

MODULE 10

TESTING PROVIDERS



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 testing providers module

This module is designed to support national HIV programme managers and other decision-makers who have an interest in implementing pre-exposure prophylaxis (PrEP) and require guidance in selecting the relevant testing services, including appropriate screening of clients before PrEP is initiated and monitoring while taking PrEP. Information is provided on testing for HIV, creatinine, hepatitis B virus (HBV), hepatitis C virus (HCV), pregnancy and sexually transmitted infections (STIs) such as *Treponema pallidum* (syphilis), *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT).

This module also describes the frequency with which PrEP users may require different types of testing services. In addition, testing strategies and testing algorithms are discussed, including how to use testing results to inform clinical decisions about PrEP initiation and management.

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*).

Key messages: testing services in the context of PrEP

Several testing services must be delivered before a person can start taking PrEP safely and effectively. Periodic retesting while a person is taking PrEP is also needed. (See Table 1 below for a summary of suggested testing services for individuals starting and taking PrEP.)

Testing for HIV is required to rule out infection prior to initiating PrEP. Once an individual has been initiated on PrEP, HIV testing is suggested every three months and whenever restarting PrEP after a gap in use to rule in or rule out HIV infection. Some services and programmes are currently conducting an additional HIV test one month after starting PrEP.

Individuals on PrEP with an **HIV-inconclusive status** should be retested in 14 days; stopping PrEP to determine their true HIV status may also need to be considered. Individuals on PrEP with an HIV-positive diagnosis will need to be placed on a fully suppressive antiretroviral treatment (ART) regimen.

Monitoring kidney function is particularly important to ensure safety among PrEP users. Since tenofovir disoproxil fumarate (TDF) is known to have an impact on the glomerular filtration rate, testing for serum creatinine is suggested.

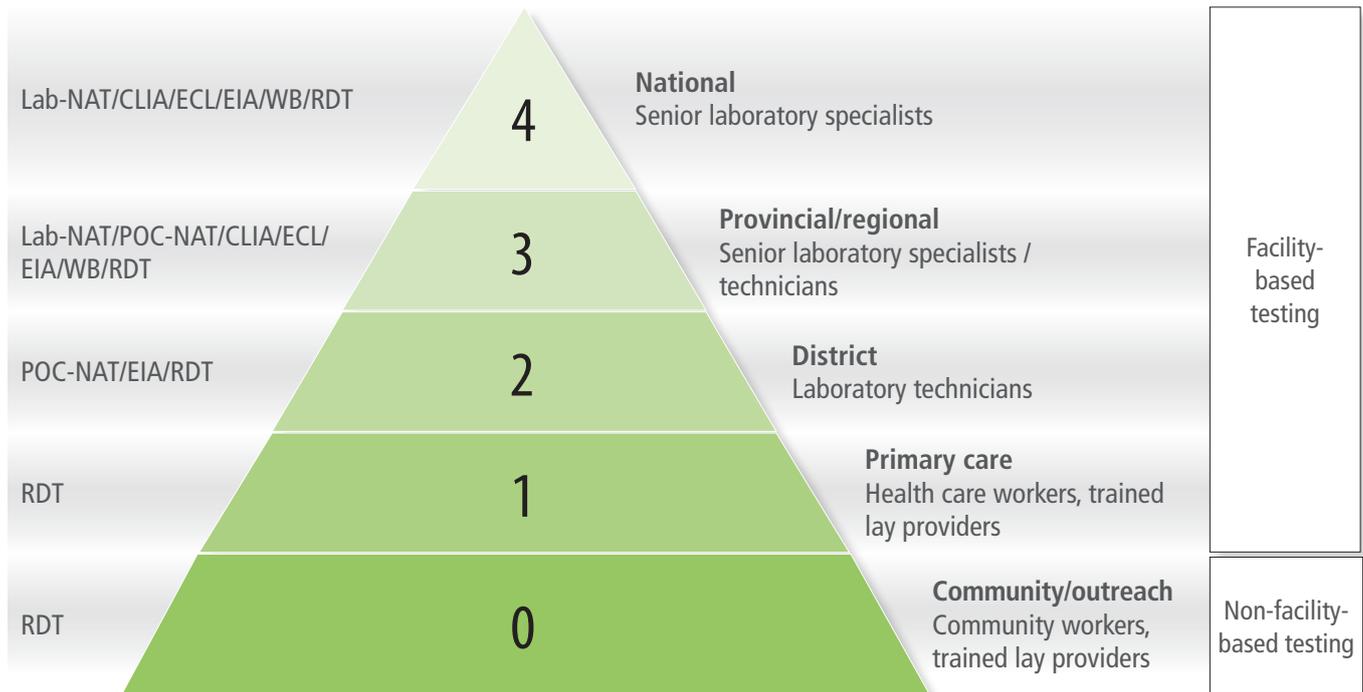
Testing for chronic HBV is important for people before they start PrEP, as it will help in making decisions about PrEP initiation, HBV vaccination and future management of HBV. It is safe for people with HBV to use PrEP, and PrEP can be initiated before HBV testing results are available. For those who are **hepatitis B surface antigen** (HBsAg) negative, HBV vaccination could be considered. For individuals who are **HBsAg** positive, and therefore likely to be chronically infected with HBV, further laboratory tests and clinical assessment will be needed.

