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

JULY 2017



MODULE 3

COUNSELLORS



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Contents

INTRODUCTION	2
THE COUNSELLORS MODULE.	4
Counselling goals related to PrEP	4
PrEP and "seasons of risk"	5
Who can counsel about PrEP?	5
Counselling strategies	6
Differentiated care.	
Monitoring efforts	13
SUPPLEMENTARY INFORMATION	14
Counselling example I: Integrated Next Step Counselling (iNSC)	14
Counselling example II: Informed choice counselling	16
FURTHER READING.	19
REFERENCES	20

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 preexposure 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 counsellors module

This module is for staff in clinical and other settings who counsel PrEP users. Those who counsel PrEP users may be lay, peer or professional counsellors and healthcare workers including nurses, clinical officers and doctors.

This module does not include information about community education; that is the focus of the module for community educators and advocates. Community education can shape awareness of and demand for PrEP, HIV testing and treatment. If people receive accurate information about PrEP in the community, counselling may support plans for effective use, for example promoting adherence in PrEP users.

WHO Recommendation for PrEP

The World Health Organization recommends that PrEP containing tenofovir disoproxil fumarate (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*).

PrEP as an additional prevention choice should not replace or undermine other effective and well-established HIV prevention interventions, such as condom programming and harm reduction.

Counselling goals related to PrEP

The goals of counselling depend on whether the client is starting PrEP or is already using PrEP. Counselling may explore current sexual health and drug use protection plans and raise awareness about PrEP and other prevention strategies. Mixing sexual health education with client-centred discussion (see below) can facilitate open communication about sexual health desires, goals and plans. Counsellors can help clients develop broader plans for fertility, pregnancy prevention and sexual health, and the ways to carry out these plans without acquiring sexually transmitted infections (STIs). Counselling also plays a critical role in reducing risks associated with injecting drug use and in adopting harm reduction interventions.

Counselling for those interested in PrEP should focus on increasing awareness of PrEP as a prevention choice and helping the client to decide whether PrEP is right for them. For those who choose PrEP, counselling then continues into preparing individuals to start PrEP, explaining its use and making a specific plan for PrEP use. Also, counselling should inform PrEP users about issues such as:

- dosing requirements for greatest protection
- what to do if a dose is missed
- common adherence strategies
- the importance of ongoing monitoring while on PrEP
- side-effects and side-effects management
- how to safely discontinue and restart PrEP
- sexual health protection strategies beyond PrEP
- harm reduction for people who use drugs
- comprehensive HIV prevention planning.

For follow-up counselling, important goals are checking in on: current sexual health and/or drug use behaviours; intention to remain on PrEP; and facilitators and barriers to PrEP use. Follow-up counselling can also include problem-solving, such as addressing adherence problems and the challenges of disclosure to partner(s).

PrEP and "seasons of risk"

People often move in and out of "seasons of risk" and "risky situations" for HIV infection. For both antiretroviral therapy (ART) for HIV treatment and PrEP, adherence is crucial. However, adherence to ART involves lifelong therapy with daily doses. In contrast, among PrEP users, HIV exposure may be episodic. People often move in and out of "seasons of risk" and "risky situations" (*1*, *2*). Thus, people taking PrEP will not take it all their lives. Learning how and when to start and stop PrEP is key to its effective use (*3*). PrEP counselling creates an opportunity for PrEP

users and their counsellors to recognize situations that may involve exposure to HIV and to use appropriate and effective prevention strategies, including PrEP.

Triggers or specific situations that may prompt a person to consider starting PrEP include sex without a condom (planned or experienced), diagnosis of an STI (in a partner or oneself), alcohol and recreational drug use before sex, leaving a long-term relationship, entering sex work, moving to a city having a high prevalence of HIV, starting a relationship with a person with HIV who is not virally suppressed on ART. Those who leave school or leave home early may have greater HIV vulnerability and may also want to consider using PrEP. Also, PrEP use may be part of a safer conception strategy for HIV serodiscordant couples. People who use drugs may have periods of injecting drug use where HIV risk is high and PrEP may be considered.

Similarly, a variety of reasons may prompt a person to stop PrEP. Seasons of risk end for various reasons – for example, when a partner with HIV achieves viral suppression on ART, when a mutually monogamous relationship becomes a long-term commitment, when drug injecting stops or when other risks change. A critical aspect of periods of PrEP use and non-use is education and support for safe stops and restarts of PrEP use, and engaging those currently on PrEP in discussions about plans for persistence (how long the person sees him- or herself using PrEP and what the person's personal criteria are for deciding when PrEP is no longer needed or desired). PrEP providers should position themselves as a valuable part of this decision-making to the greatest extent possible.

