MODULE 2 COMMUNITY EDUCATORS AND ADVOCATES

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 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 community educators and advocates module

This module is for community educators and advocates who foster discussions and disseminate information through mass media channels, educational activities, small-group discussions and one-on-one meetings.

The World Health Organization (WHO) recommends that pre-exposure prophylaxis (PrEP) be offered as an additional prevention choice to people at substantial risk of acquiring HIV infection (see box). Implementing PrEP involves more than providing PrEP medicines. PrEP services and programmes also: provide information about PrEP and other HIV prevention, care and treatment services; offer regular testing for HIV as well as screening and treatment for other sexually transmitted infections (STIs); offer adherence support; and link to treatment any people who receive an HIV-positive result when they are tested for HIV before starting PrEP or if they become HIV infected while using PrEP.

It is important to provide education and information about PrEP to a variety of stakeholders who will be involved in deciding how PrEP should be included in national and local HIV plans. Community education can also shape appropriate demand for PrEP and help reach and inform people who might benefit most from taking it.

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).

Stakeholders' concerns and responses

PrEP advocates remain critical partners in the HIV response, and can support the broader dissemination of accurate information about PrEP to a range of stakeholders.

Community educators can provide information on PrEP directly to communities that may benefit from taking it. They can help people who are at substantial risk of HIV infection in their communities to make informed decisions about whether or not to consider PrEP. Although settings will differ, community educators are often peers who have good interpersonal and communication skills and are able to provide information on how to recognize risk, basic information about PrEP and other prevention options, as well as strategies for adherence.

Concerns and information needs vary according to the context and person involved. This module highlights specific concerns often raised by stakeholders involved in discussions about PrEP, and suggests possible responses that can be provided by community educators and advocates. More general information on PrEP safety, use and delivery is available in other modules in this implementation tool.

1. Community-based organizations (CBOs)

CBOs often have great success in promoting the needs of their communities and finding solutions. Because of their direct involvement in and knowledge of the challenges and opportunities specific to their own settings, they can be effective in identifying and mobilizing community members at higher risk of HIV infection. CBOs led by key populations can be particularly successful in delivering PrEP educational services, including designing education interventions and tools, referring potential users to clinics providing PrEP and supporting those who choose to take PrEP. CBOs can also play an important role in training additional community educators on PrEP, including peer educators working with key populations and other vulnerable groups such as adolescent girls and young women.

CBOs can be key partners and leaders in raising awareness for PrEP and determining strategies for PrEP roll-out. The role and involvement of CBOs will depend on the local situation. Some CBOs provide PrEP as part of community-led HIV services. Other community groups do not provide clinical services but engage in advocacy and foster demand for PrEP and other prevention approaches. Table 1 addresses some of the main concerns and frequently asked questions (FAQs) about PrEP raised often by CBOs.

TABLE 1. FAQS ON PREP RAISED BY CBOS

CONCERN / QUESTION	RESPONSE
Is PrEP safe and effective?	PrEP prevents the acquisition of HIV when taken as prescribed. PrEP is safe (1) but people who take PrEP need to be tested to make sure they do not have HIV infection before they start. People will also need to have their kidney function checked before starting and have it monitored while taking PrEP. Some people experience mild side-effects like nausea or gastrointestinal upset when they first start PrEP, however, this typically settles after the first two weeks.
How can CBOs support access to PrEP?	CBOs can direct advocacy efforts at policymakers: (i) to persuade them to support PrEP services and ensure key populations are appropriately included in the PrEP services and programmes that are rolled out; (ii) to encourage them to make adequate funding available for PrEP-related programmes and training. CBOs can also develop materials for community education programmes and increase awareness about PrEP through websites, social media, posters, etc.
Can PrEP programmes have broader benefits?	PrEP services are likely to attract people at higher HIV risk, who may also have other health and social needs. People who test HIV-positive can be linked to HIV treatment and care. PrEP services can also act as a gateway to additional social and health services, including other access to other HIV prevention options, harm reduction and drug treatment services, screening and treatment of other STIs and access to contraceptive services, counselling, legal and social support.
Will offering PrEP interfere with other HIV prevention efforts such as condoms and lubricants?	Condoms should always be available as part of a PrEP service. However, many people who choose to take PrEP report difficulties in using condoms consistently, in which case PrEP can offer effective HIV prevention. Comprehensive harm reduction services should be made available for people who inject drugs.

