

MODULE 8

SITE 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 site planning module

This module is for clinic administrators who are responsible for identifying the resources needed to start and sustain a PrEP service as part of combination HIV prevention (see box). These resources include personnel, facilities, PrEP medicines, laboratory tests and other commodities. The information found in this module complements other modules in this WHO PrEP implementation tool.

PrEP can be provided through a number of facilities and settings, each of which will have specific resource requirements according to the populations being offered PrEP and the service delivery model/approach used. This module focuses on common elements needed by settings in order to provide a PrEP service.

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 prevention approaches (*strong recommendation; high-quality evidence*).

WHO global strategy on people-centred and integrated health services

The World Health Organization (WHO) global strategy on people-centred and integrated health services represents a shift in the way health services are funded, managed and delivered (1). Firstly, this strategy proposes that all people should have access to health services that are equitable, safe, effective, efficient, timely and of acceptable quality, and that these services are provided in a way that responds to people's needs. Secondly, the strategy proposes that health services are integrated, implying they are offered, managed and delivered in a way that ensures people receive a continuum of services – from health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation through to palliative care – at the different levels and sites within the health system and according to their needs throughout their lives. Since PrEP is being considered for integration in existing HIV services, HIV programmes need to ensure that a range of good practices are in place that are in alignment with the WHO global strategy (see Box 1).

Box 1. Good practice statements for HIV programmes (2)

HIV programmes should:

- Provide people-centred healthcare that is focused and organized around the needs, preferences and expectations of people and communities, upholding individual dignity and respect, especially for vulnerable populations, and engaging and supporting people and families to play an active role in their own healthcare through informed decision-making.
- Offer safe, acceptable and appropriate clinical and nonclinical services in a timely fashion aimed at reducing morbidity and mortality associated with HIV infection, and improving health outcomes and quality of life in general. This includes offering a client appointment system and acceptable frequency of facility visits, thereby avoiding long health facility waiting times for clinical consultations, medication pick-up or laboratory services.
- Build healthcare providers' skills for effective communication with clients.
- Provide comprehensive integrated services, as appropriate and relevant, and coordinate care when people require multiple services (such as, tuberculosis and HIV treatment, harm reduction and family-centred care).
- Promote the efficient and effective use of resources.

Planning for PrEP services

At the national level, public health officials will need to discuss how and where to implement PrEP services. It is likely that a situational analysis will have to be conducted to determine which groups would benefit most from the provision of PrEP. Moreover, selecting specific sites and facilities at which PrEP will be offered requires an understanding of where people at substantial risk for HIV infection go for health services (or where they would likely access services if they do not already do so). In countries where PrEP services are currently being offered, a phase-in approach has frequently been adopted, whereby implementation has been initiated first in a selected number of sites with the intention of including additional sites to increase PrEP coverage as demand increases.

Integration

Based on its 2016 *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* (2), WHO recommends the integration of HIV services – including HIV testing services (3) – with a range of other relevant clinical services such as those for tuberculosis, maternal and child health, sexual and reproductive health, as well as with harm reduction services for people who inject drugs and, in priority countries, with voluntary medical male circumcision programmes. The primary purpose of integration in this instance is to make services more convenient for people who attend health facilities for other reasons and to increase the uptake of HIV-specific services. The integration of HIV services is appropriate in all epidemic settings and is particularly important where HIV prevalence is high.

Similarly, the integration of PrEP in existing health services could be considered, for example PrEP could be integrated into services that are already being provided to key populations, such as HIV testing services and antiretroviral therapy (ART). Clinics that offer HIV testing services and ART will often have the resources required to initiate a PrEP service. Other settings that could consider integrating PrEP services include: sexual health clinics, family planning services, services for men who have sex with men and transgender people, services for sex workers, harm reduction services and private healthcare providers. As demand for PrEP increases, additional human and physical resources may be needed.

Clinical protocols and standard operating procedures

Clinical protocols and standard operating procedures need to be developed to initiate a PrEP service. As part of quality improvement, these documents have to be periodically reviewed and revised to address issues as they arise. The clinical module in this WHO PrEP implementation tool can provide the basis for establishing a clinical protocol for PrEP.

Standard operating procedures would need to be developed for staff involved in offering PrEP services (for example physicians and nurses). All staff would receive training in relevant standard operating procedures before they are implemented. There should also be protocols for training and supervising new staff at all levels. In addition, the clinic should have protocols for the procurement of required medicines and laboratory and clinical supplies.

Many clinics that provide PrEP will likely be able to perform onsite HIV testing using rapid diagnostic tests. Some sites may be able to perform additional laboratory tests needed for offering PrEP, while other sites will collect samples to be tested at local laboratories. Laboratory quality issues are addressed in the testing module in this WHO PrEP implementation tool.

Training for offering PrEP

The development of a PrEP curriculum and training programme would ensure all staff are informed and kept up-to-date on PrEP. An initial training session for all healthcare workers can help sensitize staff to HIV prevention by presenting the rationale for offering PrEP and the supporting evidence as well as the needs of specific populations. Additional specialized training, for example in the form of knowledge seminars, aimed at staff involved in the provision of PrEP services can cover key areas such as safety (including PrEP use in pregnancy), relevant testing before initiating PrEP, monitoring of PrEP users, counselling tools and approaches, etc. The training programme would also include mentoring, support, supervision and refresher training.

Counselling

Counselling, which is a critical element of combination HIV prevention, is an integral part of PrEP service provision. Hence, PrEP is both a biomedical and bio behavioural intervention. Counselling can include important information on PrEP use, coping with side-effects and adherence, sexual health, relationship issues, drug and alcohol matters, and screening and support for gender-based violence. Since adherence is a critical predictor of the effectiveness of PrEP, counselling is an important opportunity to offer key messages around adherence to PrEP users.

Counselling may be provided by nursing staff or trained counsellors. In some settings, peer educators – who come from the same community as people receiving PrEP services – are employed to provide counselling and support. Training, ongoing support, mentorship and refresher training will need to be planned and provided to the people offering counselling services to PrEP clients. All cadres of health workers, including peer workers, need to be legally recognized – with job descriptions outlining their roles, responsibilities and reporting lines – and provided with standard operating procedures for the duties they are assigned and remunerated for.

Human resources

The human resources required to support PrEP will vary according to the different cadres of staff that are available in a country, the duties they are assigned and the local regulations governing health services such as prescribing medications, taking blood and other samples, performing tests and providing test results.

In some settings, PrEP services can be provided in full by nurses, who can contact a doctor or clinical officer for advice and support for complex issues; for example in South Africa, where nurses are prescribing PrEP under a programme run by the National Department of Health. Table 1 provides an example of the staff required to provide a PrEP service for 600 PrEP clients attending a clinic over a one-year period.

TABLE 1. EXAMPLE OF PERSONNEL NEEDED TO PROVIDE PREP

CATEGORY	DUTIES
Experienced clinical provider (physicians, clinical officer¹ or nurse)	Provide general oversight of clinical services and be available to offer support for complex cases, including remotely (for example, via mobile phone text message, email, instant messaging, voice and video messaging, etc.).
Medical officer or nurse	Take structured sexual, drug use and medical history, measure vital signs (blood pressure and body temperature), perform phlebotomy, conduct point-of-care tests (HIV antibody, hepatitis B surface antigen), screen for sexually transmitted infections (STIs). Also, provide counselling on PrEP use and adherence, family planning and contraception, hepatitis B vaccination and STIs.

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