Who can counsel about PrEP?

Counsellors and health workers should be carefully trained on PrEP use before they counsel clients about PrEP. In addition, the user's preferences should be considered. Some users may prefer talking with a peer or lay counsellor, who has some shared experiences. Others may prefer counselling from a medically trained counsellor (for example, a nurse, doctor or clinical officer). Integrating training on PrEP counselling skills into current HIV testing training and other relevant curricula can provide an opportunity to introduce PrEP in a range of settings such as primary health, STI and reproductive health services.

PrEP counsellors need refresher training regularly so that they can provide accurate and up-to-date information to clients who may ask about new medicines and methods as they become available. Refresher training may help to sharpen counselling skills and provides an opportunity to teach new approaches.

A key role for peer and lay counsellors

Peer and lay counsellors may be the most acceptable persons to provide counselling that supports PrEP use and adherence. In many instances involving peer and lay counsellors may be advantageous, for example peer and lay counsellors may be the most acceptable persons to provide counselling that supports PrEP use and adherence. WHO has previously recommended the use of trained and supported lay providers to perform certain HIV clinical services, including HIV testing, HIV counselling and support for delivery of antiretroviral treatment (4-6). Beyond providing services, lay workers can act as role models and offer non-judgemental and respectful support that

can help reduce stigma, facilitate access to services and improve their uptake. Young women, men who have sex with men, transgender people, sex workers, people who use drugs and other groups who fear stigma in health services may feel better connected to peers and near-peers. Lay providers may cost the programme less than using health workers to perform the same tasks. However, it is important that programmes compensate trained lay providers appropriately for their work. Otherwise, high turnover is likely. These workers should receive adequate wages and/or other appropriate incentives. The main reason for involving lay providers should be to increase access to and effective use of PrEP and not to reduce costs.

Lay provider: any person who performs functions related to healthcare delivery and has been trained to deliver specific services but has received no formal professional or paraprofessional certificate or tertiary education degree (7). Creating spaces in clinical settings or elsewhere for peer and lay counsellors to conduct PrEP counselling is a crucial part of peer counselling. Often, the lack of such spaces prevents lay and peer counsellors from playing a key role. Supportive supervision and oversight of lay and peer counsellors by a professionally trained counsellor or healthcare provider is necessary to ensure that up-to-date and accurate information is routinely shared with the lay and peer counsellors, as with all counsellors.

Counselling strategies

Specific information about PrEP in client-friendly language is available in the **module for PrEP users**. Topics covered include: "What is PrEP?", "How well does PrEP work?", "Who can consider using PrEP?", "Who cannot use PrEP?", "How do I store the medicines?", "When and how do I take PrEP?", "How can I remember to take PrEP?", "What if I miss a dose?", "What if I have side-effects?", "What about PrEP, pregnancy and breastfeeding?", and "When and how can I stop PrEP?". This section describes the approaches to conveying those messages most appropriately and effectively.

Culturally relevant group activities

Providing and discussing general information about PrEP can work well with groups. Group sessions can be the first step in the counselling process, used to provide general information on PrEP, listen to questions and provide general answers. Then, clients can be invited to come into one-on-one sessions with a clinician, a lay or peer counsellor, or other counsellor.

Support groups of PrEP users can make important contributions to HIV prevention.

After people start PrEP, they can be invited to join support groups that help with adherence and retention. Support groups can address issues relating to empowerment and self-efficacy, beliefs about health issues, and stigma. Group activities can affect social behaviour, including communication with partners and potential partners about HIV and prevention strategies. Peer-led activities,

awareness campaigns and other community-based strategies can also support PrEP adherence and retention.

PrEP trials in the United States of America (ATN 082 and 110) used a group-based engagement strategy with young adults. These group communications sought to raise awareness of HIV risk, strategies for protection and how PrEP can be used (8, 9). The strategy was based on an evidence-based behavioural intervention called "Many Men, Many Voices" (10). This approach was highly acceptable among young adult black and Latino men in the USA who were anticipating starting PrEP (8). In sub-Saharan Africa, the FACTS 001 and ASPIRE (11) trials also used group strategies, as will the upcoming trial HPTN 082 (PrEP for young women in South Africa and Zimbabwe) (12).

Principles for counselling individuals

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