Screening for STIs prior to PrEP initiation, and periodically while taking PrEP, is important. People who are eligible for or who are using PrEP are often at risk for other STIs and may have an STI that requires treatment. Initial and periodic screening of PrEP users for syphilis, gonorrhoea and chlamydial infections should be considered. If signs and symptoms of STIs are visible, individuals should be treated syndromically.

TABLE 1. SUMMARY OF TESTING SERVICES FOR STARTING AND MONITORING PrEP

PATHOGEN / ANALYTE	TESTING LOCATION	TIMING AND FREQUENCY
HIV (HIV antibodies (anti-HIV))	Community/outreach; Primary care; Laboratory (district/ provincial/ national)	Prior to starting or restarting PrEP and every three months during PrEP use. Programmes can also consider testing at 1 month after starting PrEP.
Creatinine	Primary care; Laboratory (district/ provincial/ national)	Consider testing prior to starting or restarting PrEP and consider every six months during PrEP use. Increasing testing frequency may be considered if there are comorbid conditions affecting renal function.
HBV (Hepatitis B surface antigen (HBsAg))	Community/outreach; Primary care; Laboratory (district/ provincial/ national)	<p>If HBsAg test is reactive, evaluate for HBV treatment indications based on WHO hepatitis B treatment guidelines. PrEP can be started before the result is available.</p> <p>For those being treated for chronic HBV, it is important to undertake further laboratory testing before PrEP is stopped to help with deciding how to monitor for HBV flares or how to continue treatment.</p> <p>If HBsAg is not detected, with no history of immunization, vaccinating against HBV can be considered.</p>
HCV (HCV antibodies (anti-HCV))	Community/outreach; Primary care; Laboratory (district, provincial, national)	Consider testing for HCV in certain populations, such as men who have sex with men and people who inject drugs, prior to PrEP initiation and annually thereafter.
Pregnancy	Community/outreach; Primary care; Laboratory (district, provincial)	When clinically indicated, for example women who report missed menses or symptoms of pregnancy.
Syphilis (treponemal antibodies) Syphilis (rapid plasma reagin titer)	Community/outreach; Primary care; Laboratory (district, provincial)	<p>When starting PrEP, consider testing and every three to six months during PrEP use to check for active syphilis infection and to evaluate response to treatment.</p> <p>Pregnant women seeking or taking PrEP with a single reactive treponemal or nontreponemal test result should be started on treatment.</p>
Neisseria gonorrhoeae (GC) Chlamydia trachomatis (CT)	Laboratory (district, provincial, national)	<p>Consider testing when starting PrEP and every three to six months during PrEP use. Use of nucleic acid testing (NAT) technologies is preferred for testing for gonorrhoeae and chlamydia.</p> <p>If NAT technologies are not available, probe for symptoms and look for signs of STIs and treat syndromically.</p>

FIGURE 1. SUGGESTED HIV, STI AND HEPATITIS TESTING SERVICES WITH ASSAY FORMAT MENU AND STAFF QUALIFICATIONS (6)



Source: Short, medium, long term product development priorities in HIV-related diagnostics. WHO expert meeting report Geneva: World Health Organization; 2012.
Note: with evolving technology development, POC-NAT may soon be possible at Level 1 health facilities.

HIV testing services

All people at substantial risk of HIV infection who could be eligible for PrEP should be offered HIV testing services. Prior to starting or restarting PrEP, it is critical to rule in or rule out HIV infection in order to:

- i) Identify and diagnose people with HIV;
- ii) Refer and link people with HIV to treatment and care as early as possible;
- iii) Ensure people who have HIV do not start PrEP (3–5).

HIV testing services prior to and throughout PrEP use can be delivered in a variety of settings, depending on the type of test being performed (see Fig. 1).

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