. Strategic approaches that can be used to identify groups at higher risk of acquiring HIV are discussed in detail in this module.

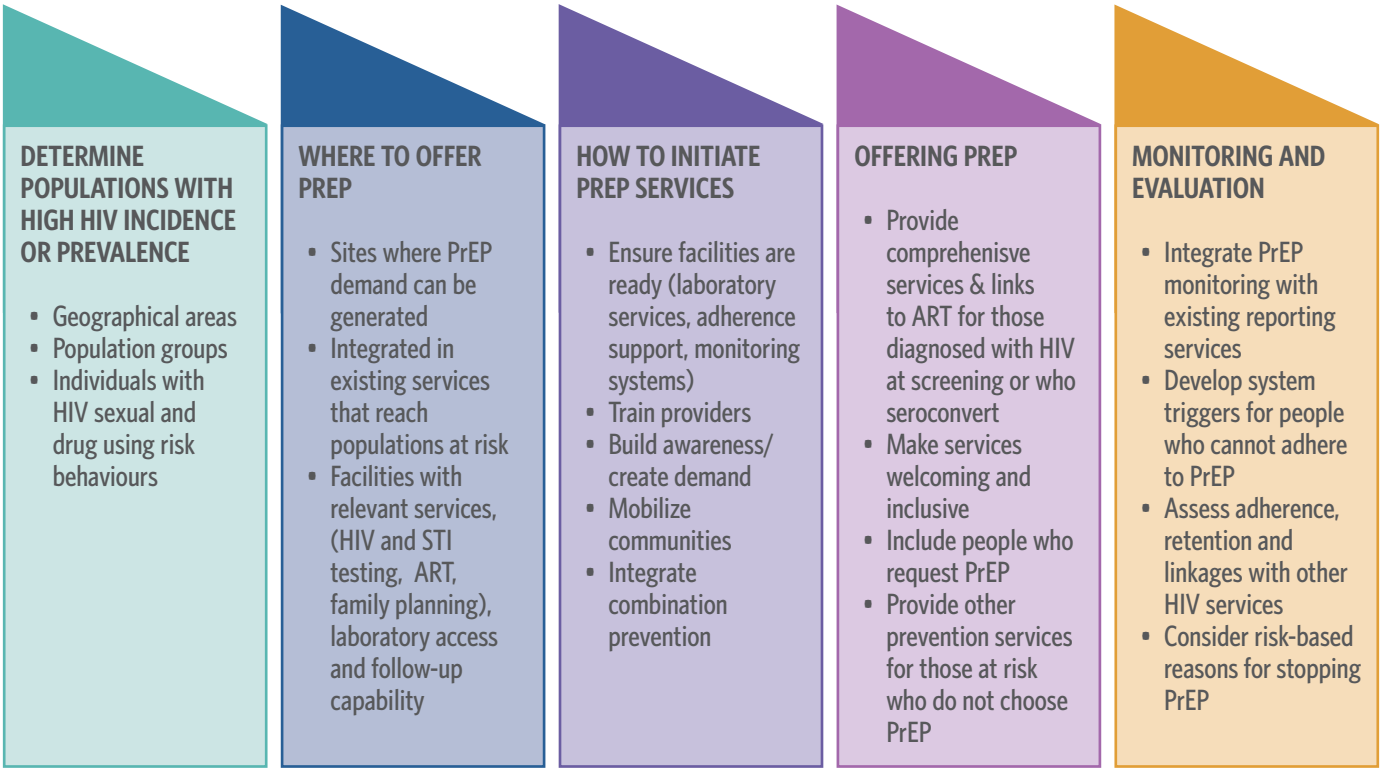
## Process for identifying people at substantial risk of HIV

From a strategic planning perspective, a multistage process could be helpful in identifying people at substantial risk of HIV, who could benefit from being offered PrEP as a priority (see Fig. 1). Firstly, a national HIV programme or public health jurisdiction will need to review the most recent epidemiological data on HIV at a national, regional and municipal level. This review would include data from specific populations, in order to identify groups where there is a high HIV incidence or prevalence and where it may be beneficial to offer PrEP services. Depending on the setting, these populations may be identified by a combination of geographical location, sex, age, or key population group.

Secondly, within populations and locations with higher HIV incidence or prevalence, a process for differentiating individuals at substantial risk of HIV from those who are not, can be considered. Individual need for PrEP could be assessed by: (1) using a risk calculator/score (see supplementary information A1-3), (2) assessing sexual and drug using behaviour, (3) considering persons who recognize their own HIV risk and request PrEP. Risk calculators have been developed and validated for different population groups, for example, men who have sex with men in the United States and Spain, and pregnant women and heterosexual serodiscordant couples in eastern Africa (see Supplementary information for examples). Clinicians may use a brief sexual and drug using history (as described in the clinical module of this PrEP implementation tool) to assess individual risk. In many situations, people who proactively ask for PrEP will already consider themselves to be at risk, and may have determined that PrEP is an appropriate prevention option. As such, they may be motivated to take PrEP and adhere to their regimen. In general, providers should consider offering PrEP to people who request it because, although these persons may recognize their own risk, they may not be able or willing to discuss this risk – either due to stigma or a reticence to talk to providers about sexual and drug using behaviour.

Thirdly, consideration should be given to where PrEP services could be established, including assessing the existing capacity and infrastructure of a given health jurisdiction (whether municipal, state or national) and factors that enable or inhibit access to, and provision of, services. Demand creation for PrEP may be necessary. It will usually not be appropriate to develop a standalone service for providing PrEP; rather, PrEP should be integrated into existing services, such as HIV testing, treatment and related services provided to key populations (for example, men who have sex with men, people who inject drugs, transgender people or sex workers). Sites that offer PrEP should cater and be easily accessible to populations that may benefit from PrEP. For example, in areas where there is a high HIV incidence or prevalence among young women, PrEP services could be integrated into facilities that are conveniently located and accessible for adolescent girls and young women, demonstrate cultural sensitivity towards women, and offer additional services, such as contraception and reproductive health services. Health services associated with tertiary education establishments could also be considered for integration of PrEP.

## FIGURE 1. STEPS IN PRIORITIZING AND IMPLEMENTING PREP SERVICES




## Observed HIV incidence rates among groups known to be at substantial risk

HIV incidence greater than three per 100 person-years has been observed among groups of men who have sex with men, transgender women, people who inject drugs, heterosexual men and women who have sexual partners with untreated HIV infection in all regions, sex workers in some settings in sub-Saharan Africa, and sexually active women and men in very specific geographical areas in southern and eastern Africa. Individual risk varies within these groups depending on individual behaviour and the characteristics of sexual partners.

Most PrEP trials have identified and recruited individuals from groups at substantial risk of acquiring HIV, as demonstrated by the high HIV incidence rates among participants in the control (non-PrEP) arms, which ranged from two to 8.9 per 100 person-years in almost all studies (see Table 1). HIV incidence in the control arms of PrEP trials was often higher than anticipated, suggesting that people drawn to participate in PrEP studies were at particularly high risk. For example,