2. People with HIV

People with HIV are often compelling and credible sources of information on HIV. Although they have been the focal point of some community mobilization to increase access to antiretroviral therapy (ART), people with HIV have sometimes felt excluded from mobilization initiatives around PrEP, which focus on people who do not have HIV. Involving people with HIV in PrEP activities can build support and advocacy for PrEP as part of a comprehensive HIV programme. Table 2 addresses some of the main concerns and questions about PrEP often raised by people with HIV.

TABLE 2. FAQS ON PREP RAISED BY PEOPLE WITH HIV

CONCERN / QUESTION	RESPONSE
What does PrEP have to do with me?	People with HIV often have sexual or drug using partners who do not have HIV. PrEP is another way of keeping these partnerships safe and addressing HIV-related anxiety. In addressing these anxieties, PrEP may also decrease HIV stigma by sharing responsibility for preventing transmission. PrEP also offers a safe option for serodiscordant couples until the partner with HIV is virally suppressed on ART. PrEP as additional protection among serodiscordant couples can be considered in the context of safer conception.
Why use limited antiretroviral drug resources on PrEP when many people still do not have these medicines for HIV treatment?	PrEP can bring treatment and prevention advocates together to focus on drug access issues such as intellectual property, supply chain, financing and accountability. In the long term, preventing HIV infections decreases the number of people who will need ART and could be cost-saving. PrEP markets will expand the volume of sales of antiretroviral medicines and other associated commodities, which may decrease unit costs.
Will providing PrEP take the focus away from the needs of people with HIV?	PrEP services provide HIV testing, therefore people with previously undiagnosed HIV who are tested through a PrEP programme can be linked earlier to ART. PrEP can serve as the gateway to additional social and health services, such as prevention and treatment of other STIs, and access to contraceptive services, harm reduction services and counselling and social and legal support.

3. Men who have sex with men

Men who have sex with men are at increased HIV risk in all regions. They played an important role in the first successful PrEP trials, for example the safety study (2) conducted by the Centers for Disease Control and Prevention (CDC) and the iPrEx trial (3). Men who have sex with men also participated in the most recent trials that demonstrated the high effectiveness of PrEP, such as the PROUD study (4) and the Ipergay trial (5). In many countries, increasing numbers of men who have sex with men are aware of the benefits of PrEP and are seeking PrEP medicines either from formal health service providers or from informal sources such as Internet-based vendors. Men who have sex with men who obtain PrEP through informal sources should be encouraged and supported to link to clinical services so that they can receive regular HIV testing and other monitoring and support. While men who have sex with men are often very supportive of PrEP, some are concerned that PrEP will cause them to lose their focus on sexual health and relationships. Table 3 addresses some of the main concerns and questions about PrEP raised often by men who have sex with men.

TABLE 3. FAQS ON PREP RAISED BY MEN WHO HAVE SEX WITH MEN

CONCERN / QUESTION	RESPONSE
Will PrEP cause men to stop using condoms?	Men who have sex with men led the widespread adoption of condoms early in the HIV epidemic. However, condom use has been declining among some men who have sex with men since ART was made widely available, such that currently only one in six use condoms consistently in some areas (6). Inconsistent condom use is not protective over time. PrEP users who decrease condom use are still protected from HIV when using PrEP consistently. Other PrEP users choose condoms to prevent HIV and STIs. PrEP programmes can provide an opportunity to discuss and offer a wider range of services as part of combination prevention.
Will PrEP cause rising rates of other STIs?	PrEP prevents HIV but does not prevent other STIs. Consistent condom use protects against the transmission of gonorrhoea and chlamydia, although condoms may be less protective against infections spread by skin-to-skin contact (such as syphilis, herpes and warts). Infection rates for syphilis, gonorrhoea and chlamydia have risen in some places since the introduction of ART and although to date PrEP has not been associated with increased STI rates, as PrEP access increases this may happen (7). On the other hand, PrEP may help decrease STI rates by providing opportunities for STI diagnosis and treatment.
Not all men who have sex with men are at risk of HIV.	Not all men who have sex with men need to take PrEP. Many protect themselves through the consistent use of condoms or by maintaining a mutually monogamous relationship with a partner who knows his status and if he is HIV-positive is virally supressed on ART. Many people move in and out of sexually active periods, including men who have sex with men.

4. Transgender men and women

Transgender women are at increased HIV risk in all regions. Information about transgender men is less available. The

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